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Vincent G. Duffy
Nancy Lightner *Editors*

Advances in Human Factors and Ergonomics in Healthcare

Proceedings of the AHFE 2016 International Conference on Human Factors and Ergonomics in Healthcare, July 27–31, 2016, Walt Disney World®, Florida, USA

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7th International Conference on Applied Human Factors and Ergonomics

Proceedings of the AHFE 2016 International Conference on Human Factors and Ergonomics in Healthcare, July 27–31, Walt Disney World®, Florida, USA

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Preface

This book is concerned with human factors and ergonomics in healthcare. The utility of this area of research is to aid the design of systems and devices for effective and safe healthcare delivery. New approaches are demonstrated for improving healthcare devices such as portable ultrasound systems. Research findings for improved work design, effective communications and systems support are also included. Healthcare informatics for the public and usability for patient users are considered separately but build on results from usability studies for medical personnel.

Quality and safety are emphasized, and medical error is considered for risk factors and information transfer in error reduction. Physical, cognitive and organizational aspects are considered in a more integrated manner so as to facilitate a systems approach to implementation. New approaches to patient handling ergonomics, emergency and operating rooms, healthcare, medical device design, human factors and ergonomics measurement and model validation are included. Recent research on special populations, collaboration and teams, as well as learning and training, allows practitioners to gain a great deal of knowledge overall from this book.

Explicitly, the book is organized into nine sections that contain the following subject areas:

I. Human Factors and Ergonomics in Surgery
II. Healthcare Professionals
III. Healthcare Systems
IV. Healthcare Safety
V. Medical Device Design
VI. Healthcare Testing
VII. Environmental Design
VIII. Healthcare Communications and Logistics

Each of the chapters of the book was either reviewed by the members of Scientific Advisory and Editorial Board or germinated by them. Our sincere thanks and appreciation goes to the Board Members listed below for their contribution to the high scientific standard maintained in developing this book.

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This book would be of special value internationally to those researchers and practitioners involved in various aspects of healthcare delivery.

West Lafayette, USA — Vincent G. Duffy
Indianapolis, USA — Nancy Lightner
July 2016

Contents

Part I
Human Factors and Ergonomics in Surgery

Analysis of Surgeons' Muscle Activity During the Use of a Handheld Robotic Instrument in Laparoendoscopic Single-Site Surgery

Francisco M. Sánchez-Margallo and Juan A. Sánchez-Margallo

Abstract The objective of this study is to assess the surgeon's performance and ergonomics during the use of a robotic-driven handheld laparoscopic instrument in intracorporeal suturing tasks as well as in digestive and urological laparoscopic procedures performed through single-site surgery, and comparing it with the use of conventional instruments. Seven right-handed experienced surgeons took part in this study. Four surgeons performed nine urethrovesical anastomoses on an ex vivo porcine model and three surgeons a partial nephrectomy and a sigmoidectomy on an in vivo animal model. Surgeons used both conventional laparoscopic instruments and the robotic instrument. Execution times, leakage pressure for the anastomosis, surgical complications and surgeons' muscle activity were measured. Similar results in surgical performance and ergonomics were obtained using conventional laparoscopic instruments and the robotic instrument. Muscle activity of the biceps was significantly higher using the robotic instrument during both surgical procedures.

Keywords Laparoendoscopic single-site surgery · Handheld robotic instrument · Ergonomics · Muscle activity

1 Introduction

Laparoscopic surgery has experienced rapid development in recent years, providing multiple advantages for the patient such as the reduction in postoperative pain, tissue trauma and infection rate, better aesthetic results, and shortened recovery period [1–3]. In this sense, laparoendoscopic single-site surgery (LESS) is being

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consolidated as a real alternative to conventional laparoscopic surgery which further reduces incision related complications and leads to better cosmetics results. Numerous studies sustaining its feasibility, advantage in pain and recovery time with respect to conventional surgery, and therapeutic safety [4–6]. In this surgical approach, a multichannel surgical port is used to have access to the abdominal cavity of the patient where articulated or prebent instruments are introduced.

LESS surgery as a new evolving surgical technique still represents a challenge for surgeons, which requires surgical expertise [7]. This surgical approach presents some technical difficulties such as the closer proximity of instruments and loss of instruments triangulation, leading to clashing and crossing of the instruments both inside and outside the patient [8]. These technical constraints lead to a restriction of movements for the surgical instruments, which makes surgeons to adopt static postures of head and torso and awkward body postures for long periods of time. This could lead to deficient ergonomic conditions during surgery [9, 10], increasing the possibilities of muscle fatigue and musculoskeletal injuries [11–13].

In order to overcome some of these technical difficulties in LESS, training is necessary to become proficient in this new surgical approach as well as using its specifically designed instruments. In addition, new handheld robotic systems have been developed for laparoscopic surgery and single-site surgery [14–16]. They provide precision-driven and articulating instrument tips, which increase the triangulation, and therefore improve the performance of some surgical maneuvers. One example of these systems is Kymerax™ (Terumo Europe NV, Leuven, Belgium), which offers interchangeable articulating instruments controlled by its handle interface.

Apart from dealing with some of the technical limitations of LESS, the use of these handheld robotic systems could improve the ergonomic conditions as compared to conventional instruments, reducing the risk of musculoskeletal injuries, since they do not require adopting forced postures to perform certain maneuvers within the abdominal cavity. The objective of this study is to assess the surgeon's performance and muscle activity during the use of a robotic-driven, handheld articulating laparoscopic instrument in intracorporeal suturing tasks as well as in digestive and urological LESS procedures, and comparing it with the use of conventional instruments.

2 Materials and Methods

2.1 Participants

Seven right-handed surgeons took part in this study. Four experienced surgeons in laparoscopy (>100 laparoscopic procedures) and with different experience in LESS participated in the study with the training environment. Three experienced surgeons in laparoscopy and LESS (>20 LESS procedures) and with experience using the

robotic instrument participated in the study with the experimental animal model. Participants used both conventional laparoscopic instruments (Conv) and the handheld robotic instrument (Rob). The type of instrument (conventional or robotic) to start the task or surgical procedure was randomly assigned to each surgeon. All trials were performed at our centre's experimental surgical theatres. Participants gave informed consent and voluntarily agreed to participate in the studies.

2.2 Handheld Robotic Instrument

The Kymerax™ system (Terumo Europe NV) is a handheld laparoscopic instrument with articulating and interchangeable instruments (scissors, dissector, needle holder and L-hook), which are driven by robotic technology. Surgeons control the movements of the instrument tip through the manipulation of the handle interface. The shaft diameter of its instruments is 8.8 mm.

2.3 Training Environment

The training environment consisted of a validated laparoscopic simulator (SIMULAP®; JUMISC, Cáceres, Spain), with a 10-mm, 30° rigid laparoscope (Karl Storz GmbH & Co. KG, Tuttlingen, Germany) as vision system, and the GelPOINT® Advanced Access Platform (Applied Medical, Rancho Santa Margarita, CA, USA) as surgical access port. The laparoscope was fixed to prevent movements and changes in the instruments. Surgeons hold an angled inline laparoscopic dissector (Epix®; Applied Medical) on the left hand. On the right hand, they hold a straight laparoscopic needle holder (Karl Storz GmbH & Co. KG) or the robotic instrument in its needle holder configuration for the conventional and robotic groups, respectively (Fig. 1). Participants were asked to performed nine urethrovesical anastomoses on an ex vivo porcine model in a period of two months using both types of laparoscopic instruments (Fig. 2). The anastomosis was performed on an ex vivo porcine bladder using 8 simple interrupted sutures.

During the first (T1) and last (T9) repetitions, execution time, leakage pressure and surgeons' muscular activity were assessed. The leakage test was performed at the end of the task to test the integrity of the anastomosis. This test consisted of introducing a silicone tube connected to an insufflator (Karl Storz GmbH & Co. KG) through the end of the bladder. While the bladder was immersed in water, the pressure at which air leaked from the anastomosis was recorded. The maximum pressure was set at 30 mmHg.

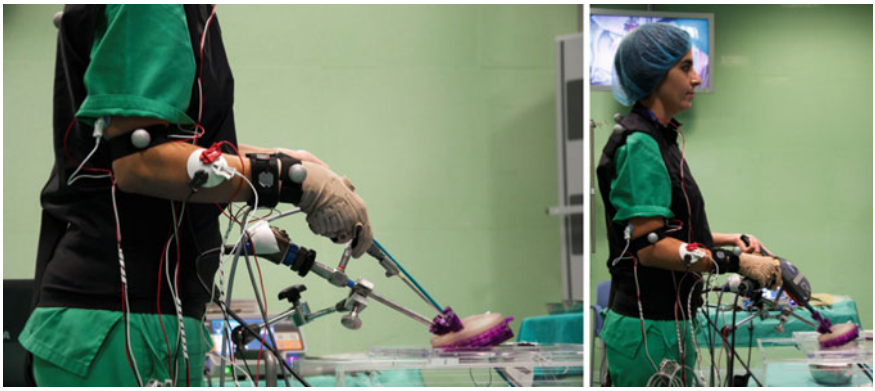

Fig. 1 Setup for the study in the training environment using (*left*) a conventional laparoscopic needle holder and (*right*) the robotic instrument

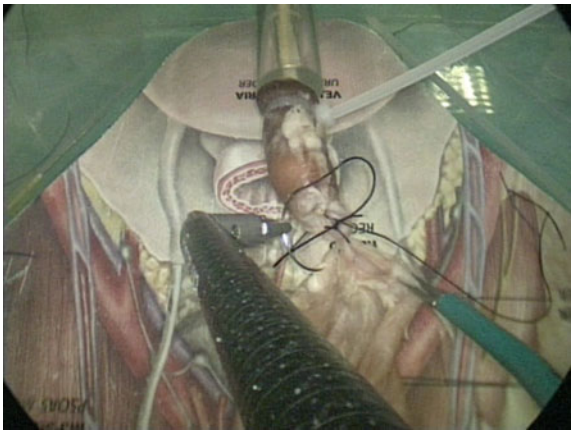

Fig. 2 Use of the robotic instrument during the urethrovesical anastomosis

2.4 Experimental Animal Model

Participants performed a partial nephrectomy and a sigmoidectomy on an experimental porcine model through LESS approach. For the partial nephrectomy, an artificial pseudotumor was previously created on the upper renal pole of the left kidney. A mixture of alginate and saline was percutaneously injected to reproduce the tumor. This study was reviewed and approved by the Institutional Review Board of the Jesús Usón Minimally Invasive Surgery Centre.

Suturing tasks were analyzed during both surgical procedures. Specifically, measurements were obtained during the hemostasis in the case of partial nephrectomy and during the anastomosis between the descending colon and rectum

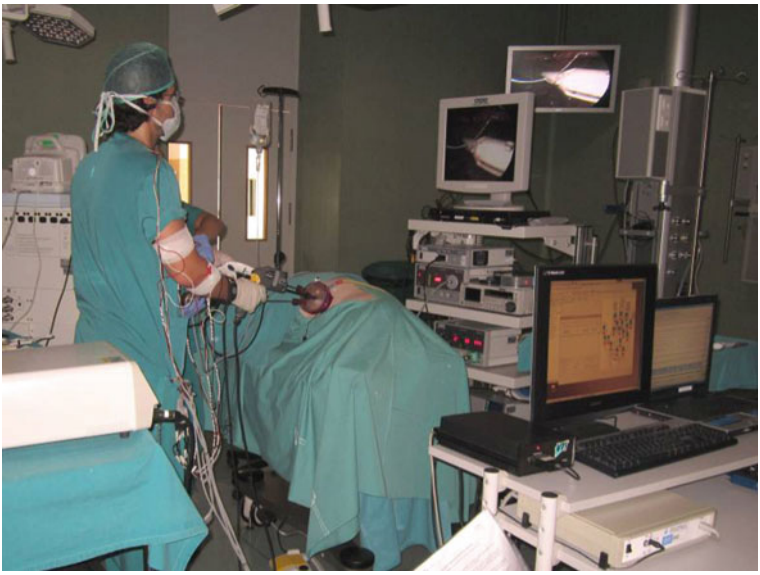

Fig. 3 Setup for the study with the animal model. The surgeon is using the robotic instrument with the needle holder end-effector during the surgical procedure. Surface electromyography is used to record the surgeon's muscular activity

in the sigmoidectomy procedure. The GelPOINT® Advanced Access Platform (Applied Medical) was used as surgical access port. In all cases, surgeons hold an articulated laparoscopic dissector (Dissect SILS®; Covidien, Mansfield, MA, USA) on the left hand. On the right hand, they hold a straight laparoscopic needle holder (Karl Storz GmbH & Co. KG) or the robotic instrument with the needle holder end-effector for the conventional and robotic groups, respectively. For each procedure, the surgery time, surgical complications and the surgeon's muscular activity were measure (Fig. 3).

2.5 Surface Electromyography Protocol

For the electromyography (EMG) analysis, we used the MP150 System (Biopac Systems, Inc., Goleta, CA, USA) connected to a laptop (VAIO®; VAIO Corporation, Nagano, Japan) equipped with the AcqKnowledge 3.7 acquisition software (Biopac Systems, Inc.).

EMG signals were obtained from right biceps brachii, right triceps brachii, right forearm flexors and extensors, and right trapezius muscles, through triple-surface

electrodes. The electrodes were placed according to the SENIAM recommendations for each muscle [17]. Before its placement, the skin was cleaned with alcohol to eliminate dirt remnants, grease, and dead skin cells that could impair the acquisition of EMG signals. To prevent movement of the electrodes, they were fixed using an elastic band. Cables were also attached to the surgeon's clothes to reduce potential artifacts. The sample rate was established at 1000 Hz.

Once the electrodes were adequately positioned, the measurement of the maximal voluntary contraction (MVC) of each muscle was recorded for amplitude normalization. MVC was recorded separately for each muscle group by asking the subject to perform specific 8-s tractions against a fixed resistance. This was used as a reference to normalize every EMG recording as a percentage of the MVC, which allows for comparison between different subjects.

After the EMG data of each group of muscles was recorded for each activity, the signal was visually inspected and filtered to remove possible artifacts. The root mean square value of the signal was calculated for each muscle, expressing the final results as a percentage of the corresponding MVC.

2.6 Statistical Analysis

For statistical analysis, the Wilcoxon signed rank test was used to compare measurements of both study groups. All statistical analyses were carried out using R version 3.2.2 (R Foundation for Statistical Computing, Vienna, Austria). The results are shown as mean and standard deviation or notched box and whisker plots. For the latter, the boxes whose notches do not overlap their medians are significantly different with 95 % confidence. For all tests, $p < 0.05$ was considered statistically significant.

3 Results

3.1 Training Environment

The average time required to perform an intracorporeal suture during the urethrovesical anastomosis was similar using both instruments during T1 (Conv: 5.652 ± 3.744 min; Rob: 5.909 ± 2.384 min). However, during T9, the average time was significantly less using the conventional needle holder than the robotic instrument (Conv: 3.570 ± 1.334 min; Rob: 4.174 ± 1.356 min; $p = 0.015$). A reduction in the execution time was shown between T1 and T9 for both study groups.

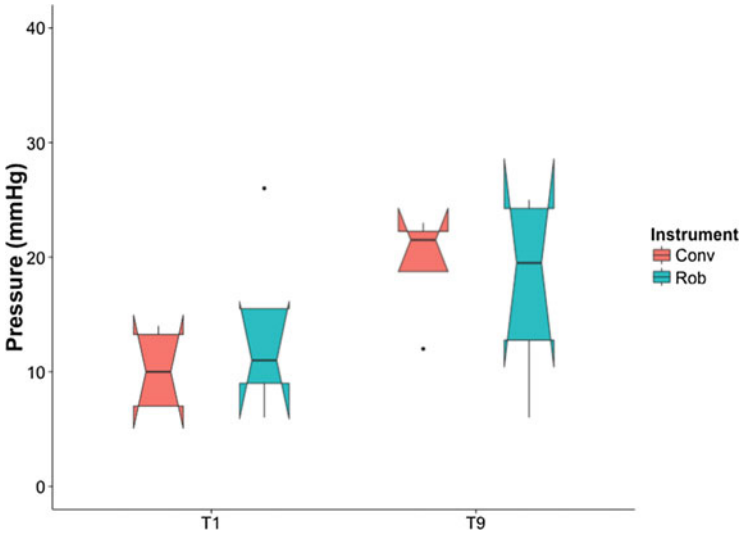

Fig. 4 Results of the leakage test during T1 and T9. The leakage pressure was measured at the end of the urethrovesical anastomosis performed by the conventional laparoscopic needle holder (Conv) and the robotic instrument (Rob)

Muscle activity of the analyzed muscles was similar between the use of both laparoscopic instruments for the urethrovesical anastomosis during T1 and T9 (Fig. 4). Muscle activity of biceps (T1: 22.448 ± 6.845 %MVC; T9: 7.867 ± 1.743 %MVC) and flexor (T1: 31.804 ± 5.630 %MVC; T9: 9.202 ± 6.074 % MVC) muscles decreased significantly from the first (T1) to the last (T9) repetition using the robotic instrument.

The leakage pressure for the anastomosis was similar during T1 and T9 for both groups of laparoscopic instruments (Fig. 5). The pressure supported by the anastomosis performed by the conventional laparoscopic needle holder increased significantly from the first (T1) to the last (T9) repetition.

3.2 Experimental Animal Model

All surgical procedures were successfully performed and no complications were registered (Fig. 6). Surgery time of both procedures was similar using the conventional and the robotic laparoscopic instruments.

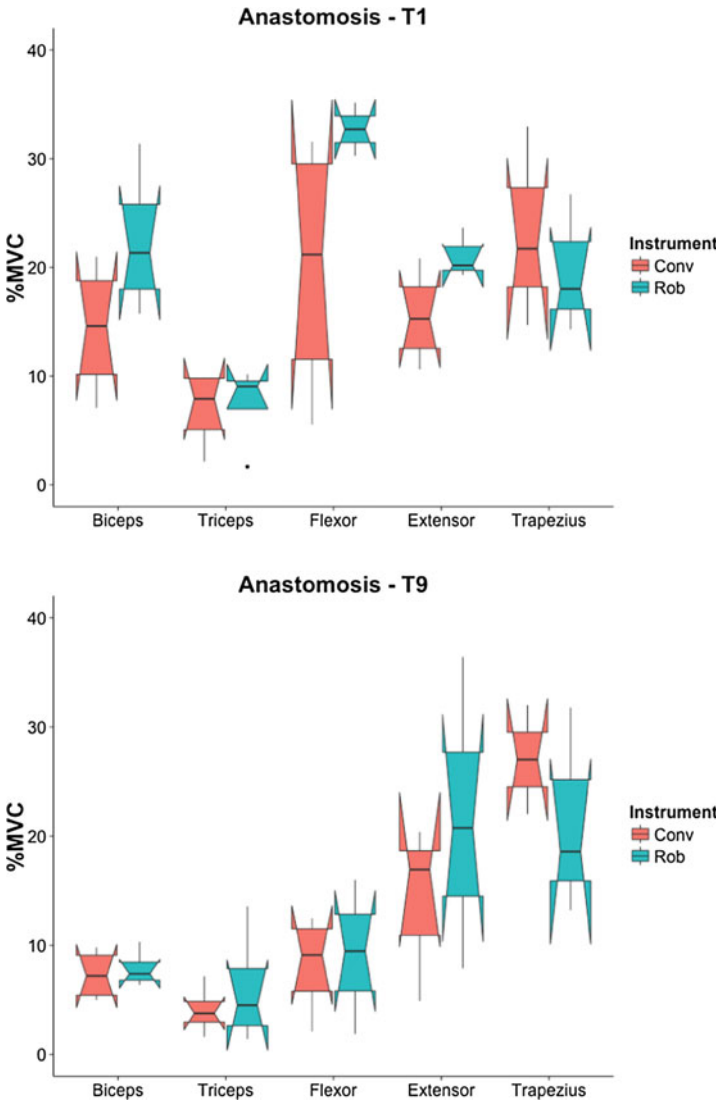

Fig. 5 Muscle activity (%MVC) of each analyzed muscle using conventional instruments (Conv) and the robotic instrument (Rob) during the first (T1) and last (T9) repetitions of the urethrovesical anastomosis task

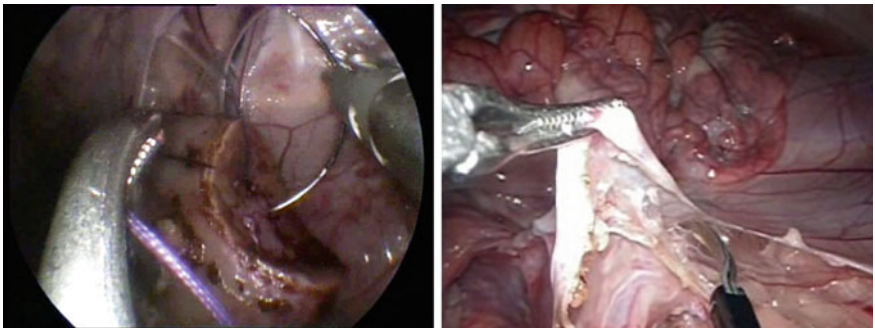

Fig. 6 Surgical procedures on the experimental animal model. *Left* Partial nephrectomy using the robotic instrument and *Right* sigmoidectomy with conventional laparoscopic instruments

Muscle activity of the biceps was significantly higher using the robotic instrument during both partial nephrectomy (Conv: 4.366 ± 2.575 %MVC; Rob: 6.774 ± 0.620 %MVC) and sigmoidectomy (Conv: 2.086 ± 0.306 %MVC; Rob: 6.254 ± 0.705 %MVC) procedures (Fig. 7). No significant differences were observed for the other analyzed muscles.

4 Discussion

LESS surgery is technically challenging for surgeons and its limited range of movements for the surgical instruments inside the abdominal cavity could lead them to adopt awkward postures for long periods of time, with the consequent possible musculoskeletal injuries [9, 11, 12]. Several devices and prototypes with articulating tip have been developed as a possible solution for these limitations [14, 16, 18]. These instruments enable surgeons to achieve movements not usually possible with conventional instruments. In this study we analyzed the performance and ergonomics using the Kymerax™ system (Terumo Europe NV), a robotic-driven handheld instrument with a flexible tip, during suturing tasks in a training environment and during digestive and urologic surgical procedures on an animal model.

Similar results in surgical performance and ergonomics were obtained using conventional laparoscopic instruments and the handheld robotic instrument during the urethrovesical anastomosis in the experimental environment and during the partial nephrectomy and sigmoidectomy procedures on an animal model using a LESS approach.

For the urethrovesical anastomosis in the training environment, there was a remarkable improvement in execution time during the last repetition for both laparoscopic instruments. In this repetition, the execution time using the conventional needle holder was significantly lower than using the robotic instrument, which

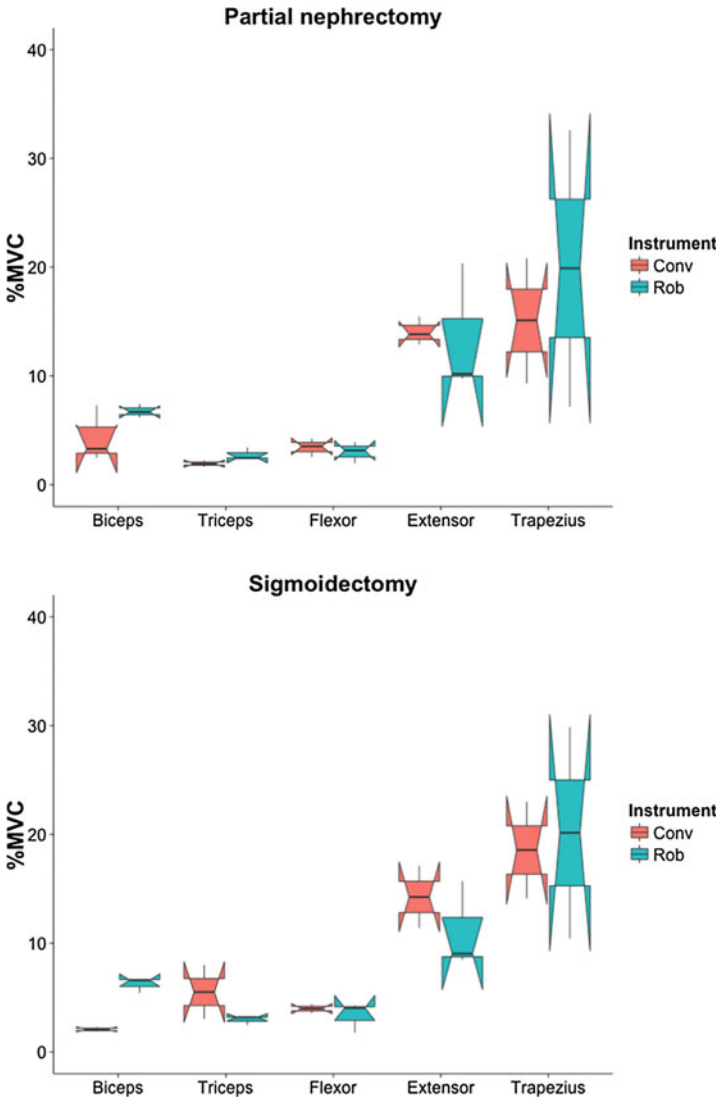

Fig. 7 Muscle activity (%MVC) of each analyzed muscle using conventional instruments (Conv) and the robotic instrument (Rob) during partial nephrectomy and sigmoidectomy procedures

might be due to the previous experience of the surgeons with conventional laparoscopic instruments. In another study with basic suturing tasks, no differences in execution time using conventional or the handheld robotic instrument were found [15]. However, in this study participants only performed three repetitions of each task. A longer training period with the robotic instrument could positively affect the learning curve for this device, improving the performance in intracorporeal suturing.

Muscular activity of both biceps and flexor muscles was reduced from the first to the last repetition during the performance of the urethrovesical anastomosis using the robotic instrument. It seems that training improves the ergonomics of surgeons using the robotic instrument. However, during the surgical procedures, this instrument demanded higher muscular activity for the biceps. This might be because the robotic instrument is bigger and heavier than the conventional laparoscopic instrument, leading to higher workload of the biceps muscle.

As was reported by Pérez-Lanzac et al. [19], the surgeons stated that the use of the robotic instrument reduced the technical difficulty of the urethrovesical anastomosis performed through LESS approach. Participants in the study with the laparoscopic simulator considered that it should be necessary a previous training to be familiarized with the controls on the device.

The use of this robotic instrument has been also proved to be feasible in other laparoscopic procedures such as total laparoscopic hysterectomy and radical prostatectomy [18, 20]. A study with sixty patients who underwent a robot-assisted radical prostatectomy reported no differences between using conventional laparoscopic and robot-assisted procedures with regard to postoperative pain, blood loss and length of recovery [20].

The main limitation of the presented study is the small sample size. Further studies should be done including other handheld robotic laparoscopic instruments to support the results obtained. Understanding how operation conditions, workplace layout and surgical instruments influence surgeons' ergonomic condition could provide inspiration for new instrument designs, as well as more targeted training methods.

In conclusion, results indicated a positive learning curve in performance and ergonomics using the handheld robotic instrument for LESS urethrovesical anastomosis. Besides, results showed that partial nephrectomy and sigmoidectomy procedures performed through LESS approach and using the robotic instrument are feasible and safe. There were no differences in surgery time and surgeon's muscle activity during both surgical procedures, except for the biceps muscle. We consider that a period of adaptation should be required for this new technology.

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Assessing the Influence of Personal and Organizational Factors on Surgeon's Performance: A Study on Surgeons' Perceptions

Rossella Onofrio and Paolo Trucco

Abstract In the emerging area of Human Reliability Analysis (HRA) applications in healthcare, a critical issue is the suitability or proper application of the existing taxonomies of Influencing Factors (IFs). The aim of the present study is twofold: (i) providing surgeons' views about the IFs to be implemented in HRA applications to surgical procedures; (ii) assessing surgeons' perception of the influence of personal and organizational factors on surgical performance in different surgical contexts (open and MIS surgery). The study methodology involved focus group and individual interviews for the former, a survey for the latter. Twenty IFs were identified as relevant for the surgical context, among a preliminary list of categories taken from extant literature. The difference of the perceived influence in the two surgical contexts, i.e. open vs laparoscopic, resulted significant for five Ifs: verbal interruptions; rude talk and disrespectful behaviors; unclear or failed communication; poor coordination; poor situation awareness.

Keywords Human factors · Performance shaping factors · Human reliability analysis

1 Introduction

A key question facing surgical units relates to the identification of factors that can influence surgical outcomes and, therefore, how knowledge of these factors can be used to enhance surgical performance. Research efforts across the world have sought to identify factors that may influence surgical performance, and with recent advances in surgical technology, a number of studies have focused on the associ-

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ation between surgical outcomes, surgical technology, and the technical skills and types of training of surgeons.

In the emerging field of Human Reliability Analysis (HRA) a critical issue in healthcare applications [1–4], as currently debated in literature, is the proper application or suitability of the existing taxonomies of Influencing Factors (IFs, also labeled as Performance Shaping Factors or PSFs), since they were primarily designed and developed for industrial contexts.

Within HRA, the choice of PFs/IFs refers to the identification of personal or organizational factors that directly affect the human performance; their influence is generally assessed by means of experts' judgments and therefore is highly subjective. In healthcare applications, the choice of these factors becomes even more critical phase due to the high number of contingencies within a complex socio-technical environment: wide spectrum of patient conditions, variety of procedures, alternative technological settings and team configurations.

In the extant literature, many HRA methods modulate the Human Error Probability (or Unreliability) with a set of factors that may affect human performance. The terminology about context factors differs from one HRA technique to another. Some HRA techniques label these factors as "Performance Shaping Factors" (PSF) [5], "Performance Influencing Factors" (PIF), "Influencing Factors (IFs)" [6], or "Error Promoting Conditions (EPC)" [7]. In fact, several different taxonomies of contextual factors are proposed in industrial literature according to the different methods.

When it comes with the application of HRA in the healthcare context, at least three issues must be addressed for a proper integration of performance influencing factors.

Firstly, there is an open debate about which IFs should be used in HRA and what is the appropriate number of PSFs to be included in the analysis. In fact, "There is considerable range in the number of PSFs provided by individual HRA methods, ranging from single factor models such as time-reliability curves, up to 50 or more PSFs in some current HRA models." [8]. For example: The US Nuclear Regulatory Commission advocates 15 PSFs in its HRA Good Practices [9], while its SPAR-H method [10] espouses the use of 8 PSFs and its ATHEANA method [11] features an open-ended number of PSFs. The apparent differences in the optimal number of PSFs can be partly explained referring to the level of detail of the human model or the different functions of PSFs in HRA [8, 12].

Secondly, PSFs are conceived in terms of the negative effects they might induce on human performance, even though a greater emphasis has been recently given to ways of modeling PSFs taking into account also their potential influence on enhancing human performance.

Thirdly, the terminology of the IFs is strictly connected to the meaning given in a specific context. For this reason, the assessment results among analysts could be different because they assess the factors with their subjective interpretations [12].

In healthcare there is need to design IFs taxonomy to be implemented in HRA for surgery, dealing with these HRA issues. Accordingly, the aim of the present study is twofold: (i) providing surgeons' views about what are the IFs to be implemented in HRA applications to surgical procedures; (ii) assessing surgeons'

perception of the influence of personal and organizational factors on surgical performance. To this end, the following Research Questions are posed:

RQ1: "What are the IFs to be included into a taxonomy for HRA applications in surgery?"
RQ2: "What is the perceived influence of the IFs on surgeon's performance? Does the perceived strength of the influence vary under different surgical contexts (e.g. open vs laparoscopic)?

The rest of the paper is organized as follows: Sect. 2 provides the research method used; Sect. 3 presents and discusses the main results; Sect. 4 draws the conclusion and suggests directions for future research.

2 Study Methodology

The study builds on results of a previous study involving a literature review of influencing factors in surgery and an observational study [13]. The present study is divided into two parts, the first involving focus group and individual interviews undertaken with Danish and Italian surgeons and anesthetists, and the second a survey, undertaken with Italian surgeons.

2.1 Qualitative Study: Focus Group and Individual Interview

The design of IFS taxonomy items, to be implemented in the final taxonomy of IFs for HRA applications in surgery, was performed in Italy and Denmark between February and June 2015. We applied the focus group methodology [14], and individual semi structured interviews. This first phase of the study was aimed at capturing the ways in which surgeons conceptualize, cluster and articulate influencing factors.

In particular, the focus group held in Denmark (in March 2015) involved surgeons only (n = 7), whereas the individual semi structured interviews involved both surgeons (n = 3) and anaesthetists (n = 9); in Italy semi structured interviews involved only surgeons (n = 5). The size of our focus group (7 participants) obeys to the common standard of four (minimum) to twelve (maximum) participants per group [14]. The participants were selected through consultation with the manager of the surgical department of the Hillerød Hospital. The informal nature of this methodology facilitated an interactive discussion and reflection about the surgeons' perception of factors that shape surgical performance.

We created an interview guide for both the focus group interview and individual semi structured interviews. It focuses on a brief presentation of the study and shows the participants an A4 paper including a table with the list of the macro categories

of factors identified from a previous literature review study [13]. A set of IFs items was developed and turned into a checklist to gather data from surgeons about each factor category and assure the traceability of answers.

The discussion was primarily focused on labels, definitions, meanings of the factors to validate items and descriptors of influencing factors. To understand the relevant IFs items, when an interviewee was referring to the specific IFs item, the interviewers marked the checklist. When some IFs items were not mentioned, the interviewers asked additional questions about the missing ones. The ending of each interviews occurred when the participants had no further thoughts on IFs.

The focus group session lasted about one hour and half and was led by two moderators, who covered each of the IFs categories in the interview guide. Each of the individual semi structured interviews lasted around 30 min of discussion. All the interviews were audio-recorded and subsequently transcribed verbatim. Data analysis steps were discussed continuously among the authors, and when possible, with other scholars, ensuring the reliability of data analysis.

2.2 Survey Method

The results of the focus group and individual interviews in Italy and Denmark were used to design a questionnaire to assess surgeons' perceptions about the influence of IFs on surgical outcome. Survey method was chosen to elicit experts' judgments. The questionnaire was divided into three sections: the first one was dedicated to the instructions, the second one was dedicated to provide the perception about the influence of each of the IFs on their performance and the third one was dedicated to the collection of demographic information, in order to successively make comparisons among results. In detail, the question repeated for each of the twenty influencing factors (X) was:

> Please provide your subjective estimate of how often the factor X has had a negative influence on your own performance and the risk of adverse patient outcome in the operations in which you have participated during the last year?
>
> Please indicate your estimate by a number from 0 and 10 where:
>
> 0 = the factor has had no influence at all, if present;
>
> 10 = the factors has had a negative influence in every operation, if present.

The demographic information we collected from surgeons were: the prevalent surgical technique used in the past year (with distinction among open, laparoscopic and robotic surgery); position/title of the surgeon; surgical speciality; years of experience; the surgical role during the last year of surgical activity, if in robotic surgery (i.e. first operator in console, or second operator at the operating table); number of surgical interventions performed (approximate number). Finally, two open questions were included; one about possible suggestion of additional factors

not listed in the questionnaire, and a second one dedicated to other general comments, if any.

The questionnaire was designed in both paper and online versions. The software used to implement the online version of the questionnaire is "Typeform". Once the draft questionnaire has been designed we tested the questionnaire with a group of surgeons of the Urology Department of an Italian hospital, Ospedale Niguarda Ca' Granda in Milan.

A convenience sample of Italian surgeons, as members of the Italian Society of Surgery, was reached through emails, inviting them to answer the online questionnaire. The first email included a cover letter and a link to the questionnaire. The completion of the survey was estimated to take between 10 and 15 min. Two email reminders were sent to non-respondents.

Data was recorded in MS Excel, and subsequently statistical analysis has been done through the Statistical Package for the Social Sciences (Stata®13).

3 Results

3.1 Focus Group and Individual Interviews

Twenty IFs resulted from the selection operated through the focus group and individual semi-structured interviews. Table 1 provides the list of IFs and respective descriptions.

3.2 Survey Results

In this paper, we limited the description of the results to the descriptive statistics of the perceived influence of IFs on surgeons' performance. Firstly, we made a cumulative analysis of the entire sample, considering the surgical context as homogenous; secondly, we investigated if there is significant difference of surgeons' perception of the influence of IFs on their performance in the two surgical contexts under analysis (open and MIS surgery).

Respondents Characteristics. A convenience sample of 93 surgeons, belonging to the Italian Society of Surgery, provided anonymous answers to the questionnaire administered online. Table 2 summarizes the demographic characteristics of the surveyed surgeons. Of the 93 responders, 56 are surgeons active in open surgery (60 %), 37 predominantly operate in laparoscopic surgery (40 %).

Descriptive Profiles. Figure 1 shows the cumulative descriptive profiles about the perceived influence of IFs considering the surgical context as homogeneous

Table 1 Validated list of IFs for HRA applications in surgery

1	Noise and ambient talk. Continuous or sudden noise; team members talking in the background or coming and going and moving around in a noisy way
2	Music. Presence of background music in operating room
3	Noisy use of social media. Team members talking about and obtrusively sharing social media content
4	Verbal interruptions. Verbal Interruptions that are either untimely or not patient relevant
5	Poor management of errors and threats to patient safety. Failure to share information promptly and openly about errors and threats to patient safety
6	Poor guidelines, procedures or checklists. Guidelines, procedures or checklists are inadequate: lacking, too complex, or not at right level
7	Rude talk and disrespectful behaviors. Derogatory remarks, behaviors showing lack of respect of OR team members, shouting and harsh tones of voice.
8	Improper use of procedures and checklists. The improper use, or non-use, of the WHO checklist (or similar), protocols and procedures
9	Unclear or failed communication. Communication that should have been given wasn't or was inadequate or was misunderstood and not corrected
10	Poor coordination. Failure in coordinating team activities; failure to anticipate the needs of the lead surgeon or lead anesthetist (surgeon at the console in robotic surgery)
11	Poor decision making. Failure to consider, select and communicate options; inadequacy or delay in implementing and reviewing decisions
12	Poor situation awareness. Failure to gather and/or to integrate information or failure to use information to anticipate future tasks, problems and states of the operation
13a	Lack of experience of surgical team colleagues. Lack of experience of within surgical team, with the surgical procedure or technology
13b	Lack of experience of anesthetics team colleagues. Lack of experience of within anesthetic team, with the anesthetic procedure or technology
14	Fatigue. Mental fatigue or physical fatigue
15	Time pressure. Psychological stress resulting from experiencing a need to get things done in less time than is required or desired
16	Perioperative Emotional Stress. Stress induced by factors not directly related to the team, or to the characteristics and evolution of the intervention, e.g. responsibility for the budget and for other hospital objectives, organizational problems of the department, other critical patients, lawsuits
17	Poor leadership. Failure to set and maintain standards or to support others in coping with pressure
18	Team member familiarity. Team members unfamiliar with each other and each other's competencies
19	Poor use of technology. Lack of ability to use relevant technology
20	Inadequate ergonomics of equipment and work place. Equipment and workplace not designed to optimize usability and reduce operator fatigue and discomfort

(93 respondents). The perceived influence of IFs with mean ratings ≥4 concern: noisy use of social media (4.00); poor management of errors and threats to patient safety (4.06); rude talk and disrespectful behaviors (5.26); unclear or

Table 2 Characteristics of respondents

Number of respondents: 93
Age of respondents: from 29 to 81
Years of experience: from 1 to 52
Total number of surgical interventions: from 10 to 20,000
Surgical setting:
Open surgery: 60 % Laparoscopic surgery: 40 %

failed communication (4.04); lack of experience of surgical team colleagues (4.05); lack of experience of anesthetics team colleagues (4.47); fatigue (4.21); time pressure (4.48); poor use of technology (4.00). In Fig. 1, the arrows indicate the IFs with the median ≥4.00. In particular: noise and ambient talk (mdn = 4.00); rude talk and disrespectful behaviors (mdn = 5.00); improper use of procedure and checklists (mdn = 4.00); unclear or failed communication (mdn = 4.00); poor coordination (med = 4.00); Lack of experience of surgical team colleagues (mdn = 4.00); Lack of experience of anesthetics team colleagues (mdn = 4.00); time pressure (mdn = 5.00).

To investigate if the perceived influence of the IFs is significantly different under different surgical contexts (open vs laparoscopic surgery), Mann-Whitney Wilcoxon test (nonparametric test) was used. The difference of the perceived influence in the two surgical contexts resulted significant (threshold of significance, $p < 0.05$) for five IFs: (i) verbal interruptions ($p = 0.0210$); (ii) rude talk and disrespectful behaviors ($p = 0.0339$); (iii) unclear or failed communication

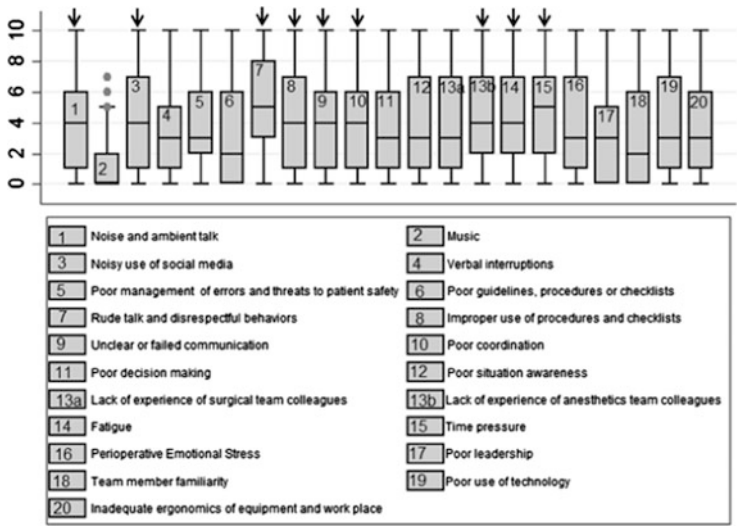

Fig. 1 Descriptive profiles of the perceived influence of each IF in a generic surgical setting (unique sample: 93 responses)

Open surgery	Obs	Mean	Std. Dev.	Min	Max
Verbal interruptions	56	3	2.522625	0	9
Rude talk and disrespectful behaviors	56	4.660714	3.41801	0	10
Unclear or failed communication	56	3.446429	2.853512	0	10
Poor coordination	56	3.392857	3.049164	0	10
Poor situation awareness	56	3.232143	3.056981	0	10
Laparoscopic surgery	**Obs**	**Mean**	**Std. Dev.**	**Min**	**Max**
Verbal interruptions	37	4.297297	2.644332	0	10
Rude talk and disrespectful behaviors	37	6.189189	2.923448	0	10
Unclear or failed communication	37	4.945946	3.299377	0	10
Poor coordination	37	4.864865	3.425088	0	10
Poor situation awareness	36	5.055556	3.430489	0	10

Fig. 2 Descriptive statistics about the perceived influence of IFs resulted significantly different in the two surgical contexts

(p = 0.0290); (iv) poor coordination (p = 0.0385); (v) poor situation awareness (p = 0.0086). The descriptive statistics are reported in Fig. 2, which presents the number of the respondents (obs), mean ratings, standard deviation, the minimum and maximum values in open and laparoscopic surgery. The descriptive profiles of the two study groups are also shown through box plots representation (Fig. 3).

Surgeons perceive the influence of these five IFs as higher in laparoscopic surgery than in open surgery. Despite the maximum and minimum values similar (with the exception of IF 4, namely 'verbal interruptions', where the maximum value is higher for the laparoscopic setting), the medians are dramatically different: values in laparoscopic surgery are higher (either by 2 or 3 points) than in open

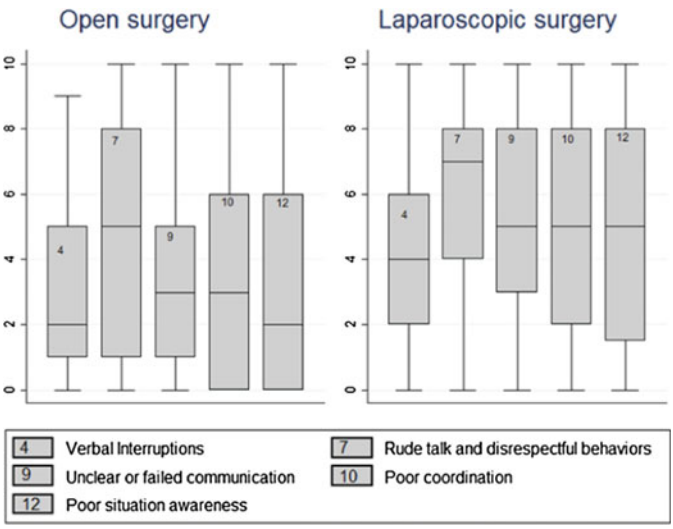

Fig. 3 Descriptive profiles of the perceived influence of IFs resulted significantly different in the two surgical context (the numbers refer to the corresponding number of the IFx shown in the Table 1)

surgery. In particular 'rude talk and disrespectful behaviors' and 'poor situation awareness' are those factors whose perceived influence present the medians 3 point higher in laparoscopic surgery than in open surgery.

Data clearly shows a strong influence of relational and communication issues on surgeon's performance (and surgical outcome as a consequence) under laparoscopic settings. These factors are perceived less influential by surgeons when referred to an open surgery context.

4 Conclusion

The study represents the first step towards a quantitative analysis of human and organizational factors affecting surgeon's performance, surgical outcome and patient safety.

Providing a comprehensive taxonomy of influencing factors and relative perceived influence on surgeons' performance is both theoretically and managerially relevant. Theoretically, the study contributes to the validation of a taxonomy of IFs specifically designed for the healthcare sector, and surgery in particular. Moreover, to the best of authors' knowledge, the study is also the first documented attempt to estimate the strength of the influence (weight) of IFs on surgeon's performance; in this regard, the results of the study foster the application of quantitative Human Reliability Analysis (HRA) in surgery, which is an emerging research stream in patient safety literature. Finally, further research effort can be directed towards a better understanding of the underlying cognitive mechanisms that make the laparoscopic setting (or MIS in general) more vulnerable to poor relational and communication factors. Further research is also needed to expand the evidence base to the identification and assessment of the relevant IFs for robotic surgery.

The results of the present study can be also a useful reference for designing and implementing effective actions targeting patient safety improvements in surgery. Indeed, by focusing on the most influential human and organisational factors in different surgical contexts, risk managers can provide useful and precise inputs to organizational development, surgical training and other safety interventions programs.

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Human Reliability Analysis (HRA) for Surgery: A Modified HEART Application to Robotic Surgery

Paolo Trucco, Rossella Onofrio and Antonio Galfano

Abstract HRA studies in healthcare highlight that PSF (or Influencing Factors—IFs) taxonomies in HRA techniques have been developed and validated in industrial contexts, and as such are not fully applicable to healthcare contexts. In this paper, a modified version of Human Error Assessment and Reduction Technique (HEART), has been developed and tested through an application to the robotic surgical Radical Prostatectomy procedure. Personal and organizational factors were modeled and assessed through an IFs taxonomy validated in the surgical domain, and then systematically translated into the corresponding Error Producing Conditions (EPCs), typical of the HEART method. The results confirmed the importance of adapting HRA methods to the healthcare sector, and added detailed information on what are the most relevant factors that should be captured by an HRA method when applied to surgery. Additionally, the analysis revealed that team related factors have the highest influence on surgeons' performance (i.e. increase of Human Unreliability Rate) in the context of different surgical tasks.

Keywords Human reliability analysis · HRA · Surgery · Influencing factors

1 Introduction

The benefits of transferring and applying to healthcare the most important proactive risk analysis methods traditionally implemented in industry are fully recognized in patient safety literature [1–4]. Literature findings highlight the lack of knowledge

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about the reach spectrum of HRA techniques and methodologies that are applicable to the healthcare sector [1–4]. On the other side, an emerging and increasing interest in HRA applications has been pointed out, especially in surgery [5–9]. Therefore, there seems to be a growing need of fostering theoretical knowledge and practical expertise on HRA application in healthcare, to achieve higher safety performance under increasing environmental complexity and technological innovation, such as in the case of mini-invasive surgery. One of the critical aspects come up from extant HRA applications in healthcare concerns the limited adoption or misuse of Performance Shaping Factors (PSF), i.e. aspects of behavior and context that impact human performance [10]. On the contrary, in HRA theory and applications in industry, contextual and organizational factors play a relevant role, and the attempt to incorporate them into new and more advanced HRA techniques represents a hot research line in this discipline since a long time.

A closer look to the few papers describing HRA applications in healthcare where human and organizational factors are included reveals that all the authors dedicated particular attention to the choice of the most appropriate influencing factors. This modeling effort generally culminated in the decision to take into account only some of the factors covered by the selected HRA technique. Nevertheless, almost all the authors highlight that PSF (or Influencing Factors—IFs) taxonomies in HRA techniques have been developed and validated in industrial contexts, and as such are not fully applicable to the healthcare contexts [5].

In order to foster the diffusion of HRA in healthcare it is not enough applying and adapting existing HRA techniques to the healthcare context. A proper translation of these techniques to healthcare environment has to be undertaken [11, 12]. To this end, particular attention should be addressed to the role of those human and organizational factors that could shape the performance of the operator (e.g. surgeon or anesthetists) under different contexts.

In this paper, a modified version of Human Error Assessment and Reduction Technique [13], has been developed and tested through an application to the robotic surgical Radical Prostatectomy procedure, that is the most widespread robotic surgical procedure.

2 Method

In line with much part of the worldwide technological evolution in surgery, Italy represents one of the leading countries in Europe for the implementation of robotic surgery, as one of the most sophisticated new frontier of Minimally Invasive Surgery. Robotic Surgery has established itself as the best technique for the surgical treatment of prostate cancer. Today, in the US, over 80 % of prostatectomies are performed with the aid of the DaVinci Surgical System. Although robotic surgery, or robot-assisted surgery, allows doctors to perform many types of complex procedures with more precision, flexibility and control [14], the advanced technology may introduce new error pathways due to the high degree of human-machine

interaction, in fact the assessment of safety, feasibility and clinical efficacy is still at an early stage of study and analysis. This is the reason why we chose to apply HEART methodology on the most widespread robotic surgical procedure, i.e. radical prostatectomy. In particular, the study focuses on the analysis of a recent robotic prostatectomy technique performed with DaVinci robot, which allows to obtain excellent results both in oncological and functional terms [15, 16].

2.1 *Modified HEART for Integration with a New Taxonomy of IFs in Surgery*

Starting from a literature review on the applications of HRA techniques in healthcare, and HEART in particular, the need for some methodological modifications was identified to make the traditional HEART more suitable for applications in surgery.

Firstly, to capture the surgical environment peculiarities, personal and organizational factors were modeled and assessed through a specific IFs taxonomy, designed and validated ad hoc for the surgical context [17] and then systematically translated into the weights of corresponding Error Producing Conditions (EPC), typical of the traditional HEART method [13]. The proposed taxonomy is composed by 20 Influencing Factors (IFs) and it is well-designed for surgical procedure and operating room environment. Secondly, a participative team approach was adopted rather than a single external expert assessor, required from the traditional HEART, in line with previous studies in healthcare [5].

2.2 *Study Methodology*

This study took place at the Urology Department of one of the largest Italian hospitals. The starting point of the study was the development and validation of the BA-RARP task-analysis [15]. Once the task analysis was validated by the team of surgeons, the two most critical tasks were finally identified: “Isolation of lateral peduncles and of posterior prostate surface” (task 1), and “Anastomosis” (task 2). This decision came up from a preliminary focused literature review, further direct observational sessions, and experts’ judgments elicitation (three surgeons were involved).

As previously mentioned, the modified HEART technique was applied with the aim of understanding what are the most relevant IFs and the degree of coverage with EPCs (Error Promoting Conditions) considered by the standard HEART technique. To achieve this aim, three surgeons, considered fully trained in the procedure, were asked to answer a specific questionnaire. In particular, referring separately to the first and second critical tasks, they had to identify which

TASK 1											
IF		PoA1	PoA2	PoA3	PoA average	EPC*		PoA* 1	PoA*2	PoA* 3	PoA* average
1	Noise&ambient talk	90	80	60	76.67	3	Low signal to noise ratio	60	56	60	58.67
5	Poor management of errors	70	70	70	70.00	2	Shortage of time for errors detection	50	56	70	58.67
10	Poor coordination	40	70	70	60.00	10	Transfert knoledge from task to task	10	63	70	47.67
TASK 2											
IF		PoA1	PoA2	PoA3	PoA average	EPC*		PoA* 1	PoA*2	PoA* 3	PoA* average
1	Noise&ambient talk	80	70	60	70.00	3	Low signal to noise ratio	40	63	60	54.33
5	Poor management of errors	80	80	70	76.67	2	Shortage of time for errors detection	50	64	70	61.33
9	Poor communication	80	80	70	76.67	8	Capacity overload	10	48	70	42.66
10	Poor coordination	90	100	80	90.00	10	Transfert knoledge from task to task	20	50	80	50.00

Fig. 1 Final IFs selection for task 1 and task 2

Influencing Factors exert a major influence on surgeon's performance. They were also asked to assess PoA and PoA* (percentage of PoA of the IFs attributable to the main corresponding EPC, estimated by the surgeons involved in this study) for each of the chosen IFs (see Fig. 1).

Afterwards, it was possible to identify the corresponding EPCs, calculate total PoA for each of them and the corresponding Assessed EPC Affect to proceed with HEART calculations about the Assessed Nominal Likelihood of Unreliability (ANLU). Subsequently, the %CUs (contribution of unreliability) were calculated, in order to identify which are the IFs to be considered as the most critical ones, hence those requiring imperative remedial measures.

Finally, a Scenario Analysis was carried out to understand how ANLU may vary by mitigating the negative influence of different categories of Influencing Factors. In particular, personal, team, and organizational related factors were investigated by setting up three specific scenarios, for which new ANLU values were calculated by considering the impact of only the IFs relevant for the scenario.

3 Results

3.1 Selection of Generic Task Category

The choice of the category could represent an issue for HEART application in healthcare, as underlined by previous studies [5] since some elements of the HEART task categories don't match the healthcare task under analysis. Since the focus of this analysis concerns the investigation of the most relevant IFs and the degree of coverage with HEART EPCs, we chose Category G for both tasks, i.e. "completely familiar, well-designed, highly practiced, routine task occurring several times per hour, performed to highest possible standards by highly-motivated, highly-trained and experienced person, totally aware of implications of failure, with time to correct potential error, but without the benefit of significant job aids" [13]. Its Nominal Human Unreliability is 0.0004.

3.2 Correspondence Between EPCs and IFs

The comparison between the two taxonomies was performed consulting the list of the EPCs proposed by Williams in his original document paper [13]. Some of them are not applicable to the surgical context, e.g. because they fit only with the nuclear context, and were excluded from the analysis (corresponding to EPCs code numbers 27, 28, 30, 31, 34, 38).

On the other hand, some of the IFs included in the new taxonomy describe recent phenomena, e.g. the use of digital devices and mobile phones in the operating room. Hence, only few of the factors resulted in a perfect matching, with a unique (one to one) clear link; for example "operator inexperience" and "stress" are conditions directly taken into account by both taxonomies. Many IFs of the surgical taxonomy are only partly captured by grouping more than one EPCs of the original Williams' taxonomy, so we assigned weights to each of them, by estimating to what extent a specific EPC describes the effect of each Influencing Factor. Table 1 shows a synthesis of the full spectrum of coverage and matching between Williams' taxonomy of EPCs and the proposed taxonomy of IFs in surgery.

According to the findings of the present study, the EPCs traditionally used in HEART method are not able to fully capture and explain the relevant organizational and personal IFs in a surgical context. This result confirms the importance of adapting HRA methods to the healthcare sector, and adds original detailed information on what are the most relevant factors that should be captured by an HRA method when applied to surgery in particular.

3.3 Identification and Assessment of IFs Through HEART Calculation

To identify the influencing factors to be considered in HEART application we chose, as first selection criterion, the inclusion of those factors that were commonly identified by all the surgeons involved in the study and, as second criterion, those factors with no controversial assessment among surgeons. By averaging assessors PoA and PoA* values—for each IF—it was possible to balance surgeons' judgements, preventing overly optimistic or pessimistic results of the individual team member. The adoption of the average criterion is in accordance with previous HEART applications [5]. The selected Influencing Factors and their corresponding PoA and PoA* values, are shown in Fig. 1 for Task 1 and Task 2, whereas Fig. 2 summarize the results of HEART application to the same tasks.

As for Task 1, the three selected IFs were translated into seven EPCs showed in Fig. 2. The most significant Influencing Factor is "Poor management of errors" (IF 5), which has a total %CU of 0.49 (see Fig. 2). In particular, EPC 2 "Shortage of time available for error detection and correction" is the corresponding EPC with the highest contribution to %CU, having the greatest Multiplier (EPC

Table 1 Matching and degree of coverage between the taxonomy of IFs in surgery and Williams' EPCs

	Williams' EPCs		
EPC Category	Organisation	Man	Technology
EPC code number [13][a]	2, 3, 4, 7, 8, 9, 11, 14, 17, 18, 21, 26, 32, 36, 37	1, 5, 10, 12, 13, 15, 16, 22, 24, 25, 29, 35	23, 19, 20, 33, 6
Taxonomy of influencing factors (in surgery)	7	11	2
1-Noise and ambient talk	*87.2 %*[b]		
2-Music			
3-Noise			
5-Poor management of errors and threats to patient safety			
6-Poor guidelines, procedures and checklist			
8-Improper use of procedures and checklists			
15-Time pressure			
4-Verbal interruptions		*83.2 %*	
7-Rude talk and disrespectful behaviours			
9-Unclear of failed communication			
10-Poor or lacking coordination			
11-Poor decision making			
12-Poor situation awareness			
13-Lack of experience			
14-Fatigue			
16-Poor leadership			
17-Team member familiarity			
20-Emotional perioperative stress			
18-Poor use of technology			*100.0 %*
19-Inadequate ergonomics of equipment and workplace			

[a]EPCs n. 27, 28, 30, 31, 34, 38 are not applicable to the healthcare context
[b]Organization-related EPCs (15) capture the 87.2 % of the scope of IFs of the same type (7)

Multiplier = 11), and the largest value of Assessed EPC Affect. The second relevant IF is "Noise and Ambient Talk", which is linked to EPC 3 "Low signal to noise ratio". This EPC has the same value of PoA of the most significant one (PoA = 58.67), but its Multiplier is slightly lower than the previous one. The last IF considered is "Poor coordination" (IF 10), with correspondence to EPC 10, which has the lowest Assessed EPC Affect and %CU values (see Fig. 2).

TASK 1						
IF	EPC	EPC Multiplier	PoA	Assessed EPC Affect	%CU	%CU IF
5 Poor management of errors	2 Shortage of time for errors detection	11	58.67	6.867	0.33	0.49
	7 No means reversing unintended actions	8	2.83	1.198	0.058	
	12 Mismatch: perceived & real risks	4	5.665	1.170	0.056	
	18 Conflict: long &immediate objectives	2.5	28.325	1.042	0.05	
1 Noise & Ambient talk	3 Low signal to noise ratio	10	58.67	6.280	0.302	0.3
10 Poor coordination	10 Transfer knowledge from task to task	5.5	47.67	3.145	0.151	0.2
	25 Unclear allocation of responsibilities	1.6	12.33	1.074	0.052	
TASK 2						
IF	EPC	EPC Multiplier	PoA	Assessed EPC Affect	%CU	%CU IF
5 Poor management of errors	2 Shortage of time for errors detection	11	61.33	7.133	0.259	0.39
	7 No means reversing unintended actions	8	3.84	1.268	0.046	
	12 Mismatch: perceived & real risks	4	7.67	1.230	0.045	
	18 Conflict: long &immediate objectives	2.5	3.84	1.058	0.038	
9 Poor communication	5 No means of conveying info	8	34	3.380	0.123	0.24
	8 Capacity overload	6	42.67	3.133	0.114	
1 Noise & Ambient talk	3 Low signal to noise ratio	10	54.33	5.890	0.214	0.21
10 Poor coordination	10 Transfer knowledge from task to task	5.5	50	3.250	0.118	0.16
	25 Unclear allocation of responsibilities	1.6	40	1.240	0.045	

Fig. 2 Results of HEART application to the task "Isolation of lateral peduncles and of posterior prostate surface" (task 1 and task 2)

The four IFs selected for Task 2 were translated into nine EPCs, as showed in Fig. 2. Also in this case, IF 5 "Poor management of errors", primarily referred to EPC 2 ("Shortage of time available for error detection and correction") resulted to be the most critical one, having the greatest value of Assessed EPC Affect and Percentage Contribution to Unreliability (%CU = 0.39) (see Fig. 2). The second IF is "Unclear communication", which is an IF that was considered as not relevant for Task 1 by the surgical team. This IF is partly captured by EPC 5 and EPC 8 (see Fig. 2); they both have medium EPC Multiplier and PoA values and contribute to a %CU value of 0.24 (see Fig. 2). Third and fourth positions are covered by IF 1 (%CU = 0.21) and IF 10 (%CU = 0.16), respectively (see Fig. 2).

Starting from the same task category (G), the final ANLU (Assessed Nominal Likelihood of Unreliability) value for task 2 resulted to be greater than task 1, since the former is subject to a larger number of IFs. Furthermore, the two tasks under analysis share the same most critical IF, i.e. "Shortage of time available for error detection and correction" (EPC 2_IF 5), as demonstrated by the corresponding EPC Percentage Contribution to Unreliability of 0.33 % for Task 1 and 0.26 % for Task 2.

3.4 Sensitivity Analysis on Single IFs and Reference Scenarios

A Scenario Analysis was finally performed to investigate the sensitivity of critical tasks to different conditions. To this end, the maximum variations of the ANLU was

Table 2 Range of variation of ANLU due to the effect of relevant IFs

	Noise and ambient Talk (IF 1)	Poor management of errors (IF 5)	Unclear communication (IF 9)	Poor coordination (IF 10)
Range of ANLU for task 1	0.00040–0.00250	0.00040–0.00400	Not relevant	0.00040–0.00135
Range of ANLU for task 2	0.00040–0.00240	0.00040–0.00470	0.00040–0.00420	0.00040–0.00160

estimated under different combinations of IFs and finally compared to the Nominal Human Unreliability for the chosen Generic Task (NHU_G = 0.0004).

A first level analysis dealt with the sensitivity of ANLU to the IFs deemed as the most relevant according to surgeons' perception. ANLU values for each IF was estimated for both Task 1 and Task 2, using surgeons' averaged assessment of PoA values (Fig. 2). The greatest range of ANLU variation results from "Poor management of errors" (IF 5) for both Task 1 and Task 2 (Table 2).

A second level of analysis was performed with reference to three different scenarios. A scenario corresponds to the selection of a meaningful combination of relevant IFs, considering three main categories of factors: *personal, team* and *organizational* related (Table 3). The Reference Scenarios represent a way of modelling with HEART plausible situations in the operating room. In the following, the three scenarios are briefly described by making use of the information obtained from direct observations and interviews with surgeons.

The first scenario considered is related to personal factors that occur during the execution of a surgical procedure. "Unclear Communication" (IF 9) and "Poor Coordination" (IF 10) were identified by the surgeons as the IFs having a strong impact on surgeon's performance, and widely detected during the observational

Table 3 Characteristics of the three reference scenarios as combination of relevant IFs taken into consideration

Influencing factors		Reference scenarios		
		Poor personal conditions	Poor team conditions	Poor organizational conditions
1	Noise and ambient talk		X	
5	Poor management of errors			X
9	Unclear communication	X	X	
10	Poor coordination	X	X	

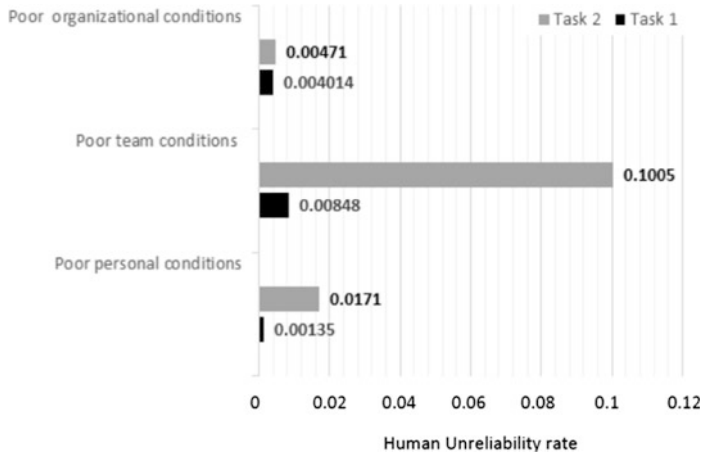

Fig. 3 Scenario analysis

phase of the study. According to surgeons' judgements, "Unclear Communication" (IF 9) was selected for Task 2 only. The new value of ANLU for Task 1 is 0.00135, which corresponds to 98.4 % reduction from the starting condition of the case study (ANLU = 0.0851) and increase of two order of magnitude from the NHU (0.0004). The new value of ANLU for Task 2 is 0.0171, corresponding to 98.3 % reduction from the reference case and increase of three orders of magnitude from the NHU (0.0004). Figure 3 shows the Human Unreliability Rate when poor personal factors influence the surgeon's performance; it also highlights that the reliability of Task 2 is more sensitive to poor personal conditions than Task 1.

The second scenario is the one concerning the influence of team factors on surgeon's performance. "Noise and Ambient Talk" (IF 1), "Unclear Communication" (IF 9), and "Poor Coordination" (IF 10) were included in this second scenario. Team members are key elements of the system. Poor coordination and unclear communication can either occur explicitly or implicitly. Team members can intentionally communicate or they can anticipate, assist and adjust without verbal instructions, relying on a shared understanding of the task and of the situation. Team members are continuously involved in reciprocal process to send/receive information that shapes and re-shapes team's attitudes, behaviors, and situational awareness. The new value of ANLU for Task 1 is 0.00848, which corresponds to 90 % reduction from the starting condition of the case study and the 2021 % increase from NHU (0.0004). The new value of ANLU for Task 2 is 0.1005, which corresponds to 89.9 % reduction from the reference case and four orders of magnitude increase from the NHU (0.0004).

According to surgeons' perception of the most relevant IFs for the considered surgical procedure and tasks, the third scenario is described by "Poor management of errors" (IF 5) only. It refers to the scenario in which procedures to share information promptly and openly about errors are compromised. The new ANLU

value for Task 1 is 0.00401, which corresponds to 95.3 % reduction from the starting condition of the case study (ANLU = 0.0851) and the increase of one order of magnitude from the NHU (0.0004). The new ANLU value for Task 2 equals to 0.00471, which corresponds to 99.5 % reduction of ANLU and 1077 % increase from the NHU (0.0004). The graph reported in Fig. 3 shows that the case of poor organizational conditions is the scenario with the lowest impact on surgeons' performance (measured by HEART as Human Unreliability rate), whereas the case of poor team conditions represents the worst scenario for both tasks.

4 Conclusions

This study aimed at contributing to the development of HRA methodologies in healthcare, and surgery in particular, as a quantitative approach to the identification of risk factors and appropriate mitigation measure against surgical adverse events.

Furthermore, although the study confirms the value of adopting HEART technique in the context of Clinical Risk Management, results support the argument in favor of a deep adaptation and translation of HRA techniques to the healthcare context. In this regard, the present study offers a systematic approach to matching and quantification of the correspondence between a taxonomy of IFs in surgery [17] and the Williams' taxonomy of EPCs normally used in HEART applications [13]. The assessment of surgeon's reliability/unreliability in robotic surgery was assumed as a significant case study, since it is an increasing innovative mini-invasive surgical approach, whose advanced technology needs to be managed in order to limit the possible new error pathways due to the complexity of human-machine interactions. The major role of team related factors in determining surgical performance, when compared to other personal or organizational factors, is another original contribution of the present study. Further developments of this research may concern: (i) the investigation of an entire surgical procedure, so as to also consider task dependencies and error recovery procedures; (ii) the adoption of HRA techniques in the context of surgeons training and proficiency assessment.

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Prospects and Problems of Smart Glasses as Tools for Surgery

Kazuhiko Shinohara

Abstract The feasibility and problems of using smart glasses (SMG) in surgery were investigated in this study. The prospects and challenges of SMG in surgery are as follows. The advantages of SMG are that various kinds of medical information can be provided, including surgical navigation and consultation with other physicians. Since SMG are hands-free, they are clean and safe to use in surgical practice. The challenges and unresolved problems of SMG are ergonomic problems such as eyestrain and fatigue, and technical problems such as Internet security and electromagnetic interference. Further collaborative investigation and development of the technology and ergonomics of SMG are important for their successful application in surgery.

Keywords Smart glass · Clinical surgery · Ergonomics

1 Introduction

As hands-free interactive computing devices, smart glasses (SMG) and other wearable devices are expected to play valuable roles in various human activities. These hands-free and voice-controlled systems that allow users to obtain information and videos through the Internet could be useful in the field of surgery. The feasibility and problems of the application of SMG in surgery were investigated in this study (Fig. 1).

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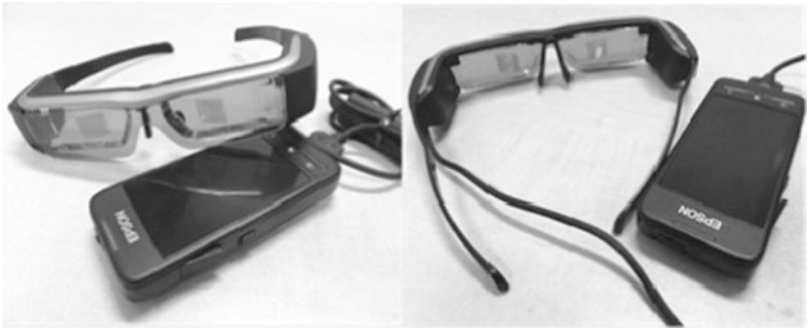

Fig. 1 A smart glass (Epson Co.)

2 Materials and Methods

Possible uses of SMG in surgery were investigated at sites including the operating room, ambulatory care, intensive care units, and patient wards (Figs. 2 and 3) Prospects and problems of SMG as a tool for surgery were analyzed from the perspective of technology and ergonomics.

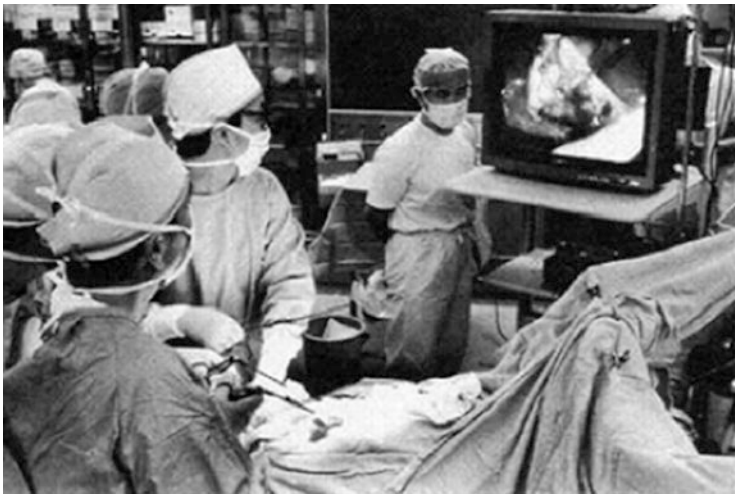

Fig. 2 A scene of conventional endoscopic surgery

Fig. 3 Conventional computer terminals for clinical records such as medical history, vital signs, laboratory data and medical images

3 Results

Possible uses of SMG in surgery were revealed and are listed below.

1. As a display for medical information such as laboratory data and medical images.
2. As a display for the real-time navigation system during the operation.
3. As a display for the user's manual of medical devices and drug information during surgical practice.

4. As an interface for remote guidance for consulting physicians and specialists.
5. As a display for a live streaming video of a patient's status for surgeons while they are performing surgery or caring for another patient.

The following problems of SMG in surgery were identified.

1. Eye strain and fatigue, and instability when wearing SMG over eyeglasses.
2. Cognitive confliction between SMG images and real images.
3. Image quality.
4. Electromagnetic interference from high-powered medical devices.
5. Privacy and Internet security.

4 Discussion

Interest in and the range of applications for SMG and other similar wearable devices are rapidly increasing, as they can provide different kinds of information, including interactive computing through the Internet to users during other human activities such as walking and working. Wearable and hands-free uses are great advantages of SMG. Since SMG are hand-free, they are cleaner and safer to use in surgical practice compared with tablet PCs and smartphones. These advantages are promising and are useful peri-operatively.

Surgeons and anesthesiologists can check patient information such as laboratory data and medical images during the operation without having to move and read the medical records on paper or on computer terminals. Recent advances in computer-aided surgery have made intra-operational navigation possible by superimposing three-dimensional anatomy onto real images acquired by endoscopy. These navigation images had been shown on external displays or tablet computing terminals. By using SMG as a provider of intra-operational navigation images, the surgeons can check the navigation information with minimal eye movement. Thus, SMG can be an optimal human-computer interface for the intra-operational navigation system (Figs. 4 and 5).

Due to the rapid development of medical devices and drugs, surgeons and nurses encounter new medical devices and drugs in the operating room. Surgeons and nurses have to check the manuals to answer questions and resolve unknown points during surgery. SMG are useful as a hands-free display for manuals of medical devices and drug information during clinical practice and patient care.

By using SMG, surgeons and medical students can consult with other physicians and specialists and share information during the operation. Also, nurses can consult with other technicians and receive guidance for difficulties in the operation of medical devices during the operation via SMG.

SMG is useful as a tele-monitoring device for monitoring a patient's status and vital signs. Surgeons and nurses can treat and care for other patients by watching a live streaming video that is focused on the patient's symptoms and vital signs, such

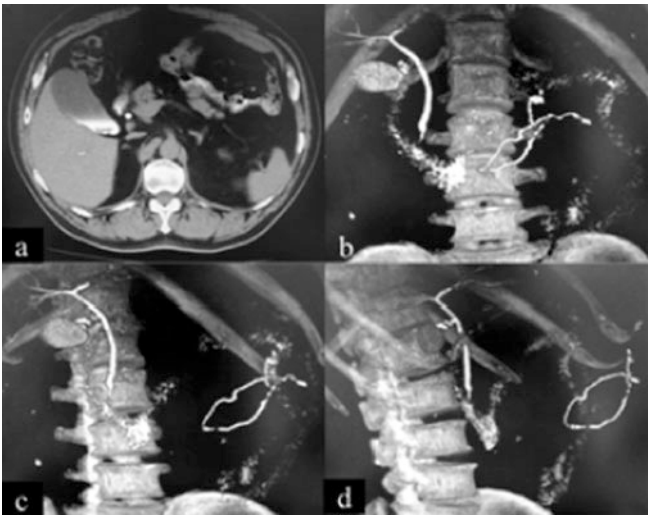

Fig. 4 Computed tomography (CT) images for cholecystectomy **a** conventional horizontal scan of gallbladder. **b–d** 3-D navigation images of bile duct and gallbladder reconstructed from original CT images

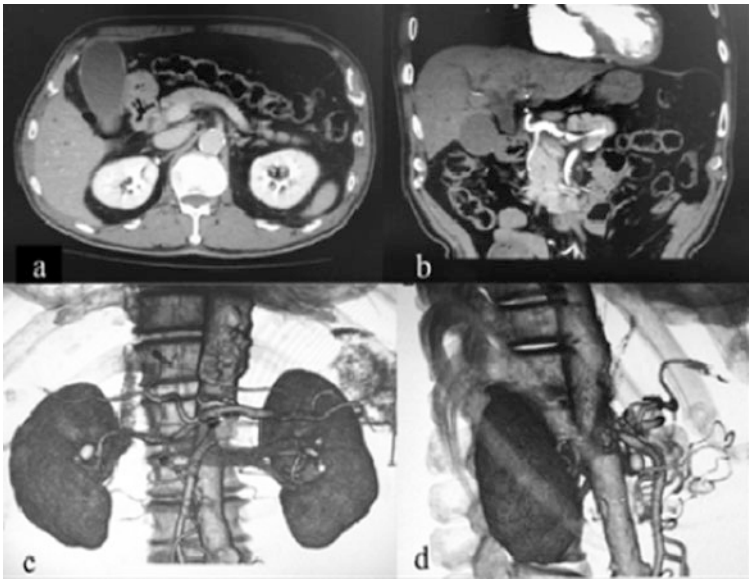

Fig. 5 CT images for pancreas surgery. **a** Conventional horizontal scan. **b** Sagital view reconstruction. **c** 3-D angiographic reconstruction. **d** Lateral view of 3-D angiographic reconstruction

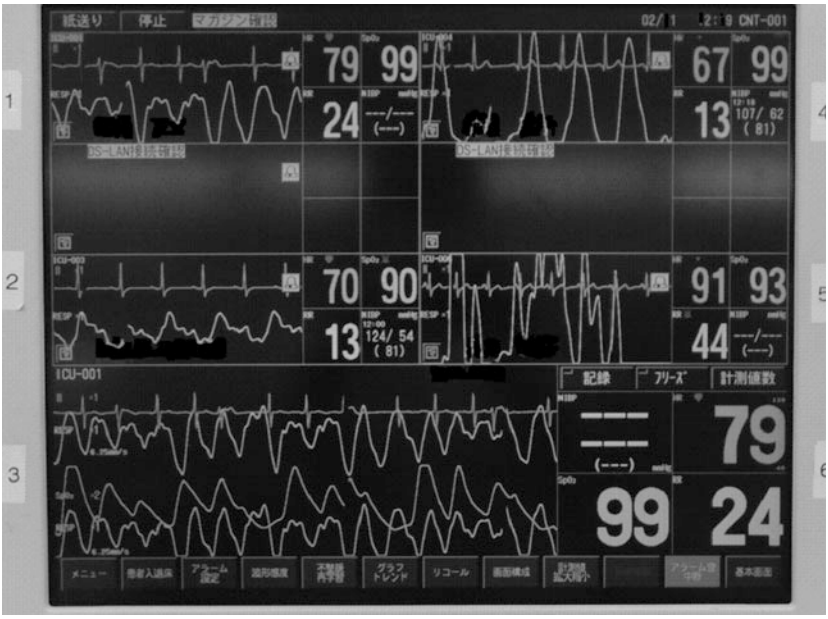

Fig. 6 A display of central patient monitoring system. 5 patients' vital signs such as blood pressure, heart rate, respiration rate, electrocardiogram and pulse-oximetry are displayed

as tracings of an electrocardiograph (Fig. 6). The ease of sharing of patient's signs and symptoms between nurses and consulting physicians is an advantage that can be applied to home-care medicine and disaster medicine. The provision of video streaming and images to attending physicians can assist their diagnosis and decision-making regarding prescriptions and emergency medical care outside the hospital.

On the other hand, there are some problems in the surgical application of SMG. Surgeons have to wear SMG for several hours during the operation. For example, standard laparoscopic cholecystectomy can be performed within 1 h, but laparoscopic colectomy needs about 2–3 h. Other major surgeries such as hepato-pancreatic surgery need 5–6 h. So ergonomic problems such as eyestrain and fatigue, and instability when wearing SMG over eyeglasses are significant concerns that should be addressed. Surgeons watch the actual image of the surgical field and SMG images simultaneously, so ergonomic and psychological investigations of the problems of cognitive confliction between SMG images and real images are essential. Preceding research and achievements of the head-mounted display for pilots may be useful. Medical images from endoscopy and computed tomography are of high-quality with a high volume of data, so technical considerations should be taken into account when displaying these images on SMG. There are high-powered energy devices such as electro-surgical units, X-ray fluoroscopy, and magnetic resonance imaging in the operating room. So countermeasures for

electro-magnetic interferences from these medical devices should be considered. Also, ethical and technological issues of privacy and Internet security should be considered [1, 2].

5 Conclusion

The feasibility and problems of the application of SMG in surgery were investigated in this study. As SMG is wearable and provides a hands-free human-computer interface, they are clean and safe to use in surgical practice. Application of SMG in various fields of surgery is promising and useful. Unresolved problems in the surgical application of SMG are related to ergonomic and technical problems such as eyestrain, Internet security, and electromagnetic interference. For the successful application of SMG in surgery, ergonomic and technological problems should be resolved through further analysis of the workflow of the medical devices and surgical staff involved.

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Part II
Human Factors and Ergonomics and Healthcare Professionals

A New Elderly Clothing Design Reduces Nurse Aides' Occupational Injury in Nursing Homes

Wen-Yu Yang, Fong-Gong Wu and Adam Book

Abstract Nurse aids assist the elderly to dress for a long time, they always get work-related musculoskeletal disorders (WMSDs) owing to inappropriate application of force. The purpose of this study is to design a new elderly clothing to reduce the cumulative damage of nurse aids from assisting the elderly dressing effectively. We designed two new elderly clothes with two different methods, one is Morphological Analysis (design A) and the other is Co-design (design B). Design A uses Velcro to join fabric to reduce the time nurse aids spend on finding cords. Design B is a one-piece cloth which wear from front in order to reduce unnecessary rotate of joint. Results showed that design B spend the least time. The shortage of design A is it will take time to separate Velcro when they stick together. Design B should care more about elderly's perception, sense of security and exposure, especially for the heavy elderly.

Keywords Occupant injury · Elderly clothing · Ergonomics design · Nursing home · Dressing

1 Introduction

According to the American population reference bureau estimate, the number of world's population aged 65 and over is about 580 million people in 2014, and it will grow to 1.5 billion people in 2050 [1]. More and more elderly live in nursing homes to get better care. The more complete care of the elderly get in nursing homes, the more occupational injury nurses' aides are affected, such as work-related

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musculoskeletal disorders (WMSDs) [2]. Helping the elderly to dress is a hard task, and it has been ranked as one of the most difficult tasks of daily life in the nursing home. In nursing homes [3], most of the elderly need to change clothes with the help of nurse aides [4]. Under normal circumstances, one nurses' aide needs to care for many patients and usually spends 4–9 min to change an elderly clothing [5]. In order to reduce the pressure on nurse aides, nursing homes often using different types of dressing aides though some of the elderly think existing equipment are too bulky [6].

There are few researches about reduce nurse aids' occupational injury by designed clothing. Clothes are very important items that people wear and are used to offer dignity and comfort [7–9]. Clothes wore by the elderly who live in nursing homes are not specifically designed for the elderly and they need nurse aides' help to wear. Both the elderly and nurse aids are often injured during the dressing process [2]. According to records of health care claims, it was found that back injuries among nurses were one of the five most common occupational injuries [10]. These problems make nurse aides' psychological pressure become worse and worse in the low-paid care industry [11].

The purpose is to reduce nurses' occupational injuries and increase efficiency. To analyze the interaction during changing clothes between the elderly who live in nursing homes and nurses' aides. By observing and analyzing the process of changing clothes, find the main reasons why nurse aides get injuries and pain under long-term work, and track the movements that the elderly cannot accomplish by themselves because of physiology degradation. Based on the above points of view, in-depth exploration of the impact of physiological degradation and of nurses' aides, find the key parameters of design and follow the suggestion of Rosenblad-Wallin and Karlsson [8]. Standing on the perspective of ergonomics to find the best solution, provide users comprehensively designed elderly clothing. Consider the behavior of nurse aides and the elderly to design elderly clothing, make the new elderly clothing that can more directly reduce nurse aides' injuries because of dressing.

2 Research Methods

2.1 Preliminary Investigation

Interview. Interviews three experts of the elderly to find out nurse aides' daily work, the difficulties during dressing assistance, the injuries received from occupation and the degree of pain experienced, questions for elderly dressing's expansibility were also asked, including the detail of nurse aides' helping the actual situation and the injuries and pressure received from caring and the interaction

between nurses' aides and the elderly. Based on the position of the nurse aide, the whole process was analyzed.

Observation. Observations were conducted to find out the interactions between nurse aids and the elderly, nurse aides' daily work, the difficulties during dressing assistance, the injuries received from occupation and the degree of pain experienced. We observed the nursing home under Kaohsiung Veterans General Hospital Tainan Branch, Taiwan.

2.2 Design Clothing

Morphological Analysis. Morphology is the method that concerned with structure and arrangement of all parts of factors, and create a whole or Gestalt suit [12]. Invited two experts from Industrial Design to conduct Morphological Analysis.

Co-design. Use the co-design method with six people (two medical experts and four designers), a free and interactive discussion was had for the elderly clothing. By interaction with the participants, information was quickly gathered and more in-depth views and opinions were obtained. The possibility of the elderly clothing design features will develop to new clothing.

Experimental Equipment and Environment Planning. To avoid the participants' interference, experiments were held in a classroom without any noise. Let each participant discuss together, in order to avoid interruption of recording, incomplete, and effectively record the participants' thoughts on various ways, a video recorder was set up to record.

Protocols.

(a) Use fixed video recorder to record all the process in same angle: In case has wrong record by myself.
(b) Introduce this project is to explore the elderly clothing to reduce nurse aides' occupational injury and enhance the efficiency.
(c) Share the information:
Including existing status, goal, target, observation, efficiency, existing clothing.
(d) Discussion.
Allow participants to write down their ideas.
(e) Let participants exchange ideas.
(f) Let participants draw or talk about the ability of the elderly clothing.

3 Result

3.1 Preliminary Investigation

Interview.

1. First expert of the elderly care:
   According to law, a nurse aide can only care for 15 elderly people, but in actuality, manpower shortage results in caring for more than 15 people. It shows a shortage of human resources, and also cause a lot of body burden to nurse aides. There are daily dressing routines, bathing, pain testing, distributing drugs, etc. Dressing is usually in bed; this is also used for wheelchair patients. Expert believes that Velcro is designed for nurses' aides to easily and quickly use. But for the elderly, buttons can be used to promote their autonomy and hand movements.
2. Second expert of the elderly care:
   A nurse from the United States indicated that a nurse will take care of 44–56 older patients, and there are 6 nurses' aides to help the nurse. Each nurse aide has to take care of about 7–10 elderlies. Nurse aides usually have knee and hand arthritis. Body temperature can easily be lost, causing poor blood circulation and dry skin because of clothing. The elderly need exercise in daily life, no matter how small of an activity or limbs movement exercises. Both need to concern about avoiding cramping and falling.
   Another very important point is efficiency, because a nurse aide needs to take care of numbers elderlies. Due to elderlies' muscle recession, slow dressing often spends a lot of time and increases the degree of difficulty; this affects breakfast time in the nursing home. So how can nurse aides be more efficient? By reducing the pressure and time burden in helping the elderly to dress; this is very important. Experts also suggest that the physiological condition and warming mechanism need to be concerned.
3. Third expert of the elderly care:
   When nurse aides care for the elderly, the prolonged actions of raising hands easily causes scapula pain and waist injury because of moving the elderly. During the dressing process, nurse aide will let the elderly raise their hands first, then put the clothing on. If there is disordered limb, they will put on disordered limb first. After putting on clothing, let the elderly fasten buttons. Zippers are too small for elderly to use. Some advice was stated for elderly clothing: (1) pre-opened clothing should be used as much as possible (2) flexible (3) big buttons (4) avoid big stretching to cause damage (5) Velcro can't suit the elderly to take care of themselves, but there is also fear that it will be opened when lifting or moving accidentally.

The following findings were obtained from the expert interviews:

- Nurse aides really need to have efficient dressing solutions.
- Nurse aides really get occupational injuries while helping the elderly dress.

Fig. 1 Interaction between nurse aide and the elderly

- Because of the elderly's lower flexibility, they need an easier way to dress.
- The elderly clothes need to consider physiology.

Observation.

Dressing Process. When putting on clothing, nurses will dress the disordered limb first, then dress healthy limbs; but when taking off, nurses will undress healthy limbs, then undress disordered limbs. The main idea is to try to avoid moving disordered limb, causing unnecessary harm. About the clothing styles, shirt better to be loose, flexibility and front opened. But consider winter, front opened have poor thermal effect. Paints better to use elastic. About the choice of clothing materials, breathable, elastic and low friction coefficient of the fabric will be better, such as cotton, but avoid such as denim material.

Interaction between Nurse Aide and the Elderly. The elderly living long-term in nursing home, the relationship between nurse-aides the elderly are as close as family. During the dressing process, nurse aide give the elderly many opportunities to accomplish some simple actions, such as lifting arms, putting hands into the sleeves, feet and waist elevation. Through the process of changing clothes, the elderly practice seldom-used areas of focus (Fig. 1).

Nurse Aide Injury Condition. After interviewing nurse aides, finding the most difficult work in nursing home is helping the elderly to bathe, second is helping the elderly to dress. During the process of helping the elderly dressing, nurse aides should avoid using hand and wrist strength to move the elderly by tensile force. They need to use the power from their back and shoulder for their hands, use the power from waist to move the elderly, but it always causes to occupational injury. However, in the case of long-term accumulation, more than half of nurse aides are suffering from neck pain, back pain, shoulder pain and waist problems.

3.2 Design Clothing

Morphological Analysis. After interview and observation, the following table was arranged (Table 1).

Table 1 The result from morphological analysis

Clothing type	Way of opened	Fabric type	Fastener type	Sleeve length
Shirt	Front strait[a]	Cotton[a]	Velcro[a]	0 (Tank)
	Front cross[a]	Polyester	Button	2 (Standard)
	Side	Blend[a]	Cord	5 (Half)
	Top		Zip	7 (3/4)
			Snap button	10 (Full)*
Pants	Front	Cotton[a]	Velcro	Short
	Side	Polyester	Button	Long[a]
	None[a]	Blend[a]	Cord	
			Zip	
			Elastic	

[a]This study selected these items as design element

Design based on the table, can achieved the following suit (Design A) (Fig. 2). Design A was made from blended fabric. About shirt, keep the same opening way of original clothing. Adjust cords into Velcro, increasing efficiency. About the Velcro, special design can save time in aligning, also can adjust with different size of the elderly. About paints, outlook is almost the same with the original one. Adjust cords into elastic, it cannot only save the time in tying, but also adjust can with different size of the elderly. Also feel comfortable.

Followings are the points came out with co-design (Fig. 3).

Fig. 2 Design from morphological analysis

Fig. 3 Co-design

Fig. 4 The design from co-design

(a) Good to nurse aid-reduce occupational injury.

1. Loose.
2. About dressing direction: Avoid from bottom to top.
3. About working plane: Suit nurse aide height.

(b) Good to nurse aid: Efficiency.

1. Two pieces transfer into one piece.
2. Wear both hands together.
3. About junction: Velcro.

(c) Good to the elderly.

1. About length of sleeve: Long. Reasons: Warm, collision avoidance (slow recovery), prevents sunburn (the elderly have thin skin).
2. About clothes opening: Front. The reason is the elderly's sense of security.

Follow the points, we design a new cloth (Design B) (Fig. 4).

4 Discussion

4.1 Interview

By interview to the expert of elderly care can get following.

Design A. The used of Velcro is much better than the clothing nursing home used now, because nurse aides spend lots of time finding cords. The arrangement of Velcro is good, nurse aides don't need to align and can adjust with the waistline of the elderly easily. But the shortage of Velcro is that they will stick together. It will take time to separate them, if the cloth can improve it, it will be better.

Design B. First, one-piece really save a lot more time than two-pieces. Wearing one-piece cloth is no problem to female, but there are some problems for men. Should care more about elderly's perception. Second, because it may break free and they wear nothing in their lower body, the elderly will feel strange. Care should be taken about the elderly's sense of security. Third, holding both hands together in front of them can give the elderly comfort and also save time. Forth, because the

opening is in the back, it is important to avoid exposure, especially for the heavy elderly. Fifth, the way for wearing is much better than others. The elderly only need to raise their hands in the front. It reduces the rotary the elderly need to do.

4.2 Test

A test was made to measure how much time nurses' aides spend on helping the elderly dressing in different clothing. The nurse aide helped the elderly put on and take off three different clothing, every clothing will be put on and put off three times (Fig. 5).

Result. After testing, the following results were obtained: (Tables 2 and 3; Figs. 6 and 7).

Based on the results, putting on clothing took much more time than taking them off. It's likely due to a more detailed dressing process. On average, Design A is much more efficient than the original one. Reasons may be attributable to: shirt,

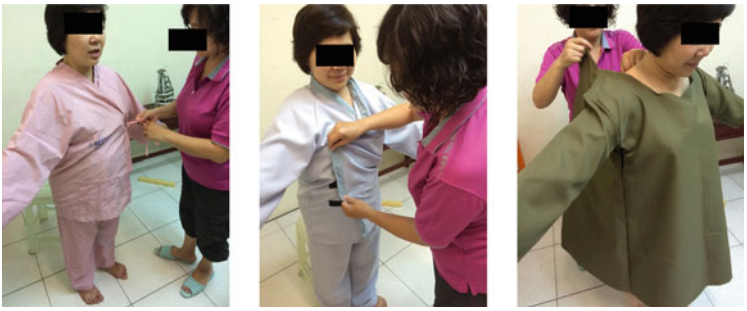

Fig. 5 Test condition

Table 2 Result from testing—put on

Style	Put on	1	2	3	4	5	6	7	Average	Set
Original clothing—pink (s)	Top	161	110	97	164	131	99	143	129	256
	Paints	99	87	95	183	173	91	161	127	
Design A—blue (s)	Top	54	63	58	112	104	60	93	78	174
	Paints	63	55	64	171	140	61	148	96	
Design B—dark green (s)	One piece	34	30	29	68	59	34	70	46	46

Table 3 Result from testing—take off

Style	Take off	1	2	3	4	5	6	7	Average	Set
Original clothing—pink (s)	Top	89	32	29	96	64	30	67	58	112
	Paints	75	32	34	82	60	33	59	54	
Design A—blue (s)	Top	63	23	24	72	52	25	50	44	85
	Paints	64	17	19	69	57	18	40	41	
Design B—dark green (s)	One piece	42	15	11	49	29	12	22	26	26

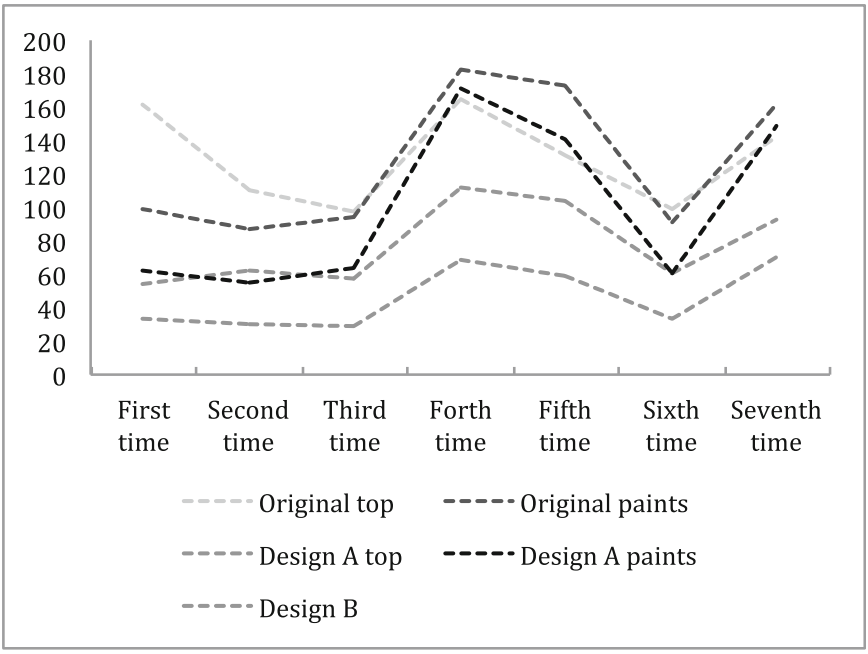

Fig. 6 Result from testing—put on

Velcro takes the place of cords and save lots of time in finding cords and tying. Pants elastic takes place of cords and save the time of tying. Design B shows the best efficiency. The reasons save more than half of time than others are following: First, combining two pieces to one piece. Second, dressing with both hands together.

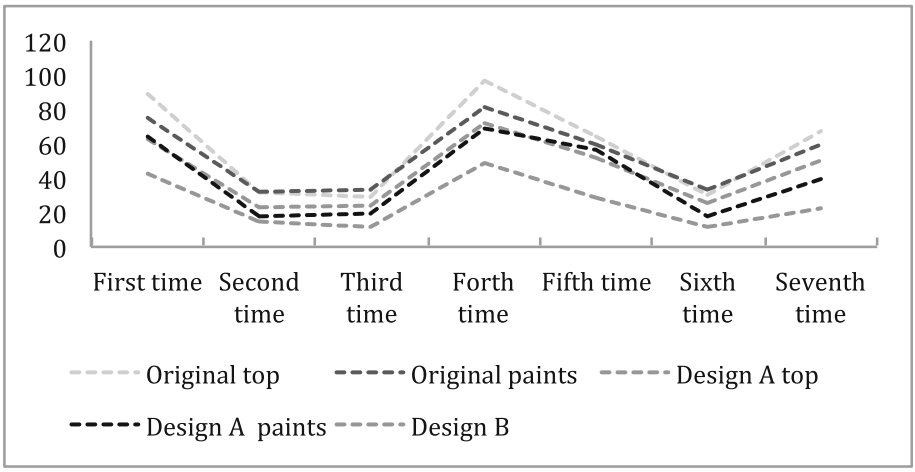

Fig. 7 Result from testing—take off

5 Conclusion

Though Design B not only shows the more efficiency in wearing but also has the less rotary, it doesn't consider a lot of the elderly psychology. Despite Design A doesn't show the best in efficiency, it does consider about the elderly. In the future, if there is chance to do more research on the elderly clothing; more care should be given to psychology. Also, recruiting the help of professional clothing designers would be helpful for higher quality samples. It is advised that those who are interest in this area should learn how to make clothing before beginning the process.

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Bedside Dialysis and the Occupational Safety and Health Impact on the Healthcare Worker in an Acute Hospital

Wai Kuen Kam, Mohd Fahmy bin Abdul Kader Alkaff and Paige Geek Pei Tan

Abstract In an acute hospital, staff from the Renal Dialysis Centre (RDC) transported haemodialysis machines to patients in various wards to enable bedside dialysis. The bedside service was provided for patients who were not suitable for transfer to the RDC due to their medical condition. The haemodialysis machines, together with the Reverse Osmosis (RO) water machines were transported from the RDC to the wards on a daily basis. The objectives of the study were to evaluate the ergonomic stress on the staff transporting the machines; and any other occupational safety concerns that may arise from the transfers.

Keywords Healthcare · Healthcare worker · Occupational safety · Push/pull force · Transporting · Haemodialysis machine · Hospital

1 Introduction

The Renal Dialysis Centre (RDC) provided haemodialysis treatments to inpatients at the main Centre with 20 dialysis stations. In addition there were inpatients that were unsuitable for transfer to the RDC and for that group, 10 haemodialysis machines with the accompanying RO water machines would be transported from the RDC to the bed-side to enable bed-side dialysis. Those patients would include inpatients

(a) in intensive care units;
(b) in intermediate care units;

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(c) in isolation wards due to their medical condition; and
(d) who were newly diagnosed with end-stage renal failure.

The machines were transported out of the RDC daily by the healthcare workers (HCW). Wherever possible, 2 HCW would transport the set of 2 machines. There were occasions when one HCW was observed to be pulling the haemodialysis machine while pushing the RO machine.

2 Methodology

1. The workload of out-centre dialysis was evaluated for a typical month taking the number of cases requiring bed-side dialysis, distance travelled and time taken by the HCW transporting the machines.
2. The initial and sustained push and pull forces required to move the haemodialysis machines and the accompanying RO water machines were taken for movement on a flat vinyl floor, movement into and out of the lift. The results were evaluated using the Snook tables of push/pull forces as used by the hospital's Occupational Therapy department Ergonomics experts.

3 Results

3.1 Workload

In a typical month, bedside dialysis for a typical month showed the following:

(a) 409 cases
(b) total distance travelled to transport the machines was 67 km
(c) total travel time taken was 133 h (5 days and 13 h)
(d) inpatient wards requiring the highest number of bedside dialysis were the Infectious Disease (130 sessions per month), Renal Medicine (94) and Respiratory and Critical Care Medicine (44) wards.

3.2 Machine Dimensions and Load

Data was taken for 3 models of haemodialysis machines that were in use and the RO water machine that was housed in its own trolley (Table 1).

Table 1 Machine dimensions and load

Machine	Dimensions mmH × mmW × mmD	Reagent load	Height of handlebar (mm)	Wheel diameter (mm)
Fresenius 4008 haemodialysis machine	1370 × 480 × 480	2 × 10 L conc. haemodialysis solution	950	70
Fresenius 5008 haemodialysis machine	1620 × 480 × 720	No load	1180	70
Gambro 96 haemodialysis machine	1305 × 620 × 585	720 g sodium bicarbonate + 3500 ml SoftPac	1050	75
RO water machine in trolley	900 × 610 × 860	2 × 10 L conc. hemodialysis solution	1060	100

3.3 Force Measurements

During the trial, the following were observed and taken into consideration for the measurements shown in Table 2:

(a) The sustained push/pull force for moving the machines were insignificant, therefore the study focused on the initial push/pull forces.
(b) Where possible, pushing was the preferred mode of action. Pulling action was only evaluated when pushing was not possible.
(c) The activity of entering and exiting the lift were significantly more difficult and therefore the measurements were taken for these activities.
(d) The Fresenius 4008 and Gambro 96 haemodialysis machines could be transported with or without additional loads of

   i. 2 × 10 L of HD-1B Liquid Concentrate Bicarbonate reagents (A)
   ii. 720 g Sodium bicarbonate (Bicart) and 350 ml SoftPac (B).

(e) The RO water machine was installed in a trolley and always transported with an additional load of 2 × 10 L of HD-1B Liquid Concentrate Bicarbonate reagents.
(f) Push/pull forces were compared with tables of maximum acceptable push/pull forces (*psychophysical limits*) by Snook and Ciriello [1].

   i. The frequency of push for the haemodialysis machines was at the average of 5.5 initiation pushes per hour over a distance of 290 m per day.
   ii. As the readings exceeded the Snook table, we took the maximum distance and the maximum frequency. Thus, for pushing/pulling task to be safely done by 90 % female for 61.0 m travel at one push every 8 h over flat floor, the initial force should not exceed 16 kgf.

Table 2 Measurement of initiation force to move haemodialysis machines and RO water machine trolley

Equipment	Movement	With load? A/B	Force direction	Force measured (kgf)	Snook table limit @ 90 percentile for females (kgf)	Acceptable?
Fresenius 4008	Flat floor	A	Push	16.9	16	No
		–	Push	9.5	16	Yes
	Into lift	A	Push	20.5	16	No
		–	Push	19.1	16	No
	Out of lift	A	Push	[a]	16	[a]
		–	Push	[a]	16	[a]
		A	Pull	27.1	16	No
		–	Pull	23.6	16	No
Fresenius 5008[b]	Flat floor	–	Push	11.8	16	Yes
	Into lift	–	Push	16.4	16	No
	Out of lift	–	Push	[a]	16	[a]
		–	Pull	22.7	16	No
Gambro 96	Flat floor	B	Push	10.55	16	Yes
		–	Push	6.92	16	Yes
	Into lift	B	Push	12.3	16	Yes
		–	Push	7.94	16	Yes
	Out of lift	B	Push	[a]	16	[a]
		–	Push	[a]	16	[a]
		B	Pull	23.6	16	No
		–	Pull	22.8	16	No
RO water machine in trolley[c]	Flat floor	A	Push	8.73	16	Yes
	Into lift	A	Push	17.6	16	No
	Out of lift	A	Push	18	16	No

[a]Not recorded as attempts to move out of lift failed for both push conditions i.e. with and without load due to wheels getting trapped in the gap between lift car and lift landing. Continued pushing would lead to toppling. Recoveries made were by pulling the equipment out of the lift
[b]Fresenius 5008 was always transported without additional reagent load
[c]The RO water machine trolley was always transported with load A

When the machines were pushed out of the lift car onto the landing the following were observed which required the staff to exert extra effort overcome the resistance.

(a) There was a very small gap of approximately 28 mm between the lift car and the landing.
(b) The lift car floor was also observed to stop just very slightly below the landing.

4 Conclusion

With reference to the Snook Table Limit for 90 % of the female healthcare staff performing the task, the forces required to push the following machines in the following manner were within the recommended safe limit

(a) Fresenius 4008 without load on flat floor;
(b) Fresenius 5008 without load on flat floor;
(c) Gambro 96 with and without load, on flat floor and into the lift; and
(d) The RO water machine trolley with load on flat floor.

All other pushing activities with the machines exceeded the recommended safe push force limit with reference to the Snook Table Limit for 90 % of the female healthcare staff performing the task.

All pushing of the haemodialysis machines out of the lift was unsafe due to an incidental risk of the haemodialysis machines toppling.

The push forces for the haemodialysis machines (with or without load) exiting the lift car were not taken. For these machines, the pull forces were taken instead.

(a) The 28 mm gap between the lift car and the landing proved too challenging to safely push the machines out of the lift as the wheels of the haemodialysis machines (70 and 75 mm diameter) were consistently trapped. An extra push was required to overcome that.
(b) There was a risk of the slim and tall haemodialysis machines toppling over. It was not possible to measure the centre of gravity of the machines but the broadest side of the base to the height of the machines ratios were less than 1:2 (refer to Table 1). The in-built pumps, detectors and monitors were located on the upper half of the machines. The handles were also located near the top of the machines for ease of handling.

The RO water machine trolley's wheels were 100 mm in diameter and did not face the same problem. As the RO machine was much shorter than the haemodialysis machines, it was also easier to push it over the gap without the fear of toppling.

5 Discussion

The push/pull forces required to push all the portable haemodialysis machines and RO water machine trolleys *out of the lift* exceeded the recommended safe limit for 90 % of female healthcare staff. That was unacceptable as the staff were required to perform multiple trips daily. The layout of the hospital made it necessary to use the lift to move between floors to the other inpatient wards.

9 months prior to the research, one senior staff nurse from the RDC reported difficulty pushing another haemodialysis machine, the Continuous Renal Replacement Therapy machine Prismaflex2. He reported having to exert force to push the machine out of the lift as the wheels got stuck in the gap between the lift car and the landing. As a result, he sustained a backache injury with a long recovery period when he was absent from work.

The RO water machine trolley's wheels were 100 mm in diameter and that could have contributed to its ease of moving out of the lift car onto the landing despite the gap and unequal floor height between the two. However, the size of the wheels of the haemodialysis machines could not be changed as the modification was not supported by the manufacturer and sales agent and would render the machine warranties null and void.

The gap between the lift car and the landing and the slight dip of the lift car floor could not be rectified by the lift maintenance personnel as the extent was inconsistent, could not be avoided and could probably be affected by the load of the lift car when it was filled with equipment and passengers.

Bedside dialysis could not be avoided but the results from the study were used to successfully augment a proposal to relocate some hemodialysis machines to the inpatient wards that had the highest requirement. In that way, the majority of the machines would not have to be transported from the RDC daily. That was an ideal solution to the problem as the other factors regarding the existing machine wheels and lift positioning could not be fixed.

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Biomechanical Evaluation of Patient Handling Jobs in Healthcare: A Case Study in India

Dharmendra Sharma, Pradip Kumar Ray and Esha Saha

Abstract The principles of ergonomics can be applied to the study and design for the components of any worksystem involving human(s) and machine(s) embedded in environment. Performance of healthcare is considered one of the sectors of industry heavily relying on humans performance that is mainly controlled by the way the human-machine interaction or interface is designed. Even though sophisticated diagnostic equipment and system may replace manual tasks, a large number of jobs like patient handling, OPD operations, nursing, etc., are irreplaceable by machines. In such a scenario, it becomes important to look at these jobs from an ergonomic point of view and identify potential risks associated with the jobs that the hospital assistants carry out on a daily basis. Patient-handling is one such job which has been covered in much of the ergonomic literature. Many alternative postures for manual unassisted handling as well as ergonomic designs of stretchers and wheelchairs have been discussed by researchers. In this paper, dynamic biomechanical models of the work postures of several health-care hospital assistants while carrying out tasks such as lifting patients from beds to stretchers, or placing them on wheelchairs, or giving support through shoulders during physical diagnosis of the patient are presented. Since the hospital assistants have to work with patients of several different anthropometry, weight, etc., these may exert a potential risk for them to acquire low-back pain (LBP) and other Musculoskeletal disorders because of sudden and inappropriate postures.

Keywords Patient handling jobs · Ergonomic performance · Biomechanical models · Healthcare systems

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1 Introduction

In the majority of the worksystems in manufacturing organizations, human-machine interactions play key role in ensuring acceptable system performance in today's industrial context. In many instances of material handling of jobs, human labour remains the principal components contributing to overall performance. Such a condition calls for a structured and scientific ergonomic evaluation of the material handling jobs that the hospital assistants perform so that any loading conditions, body motions or postures assumed by the operators remain within the hazardous limits and guidelines set by competitive authorities.

Different kinds of injuries (Cumulative Trauma Disorders, Repetitive Motion injuries, Musculoskeletal Disorders, etc.) are possible during material handling, depending upon its requirements.

When a person slips and falls while carrying a heavy equipment in industry, the instantaneous impact force can cause serious traumatic injury and even death. In contrast, repetitive manual exertions such as those occurring when one assembles something on a high-volume production line can cause gradual deterioration of tissue over weeks and even years.

Performance of healthcare is considered one of the sectors of industry heavily relying on humans performance that is mainly controlled by the way the human-machine interaction or interface is designed. Even though sophisticated diagnostic equipment and system may replace manual tasks, a large number of jobs like patient handling, OPD operations, nursing, etc., are irreplaceable by machines. In such a scenario, it becomes important to look at these jobs from an ergonomic point of view and identify potential risks associated with the jobs that the hospital assistants carry out on a daily basis. Patient-handling is one such job which has been covered in much of the ergonomic literature [1]. Many alternative postures for manual unassisted handling as well as ergonomic designs of stretchers and wheelchairs have been discussed by researchers. Many researchers deal with the concept of preventing injuries during patient handling [2].

In this paper, dynamic biomechanical models of the work postures of several health-care hospital assistants while carrying out tasks such as turning of patients [3], moving the patient up in the bed [4], lifting patients from beds to stretchers, or placing them on wheelchairs, or giving support through shoulders during physical diagnosis of the patient are presented. Since the hospital assistants have to work with patients of several different anthropometry, weight, etc., these may exert a potential risk for them to acquire low-back pain (LBP) and other Musculoskeletal disorders because of sudden and inappropriate postures [5].

In this context, biomechanical analysis of body postures of hospital assistants during handling of patient with the consideration of their anthropometry in actual hospital conditions is a critical research need for ergonomic design improvement of patient handling related tasks that are found to be occupationally risky [6, 7].

The relevant data for carrying out such a study are from one of the hospitals located in eastern part of India. An analysis of patient-handling postures in Indian health-care

industry is a very urgent requirement. A methodological study has been carried out on the techniques related to the process of collecting data, measuring mechanical work capacity and other parameters, and then assessing the loads and moments on L5/S1 region by applying dynamic biomechanical models [8]. The results as obtained clearly show the importance of such a study in biomechanical evaluation of the patient handling jobs for identification of deficiencies in the design of patient handling worksystems in healthcare and possible improved ergonomic design alternatives.

Keeping in view that identification and assessment of the effective variables contributing toward the patient handling jobs a biomechanical evaluation is proposed to be designed and developed for an organization. Hence, the objective of the study is to carry out biomechanical evaluation of a certain patient handling task with respect to a typical worksystem in healthcare in India.

2 A Framework for Biomechanical Analysis of Patient Handling Jobs

A framework for biomechanical modeling of patient handling jobs depicting all the logical sequence of steps involved to model the concerned problem is shown in Fig. 1. The proposed framework comprises of all the phases from selection phase

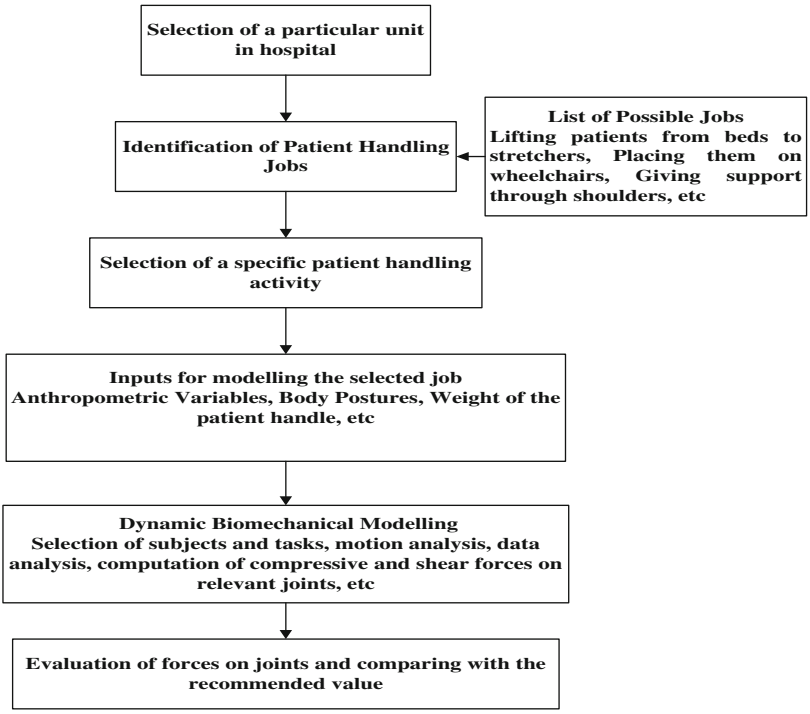

Fig. 1 Framework for biomechanical evaluation of patient handling jobs

which includes selecting the hospital unit for study, identification of various patient handling tasks and selection of the most relevant task to be studied, data collection phase which includes collecting the data required as input for modelling the problem, such as anthropometric data, etc., and modeling and analysis phase which includes the motion analysis and computation of net forces, and finally the evaluation phase which evaluates the forces acting on the joints and comparison with the recommended value.

3 Study Methodology

In order to study and analyze risk factors for different kinds of patient handling activities, a systematic methodology consisting of a number of steps in sequence, viz. (i) selection of subjects and tasks, (ii) biomechanical modelling, (iii) data collection for biomechanical evaluation, (iv) data analysis is required. These steps are discussed in brief in the following sub-sections.

3.1 Selection of Subjects and Tasks

The study includes two hospital assistants lifting the patient from the bed and placing the patient on the stretcher. They had no special training regarding patient handling activities. None of them had any pain in the spine during the experiment. No instructions were given to the hospital assistants prior to performing the task, but they used the techniques that they used during normal work. The bed is a typical functional bed found in the hospital in India.

3.2 Biomechanical Modelling

The compression and shear forces acting on the various joints of body segments of hospital assistant during the patient handling task is quantified by biomechanical calculation. A dynamic 3D biomechanical model is used to calculate the forces acting on the various joints. Kinematic analysis is done to calculate the compression and shear force. A motion analysis system called Ariel Performance Analysis System (APAS) is used to determine the compressive and shear forces on L5/S1 [9].

In this model, twelve body segments are considered which includes both the feet, legs, and thighs, lower and upper trunk, both the upper arms, forearms and hands. For calculations of net reaction forces and moments at each joint, kinematic analysis is performed on each body segment.

3.3 Data Collection for Biomechanical Evaluation

Data related to the patient handling tasks are collected through direct observations from a hospital in the eastern region of India. Most of the data required for the biomechanical evaluation were collected pertaining to body stature and weight of the hospital assistants.

3.4 Data Analysis for Biomechanical Evaluation

After subsequent data collection, the images of a selected task are produced and stored in memory. The motion analysis is done using a motion analysis system, called Ariel Performance Analysis System (APAS) of a task. For analyzing the data captured, a number of modules described below are carried out to estimate the linear and angular accelerations of the joints and the corresponding compressive and shear forces.

- *Digitize*: Digitizing helps in assisting the connection between the two points representing the segment between the two joints and as a result 3D stick figures and graphical information are displayed simultaneously.
- *Transformation*: The purpose of this phase is to compute the three-dimensional image space coordinates of the subject's body joints from the relative two-dimensional digitized coordinates of each camera's view and is used for performing this conversion process.
- *Filter*: This module is used to remove small random digitizing errors or 'noise' from the transformed image sequence. In addition, as the motion of each point is determined by a continuous smooth function, the filter module is able to compute point velocities and point accelerations for each frame in the image sequence.
- *Display*: Once an analysis sequence has been digitized, transformed and smoothed, the display module is used to obtain a complete presentation of image motion data for biomechanical analysis. This module allows simultaneous presentation of the three-dimensional stick figures, displacement, velocity, acceleration, video images and numerical data tables.
- *Kinetics*: The input parameters i.e. the anthropometric details are given and the required output parameters i.e. the joint parameters (moments, forces, and angle) and segment related parameters (velocity and acceleration) are selected.
- *Delta*: The compressive and shear forces with respect to a particular load are calculated and compared with recommended value.

A representative snapshot obtained from the APAS software showing line diagram of the hospital assistant doing the task of lifting the patient from the bed and placing in the stretcher is shown in Fig. 2.

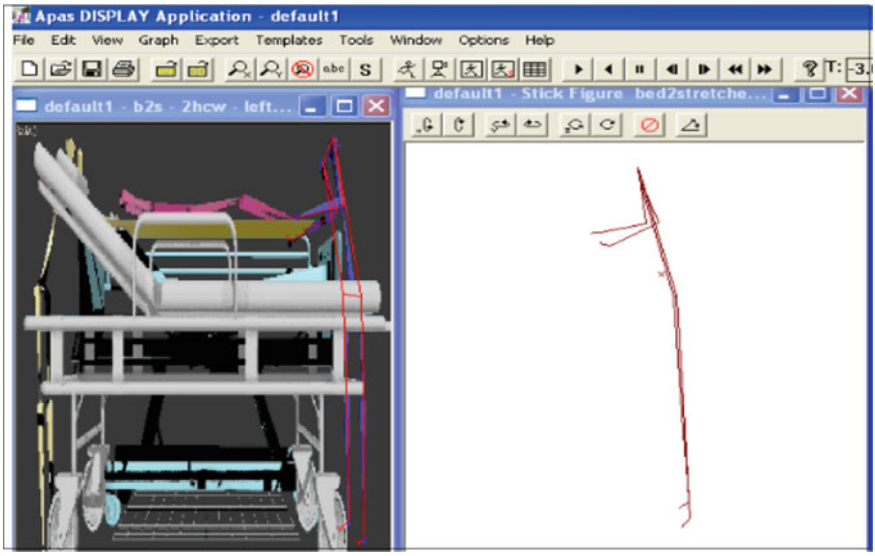

Fig. 2 Snapshot of lifting of patient from bed to stretcher

4 Results and Discussion

The biomechanical evaluation shows that the compressive forces at L5/S1 disc is 3855.1°N as shown in Fig. 3, which is beyond the recommended value of 3400 N. Results indicate that there is a need for ergonomic performance improvement for such patient handling tasks by the identified preventive and corrective measures.

Lifting of patient consists of dynamic activities where the magnitude of the muscle forces acting on a joint directly affects the magnitude of the joint reaction. As the greater the muscle forces, the greater the joint reaction force therefore, spine stability is lost through repetitive loading as continuous movements fatigues the muscles and as a result MSDs occur [9]. The hospital assistants may suffer from lower back pain because of the nature of their work and work postures. The workers involved in lifting and placing of patients because of repetitive carrying on hand. They also suffer from various MSDs which occur when normal forces are applied to abnormally weak tissues, or when abnormally high forces are applied to normal tissues. Corrective measures, such as improved work postures are suggested so that the risk of MSDs is minimized in course of time. From biomechanical evaluation, it is also found that for most of the hospital assistants, the most affected and stressed joint is L5/S1 disc in spinal column as the compressive forces exceed their threshold value. The compressive force on L5/S1 disc should be basis for designing the patient handling methods.

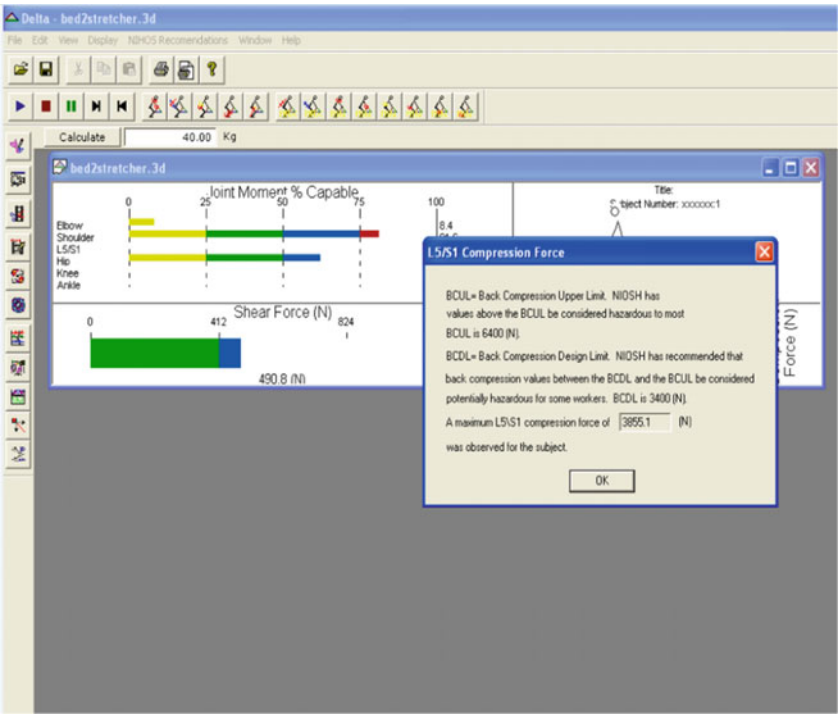

Fig. 3 Compressive and shear forces at L5/S1 disc

5 Conclusion

The analysis of the biomechanical model may help in identification of specific MSDs and their causes for hospital assistants lifting patients. This may lead to identification and consideration of alternative worksystems for the tasks as a means to reduce the forces on the body joints thereby improving the health of the hospital assistants. It is essential that alternative worksystems against a particular patient handling task is to be appropriately analyzed through experimentation in actual working environment and is a scope of future work.

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Difference in Problem-Solving Thought Concerning the Infection Control of Japanese Nurse and Indonesian Nurse: Comparison of the Result by 4M4E Matrix Analysis

Manami Nozaki, Hiromi Ogasawara and Reiko Mitsuya

Abstract In nursing world, the opportunities when a nurse with a different background interchanges increased. Regardless of a country, it may be said that the safety management of the patient is a main premise of the nursing. We focused on the infection management and compared problem-solving thought for the infection management of the Indonesian nurse and Japanese nurse using 4M4E model. As a result, we understood that they were common basically. The nurse Indonesian tended to demand the intervention to an individual and an offer of the knowledge. On the other hand, the Japanese tended to consider systematically. The expansion of each other's fields of vision would be expected by using each strength and continuing cross-cultural communication.

Keywords Nursing · Infection control · Safety management · Cross-cultural communication

1 Introduction

With the economic partnership agreement (EPA) conclusion, the opportunities when a foreign nurse such as Indonesia engaged in nursing practice in Japan increased. On the other hand, we proceed to a nursing theory and the technical guidance to Indonesia from 2011. In nursing world, the opportunities when a nurse with a different background interchanged increased. Actually there is some trouble

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when we tell nursing practice by economic conditions, medical circumstance and the difference of the cultural background. What a nurse is responsible for four of the maintenance increase of the health, the prevention of the illness, restoration to health, relaxation of the pain, association of world nurse (ICN) proposed. Regardless of a country, it may be said that the safety management of the patient is a main premise of the nursing.

In this research, we focus on the infection management in the safety management as the nurse. We think that we can extract the sense of values in the background by asking the thought for the infection management.

2 Purpose

The purpose of this research is to compare the contents the factor and the steps which an Indonesian nurse and a Japanese nurse think about problem situation of the real infection management, and it is to clarify the difference of the viewpoint for solutions of the problem.

3 Methods

3.1 Subject

Indonesian nurse: 13 Indonesian nurse who received training as EPA candidate in Japan to be able to discuss it in Japanese.

Japanese nurse: 9 Japanese nurse who lives in Indonesia as she exposed Indonesian culture. However she does not work as a nurse in Indonesia.

Both was the person that the agreement was provided for research cooperation.

3.2 Data Collection Method

We set the group fivesome as the group discussion. We had them list the content that they talked. There were five scenes: use the dirty swab, add antiseptic solution, hand-washing manual skill is uncertain, the timing of wearing on/off of gloves is bad, the inappropriate action at the time of the gloves wearing. While we showed the photograph of each scene, we explained the situation in Japanese. We supplemented information by Indonesian.

3.3 Data Analyzing Method

We used 4M4E matrix analysis used by medical safety measures about a nursing scene about the infection management that we met with in Indonesian fieldwork, and analyzed it. The 4M4E matrix analysis is technique used for accident analysis in American National Aeronautics and Space Administration (NASA) and then [1]. It is a method to classify measures in from four E (EDUCATION, ENGINEERING, ENFORCEMENT, EXAMPLE) viewpoints for the factor of the accident from a viewpoint of four M (MAN, MACHINE, MEDIA, MANAGEMENT). We compared the result that three Indonesian nurse groups analyzed based on a 4M4E matrix list with three Japanese nurse groups.

3.4 Ethical Considerations

We tried for the exclusion of the compelling force and the protection of the personal information in data collection. In addition, we carried it out with the approval (approval number 2) of the ethic screening committee of Japanese Asian medical upbringing society (Table 1).

4 Results

Discussion contents of Indonesian nurse and Japanese nurse are indicated Table 2. It shows the steps based on 4E in the lower column and the factor based on 4M in the upper column. The common item is no mark, the Indonesian special answer was written down <I>, the Japanese special answer was written in the lower column <N>.

Table 1 4M4E matrix analysis model

<4E>	MAN	MACHINE	MEDIA	MANAGEMENT
<4M>				
EDUCATION				
ENGINEERING				
ENFORCEMENT				
EXAMPLE				

Table 2 Analysis result by 4M4E model

	MAN	MACHINE	MEDIA	MANAGEMENT
	Human	Thing machine	Circumstance	Management
Concrete factor 4M	Problem situation ①The use of a dirty swab			
	②The incomplete hand-washing manual skill			
	③The timing of wearing/the desorption of gloves			
	1	1	1	1
		1	1	1
		1<I>	1<N>	1<N>
			1<I>	
EDUCATION	1			
	1			
ENGINEERING	1<N>	1		1<N>
	1	1<N>		
		1		
ENFORCEMENT	*1*	1<N>	1<N>	1<N>
	1			1<N>
	1			1<N>
EXAMPLE	1<I>			1<N>

4.1 The Factor Analysis of Steps Based on 4E

It was pointed out for a factor about the problem situation as follows.

1. MAN (human being): The two countries were common, that was "left washing at the time of the hand-washing", and one item was pointed out.
2. MACHINE (thing, machine): The two countries are common, that is "cannot keep a sterilization effect"; the dirty bottle of the antiseptic solution and then two items were pointed out. Furthermore, one item "that there was a problem about the tool" for indication peculiar to an Indonesian was pointed out.
3. MEDIA (environment): The two items that "a medicine was not kept adequately" and "recycled the bottle of the antiseptic solution" were pointed out in both common. Furthermore, one item to "keep a different kind medicine to a bottle" as a Japanese special item was pointed out. It was extracted one item a reason to "be in danger of bacteria propagating as for adding" it as an item peculiar to an Indonesian.
4. MANAGEMENT (management): The two items that "be in danger of oneself being contagious" and "oneself became the infection course" were pointed out in both common. One item that "the understanding of the rule and principal was lack" as a Japanese special item was pointed out.

4.2 The Analysis of Steps Based on 4E

There was the following suggestion for steps to problem situation

1. EDUCATION (education/training): The two items that "teach hygienic hand-washing" and "explain a timing of wearing/the desorption of gloves" were suggested in both common.
2. ENGINEERING (technology/engineering): The three items that "establish the substitute method", "arrange a disposable product" and "use up antiseptic solution" were pointed in both common. As a Japanese special item, three items that "manage every time limit", "arranged a sterilized article" and "arranged the expiration date, and to display" was suggested.
3. ENFORCEMENT (reinforcement/enforcement): Three items that "observed right hand-washing/sterilization method", "carried out instructions at the time of the gloves wearing thoroughly" and "carried out 1 gloves thoroughly for 1 measures" was suggested. Five items that "made a rule not to confuse a medicine", "confirmed each other in a post", "examined a safekeeping method with the person concerned", "put the contents which careful, and wanted to rouse it on the poster" and "arranged an appropriate article near a use scene" was suggested as a Japanese characteristic item.
4. EXAMPLE (model/example): One item that "sponsored an opportunity to confirm a concept of the infection prevention, action mechanism of the sterilization" was suggested as an Indonesian characteristic item. That "checked the enforcement situation with a machine regularly in a post" as a Japanese special item was suggested.

5 Discussion

5.1 Differences of the Consciousness to the Problem

The Japanese and Indonesian analyzed it by four viewpoints equally in common. Furthermore, the Indonesian turned interest to MACHINE. On the other hand, the Japanese tended to grasp the problem by the large fields of vision such as environment or the management. We guess that this result is originated in an environmental difference surrounded the medical care including economic conditions.

As practicing medical materials that are not deployed abundantly in Indonesia, the interest may always go in MACHINE. On the other hand, the latest medical materials are abundant in Japan, however by the introduction of [2] inclusion payment system Bundled payment of the medical examination and the use of time and thing without waste is demanded. Therefore they may come to be always conscious of cost. In addition, team medical care is demanded in the Japanese medical scene, and cooperation with the many type job is emphasized. As a result,

they come to observe the whole and think that their field of vision may have been expanded.

5.2 The Difference in Thought of the Problem Solution

Both Japanese and Indonesian focus on the personal intervention to MAN in common. Furthermore, what the Japanese nurse tended to solve the problem systematically was shown. We think that this depends on a difference of the nursing basic education. The difference of the nursing education between the two countries in the background existed in the background [3, 4]. For example, an organized thought may grow up to learn nursing management from a nursing basic education course in Japan. The nurse Indonesian demanded an offer of right knowledge. On the other hand, the Japanese nurse demanded the making the structure for evaluation. It is guessed that there is difference in the nationality or the maturity degree of the occupation between the backgrounds of these difference.

6 Conclusion

The basic critical consciousness concerning the infection management was the same, and we confirmed the common tendency on thinking the intervention to an individual. Furthermore, in a critical consciousness, a thought for problem solution, a strength was recognized each country. We would exchange information in future by continuing cross-cultural communication and expect it that we lead to the expansion of the field of vision each other.

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Examination of the Validity of Anatomical Knowledge Associated with Daily Lifestyle Issues: A Comparison Between Perspectives of Anatomy and Nursing Researchers

Masaaki Takayanagi, Manami Nozaki, Reiko Mitsuya, Teruko Takayanagi and Fumi Sato

Abstract Although anatomical knowledge is vital in nursing practice, it is considered to be difficult to understand. Therefore, we attempted to arrange anatomical knowledge based on the framework of nursing to enable students to learn anatomical knowledge. Anatomical knowledge associated with eight lifestyle issues were considered to be necessary by nursing and anatomy researchers were recorded, and concordance rates were examined. Therefore, we confirmed the validity of the learning content. However, results suggested that a prospective, multifaceted study is required.

Keywords Nursing education · Anatomy knowledge · Nursing · Nursing problem

1 Introduction

Anatomical knowledge in the field of nursing must promote scientific understanding of the subject and provide the grounds for nursing support. However, various 1st-year courses teach anatomy unrelated to pathology/physiology and nursing support. This causes nursing students to dislike anatomy, causing difficulty for them to correlate anatomical knowledge with diseases, lifestyle, and nursing support.

The original version of this chapter was revised: The family name of the author was changed to "Takayanagi" from "Takayanagil". The erratum to this chapter is available at 10.1007/978-3-319-41652-6_43

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Although it has been reported that 66.2 % of nurses have experienced difficulty with anatomical knowledge and 98.7 % require more anatomical knowledge [1], only approximately one-third of the nursing students are interested in anatomy but find it difficult and boring. Therefore, these students wish to learn regarding anatomy in an easy-to-understand and interesting manner [2].

Anatomical knowledge is vital to understand the pathological state and to scientifically develop the field of nursing. Without the knowledge regarding structures and functions of the body, while performing a health checkup for physical assessment, it is not possible to accurately assess the areas examined and differentiate these findings from normal findings. The role of nurses is to support the patient convalescence. An anatomical basis is important for understanding patients with regard to their daily lifestyles. To maintain the motivation for learning anatomical knowledge that nursing students tend to dislike, such knowledge should be learned in association with field of nursing, in which they are interested. To efficiently acquire anatomical knowledge that is considered to be difficult by nursing students, they should acquire the basic level of knowledge, following which they should gradually expand their related knowledge before aiming to establish systematic knowledge. Therefore, we have proposed a learning method in which anatomical knowledge is unified at the beginning from the perspective of nursing. Thus, we aimed to have students learn anatomical knowledge by incorporating it into the framework of nursing.

We are currently formulating a learning method to enable the understanding of anatomical knowledge with regard to daily life issues. This will enable students to understand anatomical concepts as ordinary people. Traditionally, knowledge is systematically learnt based on the organ. Conventional learning methods aim to establish knowledge by following a reverse path of learning processes. In the new learning method, both deficiencies and excesses in anatomical knowledge should be avoided to extract learning content from the perspective of nursing

2 Purpose

This study aimed to confirm the validity of learning content for anatomical knowledge associated with eight lifestyle issues (fever, dysphagia, constipation, insomnia, susceptibility to infection, fracture site pain, neuroplegia, and postoperative delirium). Furthermore, we clarified the characteristic patterns of thinking based on differences in the academic fields of nursing and anatomy to gain suggestions for learning methods.

First, we used a grading system of requirements to rank the eight lifestyle issues from low to high. Next, a nursing researcher selected the lifestyle problem that most frequently required intervention while administering nursing support.

3 Methods

3.1 Subjects

Subjects comprised one nursing researcher and one anatomy researcher.

The anatomy student best understood the intent of the questions; therefore, a selection criterion for this study was that the subject should have offered lessons to nursing students in basic nursing education.

3.2 Data Collection Method

Students were expected to learn regarding each of the eight lifestyle issues based on the knowledge of normal functions. We aimed to confirm whether the content considered to be necessary in nursing is anatomically valid. Therefore, the anatomy and nursing researchers noted anatomical knowledge that they believed was necessary to learn with regard to normal functions and challenging situations for each problem in a matrix table.

3.3 Data Analysis Methods

Content recorded in the matrix was compared to calculate concordance rates and confirm the validity of learning content. We elucidated the characteristics of the general thoughts in each academic field by qualitatively analyzing the differences in perspectives between the two fields. From the results, we were able to provide suggestions to consider when imparting anatomical knowledge to nursing students.

4 Results

4.1 Description of the Nursing and Anatomy Researchers

Here we discuss the content recorded by the nursing and anatomy researchers regarding knowledge for understanding normal actions and issues when each lifestyle issue listed below occurred. Table 1 shows concordance rates with description states for each unit.

Fever The nursing researcher described five normal actions, whereas the anatomy researcher recorded none. The concordance rate was 0 %. The nursing researcher mentioned that the liver, brain, muscles, sympathetic nervous system, and skin were associated with the generation and expression of fever.

Table 1 Concordance rates between nursing and anatomy researchers for learning content

Unit (lifestyle problem)	Normal function concordance rate (%)	Problematic state concordance rate (%)
Fever	0	100
Dysphagia	66[a]	0
Constipation	100[a]	23
Insomnia	100	0
Susceptibility to infection	100[a]	None
Fracture site pain	100[a]	40
Neuroplegia	40	None
Postoperative delirium	100	None

[a]Matching content but different levels of abstraction. *None* no response

The nursing and anatomy researchers mentioned one related issue each, stating that it was located in the thermoregulatory center in the hypothalamus. The concordance rate was 100 %.

Dysphagia The nursing and anatomy researchers described three normal actions each. The concordance rate was 66 %, with concordance between intraoral structures, such as the tongue and teeth.

The nursing researcher described three related issues, whereas the anatomy researcher described six. The concordance rate was 0 %. The nursing researcher stated that the sites of the related issues were the eyes, nose, and cerebrum because these organs could be involved in difficulty to understand food. In contrast, the anatomy researcher described the cranial nerves associated with taste and olfactory sensation in detail and the muscles and secretory glands associated with mastication.

Constipation The nursing researcher described one normal action, whereas the anatomy researcher described four. The nursing researcher mentioned the colon, describing the formation of feces. The concordance rate was 100 %, with both nursing and anatomy researchers describing the same content.

Descriptions of related issues were broadly classified into those regarding the mechanisms of defecation and those regarding defecation behavior. Although the nursing researcher only described one defecation mechanism, the anatomy researcher described a wealth of information by mentioning seven items. The concordance rate was 38 %. The nursing researcher described three defecation behaviors involving the upper and lower limbs, whereas the anatomy researcher described two items including the diaphragm, which creates abdominal pressure. The concordance rate was 0 %.

Insomnia Both nursing and anatomy researchers mentioned one normal action each. Here both mentioned the reticular activating system in brainstem associated with sleep mechanisms. The concordance rate was 100 %.

The nursing researcher described wakefulness as an issue associated with the cerebral cortex, whereas the anatomy researcher did not mention anything. The concordance rate was 0 %.

Susceptibility to Infection Skin as a mechanism for infection prevention was stated as a normal action. The nursing researcher described one normal action, whereas the anatomy researcher described three, providing more details.

However, no researcher described any related issues.

Fracture Site Pain The nursing researcher described one normal action regarding bone structure, whereas the anatomy researcher described two, both related to bone structure. The anatomy researcher described items and divided them into specific details; therefore, there were differences in the degree of abstraction. However, because the same content was described, the concordance rate was 100 %.

The nursing and anatomy researchers described mechanisms for transmitting pain as related issues. The nursing researcher described the sensory nerves only. The anatomy researcher's description included the same content; therefore, the concordance rate was 100 %. Furthermore, the anatomy researcher described a wealth of information in the form of four related issues, specifically describing the ascending conduction pathway and spinal nerves in detail.

Neuroplegia The nursing and anatomy researchers described the sensory nerves as normal actions, and the concordance rate was 100 %. Although the nursing researcher only described one normal action, the anatomy researcher described a wealth of information in the form of four items describing mechanisms up until the transmission of sensations.

No researcher described any related issues.

Postoperative Delirium The nursing and anatomy researchers described the cerebrum and its cognitive function as normal actions. The concordance rate was 100 %.

No researcher described any related issues.

4.2 Differences in Perspectives Between Nursing and Anatomy Researchers

With regard to normal functions, concordance rates were 100 % for constipation, insomnia, susceptibility to infection, fracture site pain, and postoperative delirium. With regard to dysphagia, the anatomy researcher described more detailed content.

With regard to fever, the anatomy researcher did not respond, and with regard to neuroplegia, the only answer was that of the nursing researcher.

The concordance rate was 100 % only for fever. Constipation and fracture site pain had low concordance rates because the focus points of the anatomy and nursing researchers' responses differed. With regard to dysphagia, the focus points differed and the concordance rate was 0 %. With regard to insomnia, the anatomy researcher did not describe any content, resulting in a concordance rate of 0 %. With regard to susceptibility to infection, neuroplegia and postoperative delirium, the lack of descriptions by both researchers demonstrated the same trend.

Considering the actual content that was described, the following three features were demonstrated for the nursing researcher. These were as follows: (1) concentrating on the action itself, (2) focusing on key points only, and (3) memorizing groups of sites with the names of functions. The following three features were demonstrated for the anatomy researcher. These were as follows: (1) weighting each site equally, (2) sequencing related elements and (3) focusing on structures related to actions.

5 Discussion

5.1 Learning Content Validity

In this study, a significant number of descriptions of knowledge required for understanding normal actions were noted and concordance rates were high. Thus, it appears that the structural morphology of normal functions requires understanding.

With regard to knowledge for understanding related issues, only fever showed a concordance rate of 100 %. Higher order demands, such as susceptibility to infection, neuroplegia and postoperative delirium in particular, could not be compared because no researcher described any items. Related issues, or "deviations from normal," can be broadly classified into organic and functional abnormalities. The reason for the lack of descriptions shown above could be because functional abnormalities require physiological or pathophysiological knowledge, although organic abnormalities can be explained with anatomical knowledge. Thus, although normal and abnormal structural morphology can be described with anatomical knowledge, functional abnormalities must be explained with physiological knowledge.

5.2 Features of Ideas by Academic Field

With regard to differences in the features of ideas based on academic field, it appeared that because nursing researchers underwent training to assess patient

health status, they focused on the key points. However, as anatomy involves researching the external and internal morphology of living organisms, the specialist in human anatomy who participated in this study described the structural morphology in detail, which appeared typical of their profession. A particular difference was noted for the fields of brain and nerve anatomy, which appear to be difficult areas for nurses. The actions that showed low concordance rates could be integrated to complement the weak points in the ideas of each, thereby promoting multidimensional understanding.

6 Conclusions

Learning content appears to be valid for understanding an anatomical knowledge basis for understanding of normal actions. Responses reflected differences in academic fields for understanding related issues. Although anatomy researchers exhibited strengths with regard to describing organic abnormalities based on anatomical knowledge, physiological and pathophysiological knowledge may be useful for describing functional abnormalities. In the future, it is hoped that multiple fields can collaborate to construct multidimensional learning content.

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Study of Suitability of Computer Workstations Design for Nurses' Work Content

Farman A. Moayed, April Savoy and Celeste Turpen

Abstract The majority of published research about EMR systems regarding nurses and their clinical tasks have centered on their attitudes toward EMR systems, which have generally been positive and accepting. There is a lack of studies that would consider dimensions of clinical tasks, human factors, and available equipment to determine how nurses work with EMRs. The goal of this study was to investigate how suitable the design of computer workstations is in terms of hardware selection for nurses' work content. This was a mixed-method study (focus groups and online survey) to collect data. The survey tool was distributed among 600 nurses in a rural hospital and a series of two-way, three-way chi-square and logistic regression analysis were conducted to investigate the correlation between the human factors aspects of the clinical tasks (work content) and nurses' preference of computing device and location. The findings from 61 responses illustrated a significant correlation between cognitive and interaction design aspects and the preferred type of computer workstations. This means that better understanding of cognitive and interaction design aspects of clinical tasks by nurses as well as managers and computer software developers is critical in workstation design, resource allocation, better quality of care and patient safety.

Keywords Human factors · Nurses, computer workstations · Electronic medical records · Work content · Clinical tasks

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1 Introduction

Computer systems have been introduced and used in hospitals for several decades in many developed countries now with the goal of improving the quality of care and patients' safety. The applications of computer systems in healthcare facilities range from administrative, accounting and billing to storing, tracking and sharing patients' medical records. The latter segment of such computer systems has had great effect on healthcare provider practices [1–3]. Overall, nurses' and physicians' attitudes toward healthcare-related computer systems were positive and it is believed to enhance the quality of care and patients' safety [2]. Healthcare-related computer systems are also known and referred to as Hospital Information System (HIS), Computerized Physician Order Entry System, Computerized System, Electronic Patient Records (EPR) [3, 4], Clinical Management System (CMS) [1], and even Electronic Health Information System or Digital Medical Information.

Each type of computer workstation and Electronic Medical Record (EMR) Systems has its own advantages and shortcomings. There has been evidence that factors such as nature of the clinical task, degree of needed mobility, and device design can affect nurses' choice of computer workstations. A main aspect of EMR system implementation is the selection of computer hardware and its configuration, which should fit into the work content and workflow [5]. Few earlier studies showed that some hardware and equipment such as mobile pen computers or PDAs can have positive or negative effect on nurses tasks [6, 7] and authors recommended utilization of human factors and ergonomics engineering before designing workstations and implementing EMR systems.

Healthcare professionals, leaders, and organizations understand the importance of human factors and ergonomics as scientific disciplines capable of producing knowledge to redesign healthcare settings and workflows that integrate healthcare information technologies with the goal of improving quality of patient care, productivity, and efficiency [8, 9]. Decision-makers need scientific evidence about the conditions in which EMR systems are designed, integrated, implemented and used in optimal manner and the factors that can affect them; however currently such data is lacking. Most of the published research articles have been done at micro-, meso-, and macro-levels in the socio-economical context [10]. Probably the main reasons for such a gap between existing data and required data for decision makers are:

- Variation in EMR systems: each system's unique features and characteristics combined with work environment, work culture and users' characteristics can cause the implementation of one EMR system a success or failure.
- Increase in EMR systems use: the use of EMR systems is continuously increasing without a clear understanding of how such systems fit into the work flow and affect nurses' and physicians' performance and decisions.
- Rapid development in information technology: IT field is growing and developing so fast that organizations and hospitals are challenged to keep pace with it. Experts and decision-makers are pushed into updating computer systems and

equipment without fully understanding how well the new technology fit in their work systems.

By investing and expanding EMR systems, hospitals provide variety of options for nurses to utilize EMR systems, such as stationary computer workstations, mobile computers, bedside computers, handheld tablets and etc. It means that nurses can use different methods to complete tasks such as keyboarding (free texting), mouse clicking, touchpad or touch screen tapping, voice recognitions, generating reports on screens or papers and etc. Depending on what tasks are being performed (patient assessment, taking vital signs, reviewing lab reports, checking or administrating medication, IV Check, reviewing charts, and etc.), nurses might select a different type of computer workstation (mobile, stationary, bedside or even handheld device) with different hardware configuration [5]. If the design features and hardware configuration of any of the available computer systems and workstations is unsuitable to the work content of nurses, it can ultimately compromise the quality of care, patient safety, productivity and efficiency.

It is reasonable to assume that nurses' attitude toward EMR systems and their acceptance could be affected by the usability of such systems, which means EMR systems should match nurses' work content and environment. Human Factors analysis (AKA Work System Analysis) can help experts diagnose and point out the deficiencies in a work system both in content and context. As the result, relevant and appropriate design guidelines can be introduced to improve the work tasks [11]. Such approach can help determine detailed information about the variability, duration, frequency, and difficulty of different elements of work content, which in turn can help manage resources and plan with efficiency [12].

2 Objective

The main objective of this research was to determine the suitability of computer workstation design for nurses work content. The plan was to evaluate the correlations among demographic, cognitive, and interaction design aspects and nurses selection of computing workstations.

3 Literature Review

Most of the published literatures in this field were about nurses' attitude toward EMR systems and their acceptance of such systems. Three articles [3, 4, 13] similarly investigated the factors affecting the nurses' acceptance of and satisfaction with computer-based medical records systems. A combination of quantitative and qualitative methods was used to evaluate nurses' acceptance of a particular computer system over the course of 2 years by integrating four different validated and

previously published questionnaires and the results showed overall acceptance score was high among nurses in three wards out of four. In one of the wards, however, the introduced computer system did not fit with the workflow therefore the acceptance rate was low [13]. Separately by using a different data analysis method; included regression analysis and correlation analysis, nurses' attitude and level of satisfaction in using the Hospital Information System (HIS) in their clinical practices was studied based on factors such as perceived usefulness, IT support, perceived ease of use [3]. Meanwhile a cross-sectional study was conducted among nurses in inpatient care units in three different hospitals in Turkey. Although it was not clear if all three hospitals were using the same EMR systems, authors mentioned that they had similar modules. As the result the only correlation analysis was performed on use, quality and user satisfaction and the strongest correlation was between quality and user satisfaction [4]. Same researchers conducted a different study with similar objective and methodology with a different sample and had similar conclusion [14] but there was no statistical analysis on nurses' tasks and other factors of HIS in either of studies [4, 14].

In a different research [15], physicians and nurses satisfaction with an EMR system was studied using previously published questionnaires and at the end they reported that both nurses and physicians found the EMR system helpful, but they believed it was not improving the quality of care in terms of reduction in patients' expenses, reduction in waiting time, reduction in lab tests, reduction of hospital visits, and reduction of crowd in hospital.

In a considerably different research, the effect of personal traits on nurses' attitude toward Clinical Management Systems (CMS) was studies by using cluster analysis to identify different groups of nurses based on their demographics, skills, knowledge, and attitudes toward the CMS [1]. The results indicated that there were two clusters of nurses: one composed of older nurses with seniority and more work experience who had higher score in their attitudes toward CMS compared to the second cluster which was made of younger and junior nurses. It is not clear if the hospitals were comparable in terms of their size and operation, nor if the content of nurses' work and their department/ward could be a factor about their satisfaction with CMS.

All the studies included in this section and most of the qualitative literature excluded from this literature review were conducted and published by experts in non-engineering fields and disciplines such as nursing, health care or medicine and the researchers were predominantly affiliated with non-engineering colleges, schools and programs. That is why there was no human factors analysis included in these research. Therefore, regarding the rationale, the current study takes the first step(s) toward better understanding how the design of computer workstation (computing device) affects nurses' work from basic human factors and ergonomics perspective. In a given hospital setting, there is one EMR system; however, there is a variety of computing devices available for nurses to access the EMR system. Each device (i.e. desktop, laptop, tablet computers) offers a different interaction experience for users. With the introduction and high-turnover technological devices in healthcare, evidence-based decisions will help medical facilities design or purchase

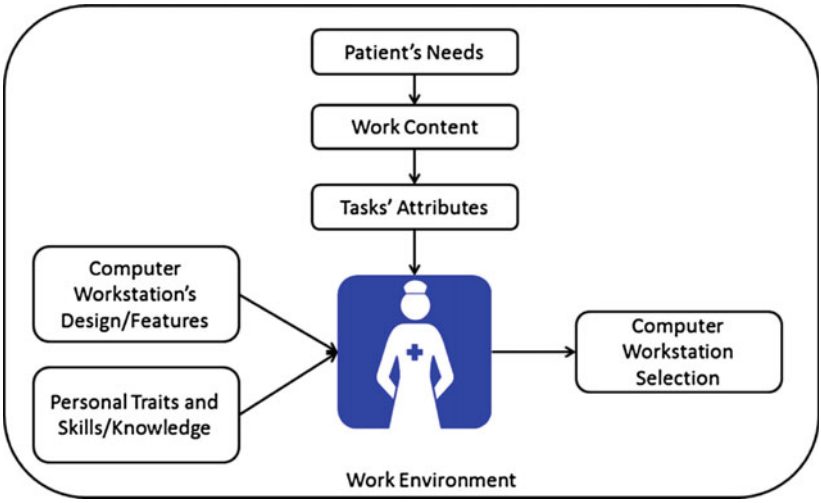

Fig. 1 Assumed model for nurses' selection of computer workstation

suitable workstations. Figure 1 demonstrates the assumption that different factors can affect nurses' decision on what type of computer workstation to use to perform their job.

4 Methods

This was a mixed methods study, which included focus groups and an online survey. The target populations were registered nurses and nurse practitioners in a hospital located in a rural region in the state of Indiana. The hospital had about 600 RNs and NPs, 300 physicians and 1800 staff employed at the time of study, and it had 347 beds and consisted of 17 departments.

After two sessions with focus groups in spring of 2014, various aspects and characteristics of nurses' work in the hospital were discussed such as work content, frequency and duration of occurrences of each element of work content, the devices used by nurses and frequency of use for each task, level of mental, cognitive, and stress for each element of work content. At the end the work content was broken down into seven major areas, i.e. patient assessment, taking vital signs, patient care, review of lab reports, check/administer medication, IV check, reviewing charts on CPOE system (Computerized Physician Order Entry) and each area was broken down into twelve elements such as abstraction (retrieving data), data entry, frequency, duration, mental level, decision making level, time pressure, stress of the work content, actual methods of abstraction and data entry, preferred method of abstraction and data entry.

A cross-sectional study and a survey instrument were developed based on the outcomes of focus group meetings. The survey was developed by using Qualtrics system and distributed among subjects with the help of the hospital's IT office. The survey questionnaire was comprised of eight sections. Section one was about demographic information and sections 2–8 were about seven major work content areas. The Institutional Review Board approvals were obtained for both phases of the study prior to conducting each phase of the study.

After storing and saving the results, set of two-way and three-way correlation (chi-square or Fisher's Exact tests appropriately) and logistic regression analysis were conducted partially by using SAS System 9.0 for Windows and some manually. All statistical tests were conducted with significant level of 0.05.

The current EMR system (SORIAN Clinicals, a Siemens' product) has been implemented in this hospital since 2010 with several significant changes, modifications and updates since its installation. The hospital was equipped with different types of computer workstations; i.e. nurses workstations (approximately 20 computers scattered across the facility), bedside computers (in every room), MAK carts, and limited access to laptops, and iPad or similar Tablets, among which nurses workstations and bedside computers were stationary and the rest of them mobile. All computers within the hospital were equipped with keyboard, mouse, and some of the workstations were equipped with touchpad, and touch screens. The MAK carts have been phased out because of their design which made them difficult to manually move and relocate from room to room.

5 Results

The online survey was distributed among target population and it was open for three months from mid-May to mid-August of 2014 with one follow up email. There were 61 responses (10 % rate of return) and not all responses were complete. Regarding the demographics; the average age and standard deviation of subjects' age were 40.9 and 11.5 years, and only three subjects identified themselves as male. All subjects identified themselves as Caucasian except one who reported Asian as his/her race. The distribution of subjects' rank and seniority from CN 1 to CN 4 (lower to higher) was 23.5, 54.9, 5.9 and 15.7 % respectively. Also all subjects identified themselves as registered nurse (RN) except one who identified himself/herself as nurse practitioner (NP).

The average number of years of experience as nurse and average number of years of experience in the hospital were 13.3 and 9.9 years and with standard deviation of 11.3 and 9.1 years respectively. When subjects were asked about their computer skills, only one subject rated himself/herself as beginner, 44 subjects rated themselves as moderate and 15 responded as experts. Also, regarding subjects' education level, three people (5 %) were diploma nurse, 20, 28 and 2 subjects (33.3, 46.7 and 3.3 %) had AS, BS and MS/MA degree in nursing respectively. In addition, two subjects (3.3 %) responded to have BS in non-medical field and

another two subjects (3.3 %) had MS/MA in non-medical field and three subjects (5 %) claimed "others" for their education.

In regards to subjects' work load and conditions, 38 subjects (62.3 %) were working during day shift at the time of answering the questionnaire and 23 subjects (37.7 %) were working during night shift. More than 83 % of the subjects were working on 12-h long shift and the average number of patients under their care was 3 or 4 patients with standard deviation of 1–2 patients.

The hospital had seventeen units (Prisoners/locked unit, Pediatrics unit, Mother/baby unit, Labor room unit, NICU, Outpatient unit, Medical rehab unit, Infusion therapy unit, Pre-and-Post Cath Lab, Telemetry unit, Stroke unit, ICU/CCU, Orthopedic unit, Oncology unit, Surgical unit, Operating room, and Medical unit) and most number of responses were received from ICU/CCU and Medical unit (30.9 and 23.6 % respectively) and no responses was received from subjects working in locked, Labor room, Infusion therapy, Pre-and-post cath lab, Stroke, and Operating room units).

At the end of the demographic section, 42 subjects (68.9 %) responded that they are aware of the ergonomics issues of the computer workstations they use on daily bases and 27 subjects (45.0 %) responded that they have received ergonomic training about the computer workstations. No question was asked about the timing of ergonomic training and its' quality/content.

In terms of performing different areas of work content, majority of nurses performed at least once or twice patient assessment, reviewing lab reports, and reviewing charts on CPOE system per shift (30, 54 and 35 % respectively), while majority of nurses perform at least seven or more times taking vital signs, patient care, check/administer medication and IV check (42, 44, 52 and 38 % respectively) during a work shift.

The results showed that there was significant correlation between the work content and portion of the abstraction and data entry performed by nurses using any type of computer workstations (p-value < 0.0001 for both chi-square tests). More subjects claimed that work content areas such as reviewing lab reports and reviewing charts on CPOE system required more abstraction than data entry, while other work content areas such as patient assessment, taking vital signs and patient care required more data entry than abstraction. It is also interesting to note that majority of subjects responded that check or administer medication required large portion of both abstraction and data entry.

The subjects were asked to select the method they currently use for abstraction and data entry for every work content area. Their options were mouse clicking, touchpad tapping, touch screen, free texting/keyboarding, manually by report papers and other methods. Mouse Clicking is the most predominant method for both abstraction and data entry for every work content area except data entry while taking vital signs. In facts, there was a significant shift and increase in free texting/keyboarding in data entry for all work content areas compared to abstraction. Chi-square tests showed that there was significant correlation between work content areas and method used for abstraction and data entry (p-value < 0.0001 for both chi-square tests). After further study it is possible that lower number of

response for touchpad tapping and touch screen were because of unavailability of or limited access to such features in every computer workstation.

In terms of preferred type of computer workstations, the data showed that subjects significantly preferred bedside computers and nurses' station more than MAK carts, laptops and iPad/similar (p-value < 0.0001). It worth noting that majority of subjects preferred nurses' station to bedside computers in every work content area except when checking or administrating medication, during which bedside computers became first choice. It was interesting to see that different equipment with higher degree of mobility such MAK carts, laptops, and iPads/similar were not among the preferred type of computer workstations.

The researchers made several assumptions that different factors such as nurses' ranking, age, number of years of experience as nurse, number of years of experience in the hospital, computer skills, education, and ergonomic awareness might affect the results as potential confounders. Further correlation and logistic regression analysis showed that there was no correlation between the nurses' rank and the work content areas which means every work content area was done by all nurses regardless of their ranks. The results also showed that subjects' computer skill was independent of their age, number of years of experience as nurse and number of years of experience working in the hospital. The question about computer skill did not differentiate between general computer skill and its relationship with the EMR system used in the hospital; but there is no clear explanation why such correlation was not found. However, one possible explanation could be that all nurses, regardless of their work experience and age, had receive enough training about computers and EMR system or they had been working with such computers long enough that they felt competent and their responses to those questions did not show any correlation.

In regard to the assumption that nurses' awareness and knowledge about ergonomic features of different computer workstations available to them can affect their decision in choosing the right workstation, researchers did not find such correlation. In other words, nurses' preferred computer workstation in every work content area was independent of nurses' awareness and knowledge about ergonomic features of computer workstations.

Beside the design of computer workstations, it was also hypothesized that the level of mental work, decision making, time pressure and stress in each work content area might affect nurses' selection of computer workstation. Further statistical analysis of data showed that the level of mental work, decision making, time pressure and stress are dependent on work content area which means there was correlation between work content areas and factors mentioned above (p-values < 0.0001).

The subjects had ranked level of mental work, decision making, time pressure and stress noticeably higher for patient assessment and check/administer medication content areas than the rest of them. Also, mental work and decision making were ranked higher for reviewing lab reports but time pressure and stress were ranked fairly balanced for these two work content areas. On the other end of the spectrum,

the mental work, decision making, time pressure and stress were ranked noticeably lower for taking vital signs and IV check by subjects.

In order to investigate the effects of mental work and stress as confounders/covariates on subjects' methods of abstraction and data entry as well as preferred type of computer workstation in each work content area, a series of three way chi-square tests were conducted. The results showed that the level of mental work and abstraction method had statistically significant correlation in patient assessment and taking vital signs work content areas (p-values = 0.0203 and 0.0154). It also showed that the level of stress and abstraction method were significantly correlated in taking vital signs work content area (p-value = 0.0165). The data entry method was significantly correlated with the level of stress in taking vital signs (p-value = 0.0003) and reviewing lab reports (p-value = 0.0434) work content areas as well as the level of mental work in IV check work content area (p-value = 0.0401). It was also found that the preferred type of computer workstation by subjects was significantly correlated only with the level of stress in patient assessment content area (p-value = 0.0167). No further correlation was found between abstraction method, data entry method and preferred type of computer workstation and the level of mental work and stress in other work content areas.

Further analysis was performed to investigate the effect of "working shift" and the "number of patients under care" on level of mental work, stress, decision making and time pressure as potential confounders. The results revealed that number of patients can affect the level of decision making and time pressure for patient assessment (p-values = 0.0261 and 0.0375 respectively), and time pressure for checking or administrating medication (p-value = 0.0315), level of mental work and time pressure for IV check (p-values = 0.0289 and 0.0469 respectively). Similarly, nurses' working shift can affect the time pressure for patient assessment and taking vital signs (p-values = 0.0325 and 0.0234 respectively), and the level of mental work and time pressure for checking or administrating medication (p-values = 0.0229 and 0.0163 respectively), and the level of mental work, decision making and time pressure for IV check (p-values = 0.0440, 0.0379, and 0.0263 respectively). No additional correlation was found with other work content areas.

6 Discussion

There has been a lot of effort put into assessing nurses attitude toward and acceptance of computer systems in their daily work [1, 13, 15] by using previously validated questionnaires, and in some cases developing and validating new ones [16, 17]. However, none of the articles reviewed here tried to research further deeper into this subject and investigate the effect of computer workstation design on nurses' work while utilizing EMR system, which in turn can affect their perception and attitude toward EMR systems.

The effect of health information technology (e.g. EMR systems) on quality, efficiency and costs of medical care was studied by conducting a systematic review on 257 published articles [18]. It was concluded that implementing a multifunctional EMR system can lead to real benefits in terms of improved quality of care and increased efficiency. It was also suggested that more study was needed to investigate the relationship between organizational change, workflow redesign, human factors, and project management issues with benefits of health information technology; which was the direction and purpose of the current study.

As described in Fig. 1, the assumed model for nurses' decision on selecting computer workstation is composed of three major components: (i) the activity or task which covers all physical, mental and/or social feature of any work such as tools and equipment (e.g. computer workstations) that a nurse has to use to complete the activity; (ii) the context in which a health care-related procedure or activity is performed and includes physical and socio-organizational work environment that can affect nurses' interactions with others (e.g. patients, physicians, other nurses and professionals); and finally (iii) the overall state of the human (nurse) which can affect nurses' performance and decision making process.

In this research, the common assumption among the nurses in this particular hospital that younger nurses were more tech savvy and therefore had different preferences in computer workstations and methods of performing different work content areas was rejected. Also, the knowledge of ergonomics and ergonomic features of computer workstations, or lack of it, was not a factor in nurses' decision about what workstation to choose or how to complete a work content area. Also, the common assumption that mobile devices and computer workstations such as MAK carts, laptops and tablets (iPad or similar) could be more practical, was rejected. The findings showed that most nurses prefer nurses' stations or bedside computers to anything else depending on what the work content was. Therefore mobility was not considered an advantage, although they might have been advertised by suppliers and purchased by hospital to improve performance.

The most important findings of this study were that two aspects of work content can influence nurses' decision on what type of workstation to choose and how complete a task, physical and non-physical aspects. The physical aspects of any work content in regard to computer workstations and/or EMR system were the frequency, portion of abstraction and data entry, and the method each task was performed. The non-physical aspects include level of mental work, decision making, stress, and time pressure associated with each work content area.

The results indicated that some non-physical aspects of work content such as level of mental work and stress can be significantly different from one content area to another and could make a nurse to select one particular workstation to another. It is not hard to understand that, for example, checking or administration medication in any unit or department could have higher level of stress than any other work content area because of the potential risk to patients' safety and health. Although it was not possible to compare responses among different units and departments in the hospital because of zero or very low responses from several departments, it is logical to assume that the level of mental work for patient assessment was higher in

one unit compared to another (for example Stroke Unit vs. Medical Rehab Unit) because of the complexity of care provided to patients in each unit.

Considering the physical aspects, some work content areas required more abstraction (data retrieving) than data entry such as reviewing lab reports and reviewing charts on CPOE system, compared to check/administer medication or IV check, which required more data entry than abstraction. Also, some work content areas were fairly balanced in abstraction and data entry such as patient assessment and taking vital signs. Further analysis of methods for abstraction and data entry revealed that mouse clicking was the dominant method for all tasks except one (data entry for taking vital signs), although the use of keyboard increased substantially for data entry. This findings indicates that mouse clicking was dominant method for data entry potentially because the computer program was designed with predetermined answers or options which nurses could choose by pull-down menus, radio-buttons, or checkboxes on the screen while occasionally keyboard was used to enter miscellaneous information. Also, alternative options to mouse clicking such as touchpad tapping or touch screen tapping were not preferred among nurses, possibly because not all computer workstations were equipped with such features and nurses have limited access to workstations with touch pads and touch screens.

7 Conclusion

As it was described earlier, the quality of EMR system (both computer program and workstation/hardware) can significantly influence the user satisfaction among nurses, while knowing that detailed information about task variation, duration, frequency, and difficulty can result in appropriate design guidelines and improvement in performance. Therefore, identifying the major work content factors and understanding their role in nurses' daily activities can help human factor and ergonomics experts, engineers, IT technicians, computer system developers and managers redesign the workstations, tools, hardware equipment and software interfaces in order to improve efficiency, increase productivity, reduce human errors and improve quality of care.

It has been shown that resource allocation to IT applications such as EMR systems can increase job satisfaction among nursing staff in hospitals. Such resource allocations can be in term of adequate and functional equipment [19] which match nurses' work content. Because any human factor and ergonomic intervention in IT applications without considering the whole system, work content and context is unlikely to sustain or have significant effect on the quality or even productivity [8].

There are numerous benefits in work design and redesign in health care system. Work design covers a wide range of areas and disciplines including implementation and use of technology such as computer workstation, EMR systems and their associated hardware. A better design of technology can improve quality of care and reduction of human error which lead to better patient safety; improve productivity

and efficiency which lead to more positive attitude toward and acceptance of technology among nurses. Other indirect benefits could be decrease in job stress and work load, efficient communication between and among health care professionals and patients, decrease in costs, and reducing the decision making process time [20].

Figuring out the way nurses perform each work content area and their preferred method of performance can potentially lead to two different approaches in workstation design and resource allocation; (i) computer workstations are custom designed for each unit or department (e.g. ICU/CCU vs. Outpatient) and appropriately distributed and allocated in any hospital because nurses' work content can be significantly different from one unit to another and with different preferences when completing different tasks; and (ii) uniformly designed workstations with similar design features appropriately distributed and allocated across any hospital because nurses' preferences in performing different work content area are similar in all units and departments, although such uniform designs may be different from one hospital to another.

Bottom line, when the tools, computer workstations, work environment match nurses' work flow and work content, their performance will improve which will lead to higher quality of care, lesser human or medical errors, improvement in efficiency, as well as reduction in costs, better training, improvement in maintenance and data security. Although this study alone was not able to answer all questions, it can be considered one of the first studies which tried to conduct a work system analysis about nurses' work content and computer workstation design, nevertheless more research is necessary in this field. It is still unclear if nurses have different preferences in computer workstations and work methods when they rotate in different units or departments. Also, it is not clear why some work content areas had higher mental work load or stress levels compared to the others, or how the computer program interface can affect nurses' preferences in selecting computer workstations.

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Part III
Human Factors and Ergonomics in Healthcare Systems

A Flexible Toolkit for Evaluating Person-Centred Digital Health and Wellness at Scale

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Abstract The Delivering Assisted Living Lifestyles at Scale (dallas) program was a large-scale, nationwide deployment of digital health and wellbeing products and services in the UK. Telehealth, telecare, mobile apps, personal health records, and assisted living technology were implemented by four large multi-stakeholder consortia and a multidimensional evaluation was carried out across the lifecycle from examining co-design and redesign of services through to rolling out services via statutory, private and consumer routes. A flexible toolkit of descriptive, process and

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outcome measures was developed and iteratively refined throughout the program. This approach enabled a longitudinal mixed-methods evaluation, underpinned by a robust social theory of implementation called 'Normalization Process Theory'. There remains uncertainty about the best approaches to real world digital health evaluation. This program provided a unique opportunity to develop the knowledge base and toolkit of qualitative and quantitative methods necessary to evaluate person-centered digital health technologies deployed at scale.

Keywords Health informatics · eHealth · Digital health · Telemedicine · Implementation · Evaluation

1 Introduction

Population demographics are changing with growing numbers of older adults who have complex health and social care needs and a concomitant rise in the prevalence of chronic illness and multi-morbidity (i.e. having two or more chronic illnesses) [1]. As a result, health and social care services are struggling to cope with the increasing care burden. To address this, health and care systems are shifting towards promoting and supporting the management of long-term conditions in the community and supporting older adults to live independently, by encouraging people to become proactive stakeholders in managing their own health and well-being through 'self-care' [2, 3].

To support this 'self-care' agenda, a wide range of person-centered digital health platforms and devices have emerged, including: telehealth and telecare systems [4], personal health records [5], various mobile 'apps' and wearable technologies [6, 7] and assisted living [8]. Many of these technologies have been deployed in a limited context however and firm and generalizable evidence of their benefits is still lacking.

Randomized Controlled Trials (RCTs) are currently viewed as the gold standard in assessing the effectiveness of health interventions and have therefore also been advocated to evaluate digital health interventions [9]. However, there is increasing recognition that these more controlled evaluation methods are not necessarily the most practical or appropriate in the context of consumer and patient digital health (eHealth) implementations [10–12]. These methodologies do not allow us to understand implementation issues in other populations, other geographies or other social, political or financial contexts. They also focus on summative end-point evaluations of stable products rather than understanding how these technologies and services are actually designed, implemented and rolled out and iteratively and formatively evaluating and improving them based on feedback from actual use in context. Alternative types of evaluation methods are required to capture complex, real world digital health 'intervention'. Mixed methods, participatory and theoretically grounded approaches are increasingly being advocated and applied to the field of 'eHealth' [13, 14].

This paper addresses this gap in the literature by describing:

1. A flexible toolkit used to evaluate an evolving large scale, national digital health deployment program;
2. How we used a robust theoretical framework, Normalization Process Theory (NPT) to interpret and understand implementation processes; and
3. How the evaluation had to adapt to meet changing requirements throughout this dynamic program.

2 Background

To address the challenges of understanding how to best scale and routinize digital health, Innovate UK funded a large scale £37 million three-year program in the UK called 'Delivering Assisted Living Lifestyles at Scale' (dallas).[1] The dallas program funded four large multi-stakeholder consortia called 'Living It Up', 'Year Zero', 'More Independent', and 'i-Focus' [15–18]. These were jointly led by a variety of health and social care services, private industry, the voluntary sector, local government agencies and in some cases, supported by academic research partners.

The dallas program aimed to:

(i) Support and evaluate the design, development and implementation of technologies and services that enable citizens to take greater control of their health and wellness and
(ii) Encourage a large-scale consumer market for person-centered technologies by driving social and service innovation.

The program specifically focused on promoting preventive care, self-care and independent living through 6 key values called the '6 Cs': '*Control, Choice, Community, Connectedness, Contribution and Collaboration*'. Each dallas community developed and deployed a broad range of technologies and services from traditional telehealth and telecare systems, personal health records, mobile health apps, assisted-living devices and online digital health portals and activities to raise awareness of self-care and increase digital access and inclusion. These were targeted at a variety of people from patients and consumers, from children to older adults, and in both urban and rural regions of the UK [15–18].

[11] https://connect.innovateuk.org/web/dallas.

3 Evaluation Framework

The breadth of technologies and range of services to be deployed in the dallas program were not defined at the outset of the evaluation [15]. Furthermore, the proposed digital platforms earmarked for development as part of the program were intended to cross many organizational and cultural boundaries (health and social care for example) as well as being targeted at multiple geographies and populations [15–18]. From the outset our overall evaluation approach had three aspects as illustrated in Table 1 (descriptive, process and outcome) with a fixed underpinning theoretical framework, Normalization Process Theory (NPT) [19, 20] to help us capture and organize the implementation data. It rapidly became necessary to adopt an agile and participatory approach to designing the *outcome* evaluation methods and toolkit (a suite of evaluation tools and approaches to assess outcomes). This included active involvement and engagement with the communities at events and iterative reflective cycles to understand what was being rolled out, to whom, and how this could be best evaluated (what the evaluation criteria should be for each product and service).

This participatory and reflective process enabled us to develop a practical and robust evaluation approach that met the evolving needs of the program. It meant that our toolkit and approach could be flexible and responsive to external contexts so it could be adapted as the socioeconomic and political landscape rapidly and radically evolved throughout the duration of the program we were evaluating. To ensure we critically and reflexively monitored and adapted the evaluation framework throughout the program, weekly research meetings, monthly project management meetings and regular consultations with the four dallas consortia and program funder were undertaken. An independent advisory board was established which included experts from a range of backgrounds (academic, health service, industry and voluntary sector) as well as a nominated individual from the funding body. This group met annually and provided considerable added value to the evaluation cycles through their collective expertise.

Table 1 Dallas evaluation framework

Descriptive	*Project documentation*—quarterly technical reports, observational logs, local evaluation data *Ethnographic observations*—dallas leads meetings, co-design workshops
Process	*Interviews*—baseline, midline and endpoint e-HIT interviews with a cross section of members from each dallas group *Focus groups*—with patients, carers, consumers and health professionals *Project documentation*—quarterly technical reports, observational logs *Ethnographic observations*—dallas meetings, dallas dissemination events *Surveys*—NoMAD surveys with health professionals
Outcome	*Minimum Data Set (MDS)*—date of birth, gender, postcode *Surveys*—core, bespoke and contingent valuation surveys *Project documentation*—recruitment reports

3.1 Study Design

The products and services being rolled out by the four dallas consortia were diverse, heterogeneous and evolved significantly throughout the duration of the program. For example some services were digital (digital personal health records) and others not (awareness raising initiatives). Some products were aimed at statutory markets (e.g. a health professional might prescribe a fall detector or a heart monitor for example) and some were consumer-based wellness or lifestyle products which one could buy off the shelf, or download from an app store (for example an app to support carers of people with dementia). Each product and service was also targeted at different populations and users ranging from older adults to new mothers to people with specific long term conditions (for example Heart Failure). The resulting evaluation therefore was largely an implementation evaluation (because there was no baseline and no single stable intervention to be studied) but one which also provided insight into how to capture outcome level data at scale in the wild for consumer based digital health programs.

3.2 Multidimensional Evaluation Aims

The evaluation aims were to understand the potential impacts of the program on:

(i) Individuals (including end users, their friends and family and formal carers)
(ii) Systems (such as healthcare, housing social care).

This required us to explore tools and instruments for gathering data on user experiences (whether the services were usable and acceptable for example), potential outcomes (whether quality of life changed because of the service), and experiences of key implementers designing, developing and rolling out the various services and products (for example barriers and facilitators to uptake and roll out). The evaluation had to be multidimensional and therefore we created a framework composed of the three aforementioned dimensions (see Table 1).

Firstly, a dynamic descriptive evaluation allowed us to examine '*Who*', '*Why*', '*Where*' *and* '*When*' in relation to the range of digital health interventions developed and also how these evolved over time. Secondly, a longitudinal process evaluation focused on the '*How*'; providing insights into the implementation journey and the way it was shaped by complex mechanisms and external factors. Thirdly, an outcomes evaluation aimed to capture the '*What*', using quantitative data in order to capture objective measures of the reach (who was accessing and using products and services) and effectiveness (actual and perceived benefits and views of using a service or product) of the dallas program.

3.3 Theoretical Underpinning

The evaluation was underpinned by a robust sociological theory of implementation processes called Normalization Process Theory (NPT) [19, 20]. NPT—in the context of change and innovation within complex organisations—provides a useful prism through which one can observe, identify, analyze and explain the variety of factors which affect how individual, collective and organizational 'agency' impact new work practices [19, 20]. NPT has four core generative mechanisms: *coherence, cognitive participation, collective action* and *reflexive monitoring*. This provided a framework through which the dallas implementation processes (captured via observations, interviews and surveys) could be analyzed and conceptualized in a robust and coherent manner (Table 2). NPT was chosen as much of its early development was undertaken in the context of studies of implementation of eHealth services and trials and it has proven useful as a tool across a broad range of contexts.

4 Evaluation Toolkit

This section presents an overview of the tools, methods or instruments used to collect data for each of the three evaluation approaches described above (descriptive, outcomes, implementation). In each, we describe what data was being collected and how; what this data allowed us to evaluate and then present some insight into the benefits and limitations of each tool or method. It is not intended that this toolkit should be used in its entirety for each digital health evaluation; *rather that people can see the value of developing a flexible toolkit based on their own aims and objectives and practical limitations*.

Table 2 The four constructs of normalization process theory (NPT)

Coherence	Cognitive participation	Collective action	Reflexive monitoring
The work of understanding and "making sense" of new practices or ways of working	The work of engaging individuals and groups to 'buy into' and adapt the organization to new practices	The work of implementing new practices and providing the necessary resources and training to operationalize these	The work of evaluating and monitoring new practices and appraising whether they are worth sustaining or not

4.1 Descriptive Evaluation: Tracking the Evolution of Products and Services

@@While the different communities adopted varying levels of co-design (co-operation and collaboration with people who might use the service) in their approaches, all involved solution exploration and user-centered design approaches from the outset [16–18] in order to design and redesign services that people needed and wanted. This meant that the exact specification of a product remained unclear while services were being designed. While this is the very purpose of co-design—i.e. getting to 'the heart' of what people really want from a product and potentially increasing eventual buy-in and take-up later on—it also posed considerable evaluation challenges.

Defining appropriate measures of success is much more straightforward with a stable system or defined service rather than ones which are evolving or effectively 'work-in-progress'. Learning about the benefits and challenges of this co-design phase itself seemed therefore an essential part of this evaluation. To accommodate this continuously evolving landscape we documented product and service development activities: how they changed over time, identifying 'critical transition points' and reasons and motivations for adaptation. This product development 'journey' is a useful research output of its own accord. Creating a set of evaluation criteria for such a diverse and dynamic set of services is a considerable challenge. Hence, the set of tools we selected needed to include both generic measures—i.e. some which capture general usability and wellness—as well as more sensitive tools where appropriate for context-specific interventions: for example, self-efficacy scales for self-management apps.

4.2 Counting Users and Measuring Reach

One of the first challenges for deployment evaluations is to agree on an objective and practically useful definition of a participant (involved in the program in some way) as well as levels of engagement (active and meaningful involvement). In conventional trials it is often straightforward to count a participant once they are assigned to a service or experimental 'condition' and "consent" to study participation. In consumer based trials however, users can be actively recruited to a service or choose to use a product or service at a time of their choosing and of their own accord (e.g. installing software or downloading an app). It is thus harder to measure and track when a person becomes an active participant and have one single baseline for evaluation. Furthermore, there is a lack of clarity in a consumer based trial regarding what the term 'engaged user' means. If a person downloads an app or registers for a service they should certainly be 'counted' as being a participant, but at what point do they become considered active and engaged. This could be based on length of time registered (someone who stays registered for the duration of a

weight-loss program for example), or on patterns of usage data (someone that logs in at least once a week for example).

For this evaluation an individual was considered '*reached*' if they engaged with a dallas product or service (regardless of whether they were currently using the product or service). This might have been active participation at a workshop or event where the products were being designed or marketed or passive engagement in terms of TV, Radio, or newspaper advertisements or posters or leaflets in a community setting. An individual was considered a '*member*' of the program when they could be counted and described in terms of their basic demographics (age, gender, socioeconomic status) which allowed us to evaluate and report on the reach of each product or service. Finally, an individual was considered a 'user' if there was direct evidence of them signing up to use a product or service and there was evidence of use (varying from logging in once, to setting up a personal profile, to having a full set of logged usage data for a product). Different categories of user might be affected by the program in different ways and therefore it is important to decide what the different outcomes might be for such a wide range of participation.

4.3 Process Evaluation

A primary aim of this evaluation was to capture key stages of the various products and services as they were designed, developed, piloted and implemented and to document and chart this in a way that would allow us to identify real barriers and facilitators for implementation of digital health at scale. Understanding barriers, facilitators and key lessons learned across dallas was a key evaluation goal from the outset as such work would provide valuable "best practice" for future large-scale technology deployments. In order to capture the full breadth of barriers and facilitators across the stakeholders and organizations in the program we collected extensive implementation data as shown in Table 3.

Using this data set and the underlying NPT framework to understand and categorize the data we were able to explore many complex barriers and facilitators to the uptake of digital health. Some of these have already been reported [18] and key lessons are being disseminated [21]. An important point was the consistent use of our theoretical framework, NPT, to underpin data collection and analysis across the program.

There is currently great interest in the factors which contribute to, or impede, the implementation of complex interventions at scale and in real world settings. Our series of in-depth, e-HIT led interviews (a tool that has NPT as its theoretical underpinning) with a purposive sample of key stakeholders from each of the four 'dallas' communities allowed us to track key implementation facilitators and or barriers in a consistent fashion. Qualitative data analysis from these longitudinal interviews showed us that key stakeholders recognized the role that the program had played in enabling them to operationalize aspects of service re-design to deliver more personalized, digital tools and services for citizens and service users which

Table 3 The implementation data collected as part of the dallas implementation evaluation

E-HIT (e-Health Implementation Toolkit) interviews (N = 46):
with key informants, stakeholders and implementers (Baseline (n = 17); Mid-point (n = 21); and End-point (n = 10) of 3 year program) to explore implementation issues
Key Implementer Interviews (N = 52) and Champion Interviews (N = 23):
to capture expectations and experiences of stakeholders involved in championing digital self-care in their community
Quarterly Monitoring reports (N = 48):
submitted to Innovate UK and analysed by us to track development of services, products and activities and identify barriers and facilitators
Quarterly Evaluation reports (N = 43):
to track services, products and activities and identify barriers and facilitators to deployment
Recruitment reports and Observation Logs (N = 11) and Meeting minutes and observation field notes:
to capture recruitment numbers, strategies and blockers and facilitators, to capture on the ground service roll out blockers and facilitators, to track development of services, products and activities and identify barriers and facilitators
NoMAD surveys (N = 153):
to explore implementation issues with health professionals, undertaken in two services

included sharing of knowledge to help sustainability at a wider program level. However, it also permitted active emergence of knowledge about implementation challenges that were noted across the life of this real-world, large scale digital health deployment.

In addition to the longitudinal set of key implementer interview we also conducted surveys with health professionals to assess "readiness" to adopt new technologies within the healthcare environment. These were undertaken using a specialized normalization survey called NoMAD (normalization of complex interventions-measure development). The NoMAD team worked with the dallas consortia to adapt the survey questions to each service and identify appropriate staff for inclusion in the respective surveys. NoMAD questions were derived from NPT, again highlighting the importance given to consistent use of theory in this evaluation, something that has been deemed important in digital health evaluations [13].

Participants (health professionals involved in rolling out services) were asked to respond to items on a 5-point Likert scale from 'strongly agree' to 'strongly disagree'. The data for each site was analyzed descriptively, using response frequencies and grouped according to professional roles. The NoMAD tool provided useful insights into health professionals' perceptions during the implementation process for certain initiatives where it was used and the findings from it resonated with the large volume of qualitative data collected in parallel as part of the wider dallas evaluation. Responses from NoMAD surveys were generally positive about engagement; but there was scope for improving understanding about the potential benefits of each initiative. The need for adequate provision of training and resources was also highlighted.

The NoMAD tool helped demonstrate that by listening to implementers, key learning can be revealed which can help allow the smooth integration of the initiative. Longitudinal qualitative data was analyzed using a framework underpinned by NPT. However, data was not "shoehorned" to fit this framework as we allowed for identification of themes that fell outside the framework to maximize knowledge generation about implementation issues and ensure that the theory did not constrain learning.

4.4 Measuring Outcomes

With a variety of digital health products all with different potential end users and different functionality it was difficult to define a clear set of primary outcomes to measure across the whole program. Due to the evolving nature of the program itself it became clear that measuring health related outcomes would be challenging as:

(i) although the program was of 3 years duration many initial offerings had to be reconsidered and it was only in the final phase of the program that the services for evaluation were more clearly defined and operational
(ii) it was difficult to define outcomes when products and services were meant to positively affect different people (end users, friends and family and carers) in different ways (increase independence, enable them to self-manage, improve their sense of control);
(iii) it was hard to attribute any measured benefits to the program when there was no "control" group for comparison.

For these reasons a suite of outcome measures were developed and this outcomes based toolkit could be used by communities to collect baseline data and potentially in the future to collect follow-up data once they had stable products with users signed up to use them. Those involved in the development and deployment of consumer digital health are not necessarily familiar with the evaluation methods required to demonstrate impact and outcomes. Companies on the one hand might want to measure metrics such as downloads and the number of kits sold whereas the statutory sector might be more interested in service use and sustainability of services. Funders and commissioners however still rely heavily on outcome-based reporting and therefore it was important that we developed methods by which people could collect data on who was using their product; the perceived usability and usefulness of the products/services and whether or not using such as service or product had an effect on their lives. At the outset this toolkit was envisaged as consisting of traditional outcome measures such as EQ-5D (to measure health related quality of life). However, by the end of the program it had evolved to consist of the following items:

- A 'Rate this Product/Service' item
- Questions on how the person found out about a product/service

- a 'Minimum Dataset' (gender, date of birth, post code, ethnicity)
- *to capture* '*reach*'
- questions on computer, internet and smartphone usage
- questions on Perceived usability and Perceived Usefulness *based on the validated Technology Acceptance* Model [22]
- Perceived influence on lifestyle factors
- Health directed behaviors [23].

4.5 Measuring Usability and User Experience

To measure usability and user experience ten items from the system usability and perceived usefulness elements on the Technology Acceptance Model survey were used. It was important for us to provide a measure of both of these elements in case products were either seen to be really useful but were not usable or acceptable or the product was highly usable but not something that would be readily taken up by the intended user group. Due to the evolving nature of the program there was limited time to collect actual user experience data via the survey because products and services were only being piloted and still refined and developed and we did not have direct access to users during the program, who were recruited via the consortia themselves.

In addition to the survey items it was important for us to conduct more qualitative evaluations inside the communities with some of the users of their deployed services and products. We therefore conducted 8 focus groups with 59 service users in order to understand what positive and negative experiences people had in relation to using the various digital health services being rolled out across dallas. This was only a sample and—although it shed important light on some of the user engagement issues that can be experienced—should not be generalized to all digital health products or roll outs.

4.6 Measuring Quality of Life and the Value of 'Wellness'

Many of the services provided within the dallas program were centered around the consumer 'wellness' market rather than 'health service delivery'. Some standard measures—such as health related quality of life measures [24]—were perceived as inadequate to the 'consumer well-being' market context. Companies rolling out wellness apps for example did not want to ask traditional questionnaire items that focus heavily on statutory care and health status as opposed to general wellbeing.

Evaluating health and wellness products and services with a range of benefits and which are not purely focused on direct health gains will mean that other wellness based measures need to be developed and validated and that further

exploration of methodologies to assess "cost-effectiveness" or the "value" of new digital health services is urgently required. To address this we included a measure of 'lifestyle wellness' in the dallas evaluation (*the dallas 6 Cs: contribution, choice, control, collaboration, community and connectedness*). This constituted both a risk and an opportunity. Although not a validated questionnaire item, it was essential to measure these aspects of the program given the novel and holistic nature of dallas.

Health economists have also highlighted the inherent difficulty in assigning personal values to enhancing 'well-being'. To address this, a population contingent valuation survey was developed as part of the dallas evaluation in order to understand what value the public might put on these lifestyle attributes [25]. This in turn enabled us to identify the "public's" willingness to pay (WTP) for digital interventions to promote health and wellbeing by directly valuing the attributes of the 6C's which were integral to the dallas products and services.

We recognize the strengths and weaknesses of using traditional (validated and accepted) instruments versus novel (no validation, harder to make comparisons across studies) measures but fully believe that new measures of wellness at scale are required for the future of digitally enabled health and wellness programs. Quality Adjusted Life Years (QALYs) [26] are unlikely to be the most appropriate outcome for assessing the benefits achieved from deployment of digital consumer wellness products. There is a need to value a wider range of benefits of consumer wellness products which go beyond health gains by using more consumer facing approaches like discrete choice experiments and contingent valuation studies in order to better evaluate their potential impact on both individuals and health and care systems.

5 Conclusion and Future Work

There is a pressing need to develop flexible but coherent evaluation frameworks to evaluate complex, consumer-centric digital health implementations. Demonstrating the potential impact of health and wellness technologies is crucial as we move into a time where care models are shifting to embrace digitally enabled self-care as routine practice [27, 28]. This paper presented an evaluation framework adopted during the dallas program that allowed us to study digital health consumer technologies at scale in 'real world' setting in a useful way. Our resulting evaluation framework enabled us to provide:

(i) a rich descriptive evaluation of the community and service journeys;
(ii) learning about the barriers and facilitators to implementation and processes for change;
(iii) data on the reach of dallas products and services and
(iv) a better understanding of the readiness for digital self-care in the UK.
While:
(v) The use of a theoretical framework, NPT, enabled us to transform descriptive qualitative data into more explanatory results and make clear recommendations.

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Application of Lean Six Sigma Concepts to Medicine Dispensation of Public Health Centers

Marina Pazeti and Leonardo Calache

Abstract For years, Brazilian public health has been focus of criticism due to its overall precariousness. One of the methodologies utilized to try to improve this processes is the *lean healthcare*, a theory derived from *lean manufacturing*, a heritage of Toyota production model. In the first semester of 2015, a project was developed with the department of medicine dispensation of a midsize city from São Paulo. The project had for objective mapping a process and its optimization, utilizing Industrial Engineering concepts. A diagnosis following the steps of DMAIC methodology was done. After mapping process and task analysis, the project consisted in a time study, leading to the utilization of 2-sample t hypothesis test utilizing Minitab software. From the diagnosis recommendations were made for process improvement in medicine dispensation. As main results there was: statistical proof of alternative hypothesis proposed, related to the amount of time used at filling out prescription forms.

Keywords Lean healthcare · Time study · Hypothesis test

1 Introduction

The public health in Brazil, best known as Unified Health System or SUS, in Portuguese, has one of the world's most inclusive and benevolent public health networks on paper. It is available and costless for everyone and has obtained impressive achievements, as raise life expectancy and decreased infant mortality. However, this Health Care System presents a lot of flaws and weakness, like insufficient beds, extensive waiting lines and presenting woeful condition. This

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situation put the public healthcare system in a high position on the Brazilians' grievances list [1].

Due to this situation, it is of huge importance to find means that can help solve this problem. One subject of Industrial Engineering, the Lean Healthcare, still under-explored in Brazil but have been developed in other countries around the world, may have an important contribution in this quest. The Lean Healthcare is a branch of Lean Thinking theory that seeks to decrease waste and unnecessary activities, saving time, space, human effort and money [2]. This savings can lead to a better investment in the core business of the healthcare, that is, the patient care quality and safety, and still grants higher efficiency to one of the most important departments in society.

In the first semester of 2015, a group of undergraduate Industrial Engineering students worked on a project that was developed with the Municipal Secretariat of Health of a midsize city from São Paulo to bring tangible improvement of its patient care. The aim of the project was to implement Lean and Industrial Engineering concepts and propose process improvements within the department of medicine dispensation. With the application of some Lean Six sigma tools, it was possible to map and propose possible improvements regarding time and efficiency in the process of filling out prescription forms and giving medicines.

2 Literature Review

2.1 Lean Healthcare

The Lean Management or Lean Thinking concept is usually connected with Japanese manufacturing, mainly the Toyota Production System (TPS). W. Edwards Deming, one of the most important intellectuals of the TPS, explains that to achieve quality, managers should emphasis on creating quality into the product and improving process, rather than rely on mass inspection [3].

The main idea of Lean Thinking is to maximize customer value while eliminating waste, that is, generating more value for customers utilizing fewer resources [4]. To achieve it, is essential to determine what is valuable in a process, and then differentiate which steps add value from that do not add value, eliminating waste. This will ensure that all work adds value and satisfy the customer's needs [3].

The process of identify value and eliminate steps that do not create value are two of five principles that guides the Lean Thinking. The third principle, create flow, concerns to make that all steps that create value occurs in an effective sequence so the product will flow easily throughout the process; The fourth principle, establish pull, imply to let customers pull value from the following upstream task; The last principle, seek perfection, is the process of continuous improvement, repeating all the process until perfect value is created and with no waste [4].

One of the main tools commonly utilized in the Lean Thinking are SIPOC, Time study and Spaghetti diagram. According to Jones, SIPOC stands for Supplier Inputs

Process Outputs Customers, and it is a powerful process map that seeks to identify all the important steps and agents of one process. Time study is a technique that aims to eliminate redundant work and create methods more effective and suitable for the worker who uses them [5]. Spaghetti diagram is a visual representation method that makes use of continuous flow line to trace the trail of an activity or product through a process, enabling teams to find redundancies in the workflow and to improve the process flow [6].

Lean Thinking in not normally related with health care, where waste of supplies, time and money are a usual issue. Nevertheless, the principles of lean management can be applied in health care in the same way as in other industries [3]. Going Lean in Health Care argue that, Lean Thinking is not just a manufacturing technique or a cost-reduction method, but a management strategy that is applicable to every organization due to the fact that it is related with improving process. All organizations, including Health Care organizations, have several processes settled to create value for customers [3].

According to Going Lean in Health Care, to increase value and eliminate waste, managers in health care, must investigate processes that matches with the value desired by patients, map the process, eliminate waste and steps that do not add value and make value flow throughout the entire process on the pull of the customer. When applied severely and all over an organization, lean principles can affect dramatically its quality, cost and productivity [3].

2.2 Six Sigma

Sigma is a Greek letter utilized in statistics, which signifies the amount of variation in a set of data, process, or anything measurable [7]. According to American Society for Quality, Six Sigma is a technique that has as main goal the capability improvement of one's business process, decreasing its process variations, increasing performance, and leading to defect reduction and improvements in employee satisfaction, profits and quality of products or service.

To achieve it, Six Sigma makes use of a data-driven quality methodology called DMAIC. DMAIC is an acronym for the five steps that compose the process: Define, Measure, Analyze, Improve and Control. The steps are: Define the problem, the project goals, opportunity for improvement, improvement activity, and customer requirements; Measure current performance of the process; Analyze the process to identify the causes of variation and defects; Improve the performance of the process by addressing and eliminating the main causes; and Control the improved process and upcoming process performance [6].

Carter argue that another important goal of the Six Sigma method is to determine what is essential to customers and eliminate anything else that does not meet the customer's needs. This way, it is possible to identify from the customer's perspective what is critical to the quality of the process or product, being called as CTQ, or critical to quality [7].

3 Methodology

The following chapter presents information regarding the methodology followed by the present paper, defining the study object, data collection and data analysis.

The method used to develop this project followed the methodology proposed by DMAIC, going through with the Define, Measure and Analyze steps. The Improvement and Control steps were not performed because the project was part of a class ministered at School of Engineering of Lorena, called Integrated Project in Industrial Engineering III and, according to the time window provided by the semester, it was unfeasible to go over all steps. But the group project made sure to clearly state the indications to improve the processes involving medicine dispensation, delivering a complete report to all interested parts in order to provide enough information and statistical proof to support the propositions, also detailing actions to be taken to improve addressed points.

3.1 Study Object

The object of this study consisted in the department of medicine dispensation of a midi sized city in the state of Sao Paulo. This department was responsible for receiving and separating medicines from suppliers in a warehouse, dividing each medicine should go to each substation related to public health care. After arriving at a substation, the medicine would be checked in a local inventory and after that, distributed to the population. To the matter of the project, only the main substation, called Specialized Ambulatory, was analyzed since it's where the three main kind of medicaments were dispensed: (i) Basic, medicines approved by a Brazilian Government's program directed to common diseases. This type of medicament may have a subgroup called Controlled. Controlled medicaments need to have written on the medic prescription the following information: Patient name, ID number, age, address, telephone number, medicament lot, quantity dispensed, shelf life and date of dispensation, information written almost always by the employees at the time of dispensation; (ii) Strategic, medicines used in the treatment of endemic diseases or diseases that present great social and economic impact and (iii) Specialized, medicines used to treat illness considered more complex and that require a differentiated process for dispensation.

3.2 Data Collection

For the original project, three kinds of data were collected, being two qualitative and one quantitative. The first data collected was through observation and conversation with employee related to the process, in order to properly understand the processes

involved. From this data, a Failure Mode Effect Analysis (FMEA) was created. The second data collected, also qualitative, was the movement of employees in their working area. This information was used to create movement diagram, also called 'Spaghetti' diagram, used to identify recurrent paths or excessive movement.

For the present paper, this two measurements won't be considered, since they would require an extensive explanation about the analysis and results obtained, making it infeasible in the present paper.

The third and last measurement made was quantitative, since one measured the time spent to deliver a medicine, since the patient walked in the dispensation booth until he or she was considered able to go and take the medicine in the right way. In order to collect this data, a sampling plan was elaborated, containing the basic steps for dispensation for the most exigent of the medicines. The sampling plan contained 4 basic and qualitative information—date, shift, employee, type of medicine—and 4 quantitative marks—time for check and fill in the prescription, get medicine in the cabinet, pack all boxes of medicine together and further explanation—if needed.

3.3 Data Analysis

The data collected through time study was compiled, measurements where errors were identified were excluded from sample and then the remaining data were analyzed using the statistical software Minitab. The final sample number used was n = 98, for 3 types of medicines: Basic, Controlled Basic, and medicines related to diabetes; even though diabetes medicines are considered basic according to Brazilian Government regulation, as it required extra time to explain for patients how exactly to apply it, the project's members decided to compute it separately. There was also a forth type of medication dispensed but as it rate was really low it was not considered for analysis purposes. For all tests, a confidence level of 95 % was used. For three types of medicines, basic means and standard deviation was calculated.

A hypothesis was proposed for the dispensation of Controlled Basic medicaments:

- H_0 = There is no significant time difference between filling or not prescriptions to patients.
- H_1 = The time spent when needed to fill prescription is greater than the time spent when no need to fill prescription.

4 Results and Discussion

Figures 1, 2 and 3 show the results for mean and standard deviation for the three types of medicaments: Basic, Controlled Basic and Diabetes. All tables are from the original report and, therefore, may contain some Portuguese labels.

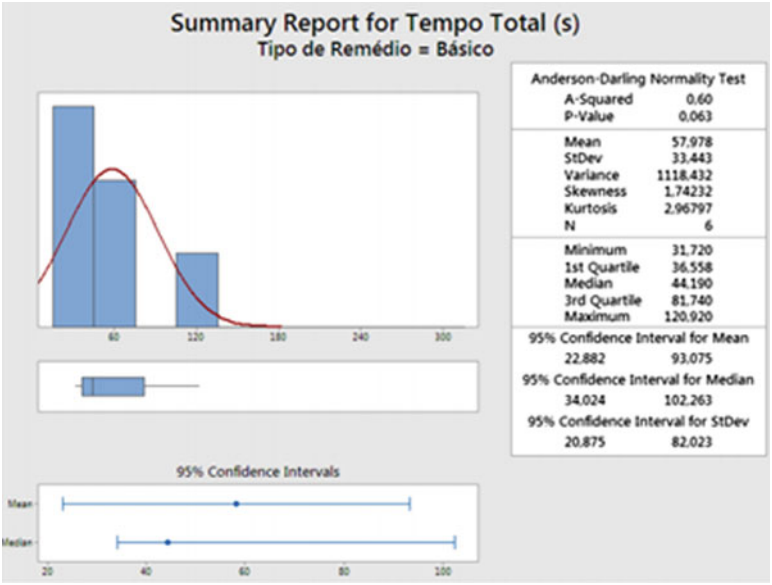

Fig. 1 Summary report for total time (in seconds) for basic medicaments. Font: Authors

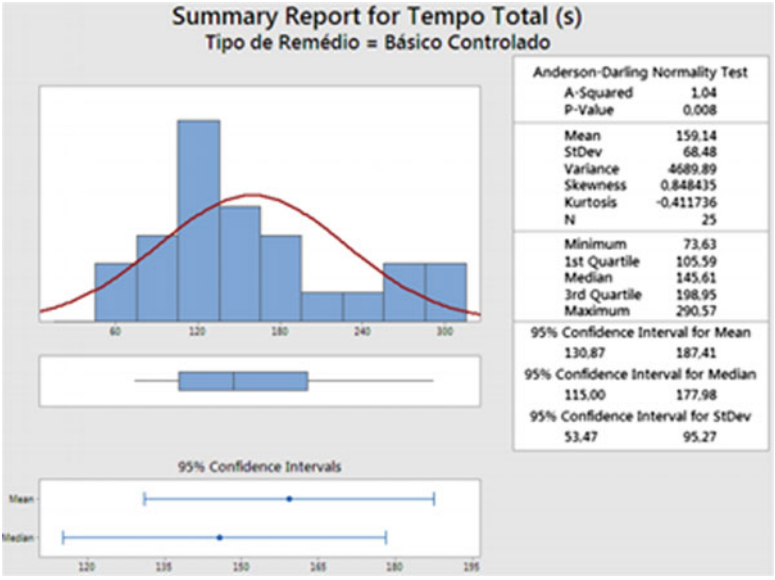

Fig. 2 Summary report for total time for controlled basic medicaments. Font: Authors

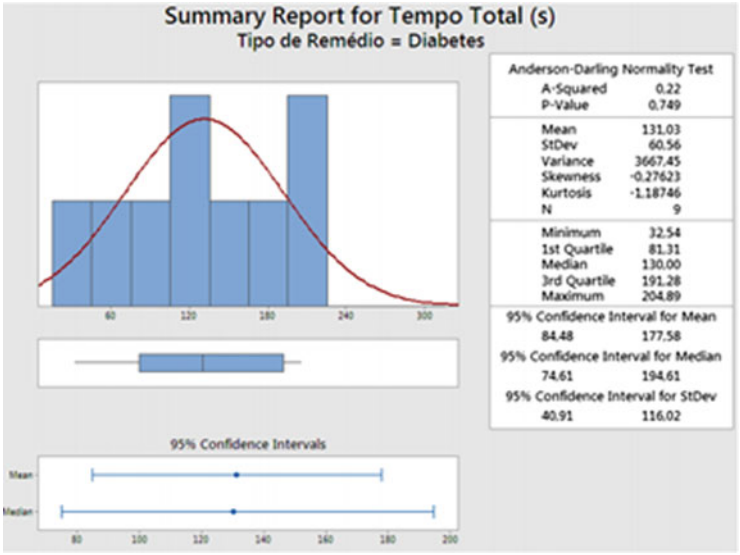

Fig. 3 Summary report for total time (in seconds) for diabetes medications. Font: Authors

The figures above allow one to see that, in terms of seconds, Basic medicaments had a sample mean of 57.978 with a standard deviation of 33.443. The Controlled Basic presented a sample mean of 159.14 with a standard deviation of 68.48. At last, Diabetes medicines had sample mean of 131.03 and standard deviation of 60.56.

The Table 1 shows the data in terms of countable quantity dispensed and percentage of it when compared with the total amount of medicaments delivered and time used for the process. Notice that during data collection, some other medicaments were delivered but in such a small amount that it didn't impact significantly the other results.

From results found, it is possible to assure that, despite the highest volume of deliveries belong to Basic medicaments—61 out of 98 medicaments—the main responsible for time spent in dispensation are Controlled Basic medicaments, responsible for 40.59 % of all time used in distribution.

In face of this results, a conversation between project members and the director of the facility revealed that a possible cause for this would be the filling of the

Table 1 Quantities and percentage of time used in dispensation

Type of medicament	Quantity delivered	% of quantity delivered	Time sample mean	% of time used in dispensation
Basic	61	62.24	57.978	36.08
controlled basic	25	25.51	159.14	40.59
Diabetes	9	9.18	131.03	12.03
Other	3	3.06	60.197	1.84

Two-Sample T-Test and CI: Com P; Sem P

```
Two-sample T for Com P vs Sem P

        N   Mean  StDev  SE Mean
Com P  25  159,1   68,5       14
Sem P  25   51,4   46,6      9,3


Difference = μ (Com P) - μ (Sem P)
Estimate for difference:  107,7
95% lower bound for difference:  79,9
T-Test of difference = 0 (vs >): T-Value = 6,50  P-Value = 0,000  DF = 42
```

Fig. 4 Results of 2-sample t test

prescriptions, since it was the basic difference between Controlled Basic and Basic medicaments. The process of filling could be divided in two parts: patient information and medicaments information.

In order to test the hypothesis that cited in data analysis, the data for total time used with Controlled Basic medicaments was disposed in a column. In a second column, the data input was the total time of Controlled Basic minus the filling time, information obtained from time study's sampling plan. After that, a Normality test was conducted for both sets of data, showing that both sets of data presented non-Normal distribution (p-value < 0.05). From this result, a 2-sample t test was used in order to test H0 and H1, which means, to test if there was a significant difference between both groups of data. Figure 4 presents the results of the test.

From this test, it is possible to reject the null hypothesis H0 (p-value < α), accepting the alternative hypothesis H1 that the time spent when there is filling of prescription is greater than the time spent when there is no filling of prescription.

In accordance with the obtained results, it was proposed that, in order to decrease the time spent in medicine dispensation: (i) the creation of a base-book distributed to patients, explaining the importance of bringing their prescriptions already filled and (ii) verbally reinforce this idea, only accepting prescriptions that had been filled. There was also a suggestion of setting up a small table with pens to allow patients to fill up their information and still get the medicines, only working the idea of autonomy.

5 Conclusion

After looking over this results, it is safe to assume that simple changes may have great impact in every day processes. The project conducted by students from Industrial Engineering showed it is possible to implement basic lean six sigma tools into processes apparently not even a bit related to engineering processes—healthcare, in this case.

Data collect from a Specialized Ambulatory from a midi-sized town in Brazil was enough to generate statistical inferences relevant to propose simple changes in the daily life of medicine dispensation. The extra time resultant from this basic transition from filling prescription for patients to delivering medicines only to prescriptions previously filled could be used in other services provided by the ambulatory.

It is important, however, to continue this study after the change has been place to compare the real results with the expected results from proposed changes.

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Lean Healthcare as a Tool for Improvement: A Case Study in a Clinical Laboratory

Karine Borges de Oliveira, Eduardo Ferro dos Santos and Lucio Veraldo Garcia Junior

Abstract In the current days the health services area presents difficulties in managing processes and staff. High costs, long queues, few qualified professionals, poor services quality and other growing problems in the population's access to health services. Great part of these difficulties comes from waste in services management and these represent a problem to be solved. Mapping the management processes is a priority involving the services provided by the sector. This paper aims to conduct a study on Lean Healthcare in a clinical laboratory in order to improve its processes management. As a result, it develops a discussion guided by practical results and difficulties from the point of view of concepts of human, quality and process optimization factors, emphasizing also the variable social system under study. Application steps are presented, such as value stream process mapping and improvement opportunities.

Keywords Lean healthcare · Quality management · Health services

1 Introduction

The increasing services demand in the health sector causes the considerable necessity for changes in the used systems, in order to implement quality process innovation, i.e. to attend the patient in time and in a proper place besides also

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reducing costs by elimination of waste and increasing efficiency. The Lean philosophy is a set of principles which uses tools aiming to provide the best care from the patient's point of view as well as consuming less resources during the process, recognizing the knowledge and skills of the employees who are responsible for carrying out the work.

The application of lean thinking concepts is relevant to the health area due to the contribution that this philosophy has given in its numerous applications in various sectors, providing also benefits to health services [1].

Considering the operations in health, it is necessary to challenge the following factors: customer expectations, increasingly demanding and their extended life expectancy. In the case of health, well-being and life that are at stake; Pressure for results and sales organizations; market pressures, in which the specialized centers and sometimes competitions emerge in the services provision; new technologies which imply rising costs.

From the point of view of the Lean application in health care, this philosophy, or rather, methodology, this paper proposes to organize operations seeking the increasing in the aggregated value to the client/patient, identifying the activities that add value and those do not, aiming to eliminate these and optimize those. The elimination of activities that do not add value and other wastes such as wasted materials, medicines unused and unnecessary delays, can help to establish a patient's value stream [1]. This flow includes the following research and clinical decision, treatment and release of the patient, allowing this patient to pass through without interruption, detours, returns or delays. Thus, the use of lean healthcare can improve the quality of operations and improve service efficiency and service delivery in health.

Thus, in this work were applied the healthcare lean concepts on a case study in a clinical laboratory facility, demonstrating the concepts of value stream mapping and process optimization. In addition, it has also proposed other challenges, such as to identify ways to reduce waste along the process and increase the overall efficiency of the laboratory, seeking direct and participatory actions of the researcher, conducting scientific researches in a real empirical problem and presenting the structured development of a study concerning the clinical analyzes process. From the collected data, actions are presented which ones can be implemented and tested, improving the quality of patient's care.

2 Lean Healthcare

Lean is a work philosophy applied to management of process that seeks the best way to run and organize several areas such as product development, supply chain, between business and customer relationships, besides production operations in which it is possible to do more with less (cost, processes, effort, equipment, time and space), and also approaching the increasing of the ability to offer customers exactly what they want. [2] Lean healthcare is a philosophy based on the concepts

of lean production, applied to health what make possible to improve the way health services are organized and managed [3].

Lean Concept was created in a study conducted in Massachusetts Institute of Technology (MIT) in the 80s which has driven to the book "The machine that changed the world" [4]. In this work, the authors performed a comparison between the mass production system and the Toyota production system in the automotive industry in the twentieth century, highlighting the features and benefits of lean production, lean manufacturing and JIT—Just in Time [5].

The JIT can be characterized as a set of principles, tools and techniques that allow the company to produce and deliver products in small quantities with short lead times in order to meet customer needs. As in manufacturing, lean healthcare is directly linked to the necessity to manage organizational change aiming offer more efficient processes and better quality services to patients. The use of lean tools is essential to provide a lean laboratory.

Several studies discuss the implementation of lean healthcare in the company Mayo Medical Laboratories. The value stream map was applied and then the lean tools (leveling work, visual management, poka-yokes, continuous flow, work standards) in order to design the future situation by conducting kaizen's [6]. As a result, researchers have reduced errors in the tests, improved operational management, what made possible the reduction in preparation time to perform the tests, increasing customer satisfaction and employees.

The Saint Marys Hospital (USA) with the application of lean tools has obtained 13 % of increasing in productivity, a 50 % reduction of demand variation and considerable increasing in employee satisfaction [7].

This conceptual framework is essential and requires the knowledge of the system details and its application to then support its replication in other companies. The Lean thinking is a management strategy to identify and eliminate waste in order to reduce costs and increase productivity in pursuit of operational excellence. It is based on the following principles: Specification of the value: the value can only be defined by the consumer and it is necessary for companies which want to stay in business; Identification of the flow of values: they are composed by all the actions necessary to deliver the final product or service to the customer and must be separated in value-adding, non-value-adding although necessary, and non-value-adding at all; Flow: arrange the steps to generate value in order to they come to happen in flow, eliminating fragmentation processes and ensuring that there is a continuous flow from the source point to the consumer; Pull production: customers are who "pull" the product, eliminating stocks and adding value to it; product sold, manufactured product; and Perfection: continuously seek improvements in the process to save time, space, cost and errors; continuously creating new forms of value [8].

2.1 Waste According to Lean

The activities of a company can be classified in value-adding (VA): activities that make the product or service more valuable to the client; activities that are necessary activities but are non-value-adding (NNVA): activities that do not make the product or service more valuable to the end customer eyes, but that are necessary for business—these are classified as type 1; And activities that do not add value (NVA): activities that do not make the product or service more valuable to the customer and are not necessary but even in the current circumstances—these are classified as type 2 [9].

The main objective is therefore increase the efficiency of production through the complete elimination of waste [10] considering all kinds of waste—time, cost, labor—those which do not add value from the customer point of view. Seven process created wastes are related bellow. These are improvement targets of lean thinking. They are the following: Overproduction: When producing too much, or before of scheduled, resulting in poor flow, unnecessary information or excess inventory; Delay: Are the long periods of inactivity (people, parts and information), which results in poor flow, as well as long delivery times (lead times); Excessive Transport: When excessive movement (people, information or parts) results in loss of time, energy and capital; Inadequate Processes: When the wrong quantities of tools, methods, systems and procedures are applied, usually when other simpler form could be more effective; Unnecessary Inventory: Excess storage and lack of information or products, resulting in excessive costs and poor performance; Unnecessary Movement: The disorganization of the working environment resulting in poor performance which may lead to problems of losses and also to health and safety issues of the operators; Defective Products: common problems in processes, quality problems of the product or service, resulting in a poor performance in the delivery to the customer. [11]

In addition, there is an eighth type of waste, which is waste of human potential [12], when the institution does not value the ideas of employees on improvements [13]. The motivation often leads employees to devote themselves even more to the work, which helps in the process of actions implementation, because the goal is always to improve the service of the patient's point of view [14].

Aiming to achieve the Toyota Production System goal, which is the elimination or reduction of waste, several lean tools can be used by organizations on different levels to ensure compliance and sustainability to lean programs such as: 5S, A3, Kaizen, Cell Layout, Flow Map value, Pokka-yoke, Standardized Work [15].

2.2 Application in Laboratories

The Laboratory and Diagnostic Medicine is considered as a specialty in the complementary health which is responsible for conducting clinical and/or image

analysis, supporting the positive or negative diagnosis of diseases. The practices of this sector must have high quality, but due to the necessary technological advances, these have a high overall cost throughout the process, not always followed by the increase in profit [16].

The request of a medical exam is appropriate when it is effective and clearly answer introductory diagnostic issues of the medical professional. In this request, it is also considered by the doctor the cost/benefit to the population requesting, or if the test will benefit diagnosis, prognosis, treatment, and whether is affordable by the patient. An incorrect diagnosis may trigger an increase in medical visits and laboratory tests and imaging, further increasing the cost of health services [17]. This has demanded the quality procedures implementation in these services as mandatory requirement, which consists in a detailed analysis of the processes involved in conducting a laboratory examination, including all aspects.

The exams implementation steps are divided classically in three phases: pre-analytical, analytical and post-analytical. It is estimated within 46 and 68 % the percentage of laboratory errors related to problems that occurred during the pre-analytical phase [18]. The observed errors in the pre-analytical phase are: misidentification, sample collected erroneously or with insufficient volume and improper condition of transport and storage [19]. Other examples consist in errors during the initial registry (misidentification of the patient or of the medic and error in the registering of the exams); requested samples and not collected; failures in the collection (wrong collecting tube, hemolysis, clotted samples and inadequate ratio of blood/anticoagulant); problems in the transport of samples.

According to the author, the difficulty of reporting the errors of the analytical phase occurs due to the difficulty of observing them, since about 75 % of them results in values in the reference range and 12.5 % produces totally inconsistent results, which are promptly corrected. Thus, 12.5 % is the range of errors that may affect patient care.

The post-analytical phase also involves the validation and release of reports. It expires after the doctor receives the final report, followed by interpretation and decision-making from the outcome [20]. Errors often associated with this step correspond to the failure in the release of the results by typing or transcription errors or failure in observing the deadline.

The technology development, especially in the information applied to this sector has contributed to decrease the errors involving results transcriptions [21]. The identification of samples using labels and/or bar code also improved the quality of information and the consequent reduction of errors [22]. The total time of releasing results is also very important, especially for exams whose releasing time influences the doctor's decision or when there are critical results to be communicated quickly. Errors at this stage of the laboratory cycle embraces around 18–47 % [23].

In some specific types of laboratories, it was noted that increase productivity and decrease of the results delivery time are possible by the use of some Lean tools [24]. The great challenge of laboratories is then to understand the methodology and implementing it correctly, according to their needs. A laboratory which uses the

Lean concepts may be able to respond to changing priorities and needs, efficiently and effectively.

3 Research

3.1 Applied Methodology

The type of research used in this work is the case study. The case study includes an empirical study, investigating a current phenomenon in the real context, considering that the boundaries between the phenomenon and the context in which it operates are not clearly defined [25]. Among the main existing benefits is the possibility of developing new theories and enhance the current understanding of the events. Thus, the working steps are: look in the literature about the concepts of this work, in this case the quality management in health and lean healthcare, outlining the proposals that will be addressed in the study; event planning, which is composed by selecting the research unit (clinical laboratory) and choosing the means for data collection; Research-relevant information filtering and analysis before inserting them into the work data.

Applying the concepts of lean healthcare on a health organization to establish the concepts of value stream mapping, improve processes and, consequently, the services rates of the research institution.

3.2 Research Site

The laboratory chosen for the field research works in the health sector, with emphasis on Clinical Pathology and Pathological Anatomy. It is located in Sao Paulo State, comprising a central unit of clinical analysis and collection linked stations. It provides laboratory testing services for Clinical Pathology and Pathological Anatomy to medical insurance, companies, medical and dental clinics, industries, hospitals and municipalities, as well as to private customers. Besides, the laboratory also conducts home collection and collections in clinics and companies. The results are delivered in laboratory units network or on Internet and differentiated service in childcare.

The services activities are carried out with a set of core processes and support processes as macro activity flow. The laboratory provides qualified human resources, specific information in the computerized system, work instructions and training to ensure the quality of the product/service at all stages of the process. The necessary instructions for the completion of the main processes involving the provided service are organized as:

3.2.1 Pre-analytical Phase

- Customer Service Process (reception/collection/transport and sorting): The laboratory works with qualified staff to the function and carries out periodic training in work instructions for each stage and trains the staff, in order to ensure the required quality in the pre-analytical phase. Main planned actions:
  - Reception: The customer is served personally or by phone. The computer program used by the laboratory provides the necessary information to customers, receptionists and collectors. More complex instructions are available in printed form as clear guidelines for customers. In the case of additional guidance to technical or administrative areas there is always a professional available. In the case of third party testing laboratories support for collecting, shipping and storage, other instructions are available for consultation on the online laboratory site. The TST (total service time) is monitored. The client document with photo is required at the registration act to ensure correct identification. The register provides all the necessary items as regulatory requirement. It meets the requirements of the requested analysis and traceability of the process at different stages. The customer at the end of the registering receives a protocol with necessary data that evidences the service.
  - Collection: trained staff performs the collection, after customer identity verification and checking of tubes and collectors in relation to their identity. The requirement of "preparation" for the collection is assured before the registration by the receptionists to ensure analytical quality. Anomalous cases are registered. For external source collections, the laboratory provides guidance and training, where required or requested. Samples are as far as possible, collected and identified on primary tubes with bar code.
  - Transport: The vehicles and professionals who collect samples from households and companies follow a standard identification. Through the procedures, the stability and integrity control of the samples are guaranteed through the temperature control of the storage containers.
  - Triage: The samples are checked and verified in the requirements of stage history (reception and collection). Aliquots of samples sent to the laboratory support are, when possible, properly stored until the completion of the analysis, thus preventing possible failures. The transfer of samples to support laboratories, when possible, is interfaced between laboratories, thus ensuring data integrity.

3.2.2 Analytical Phase

- Analysis Processes: Analyses are performed following Standard Operating Procedure as well as manufacturer's labeling guidelines preferably. In the case of equipment exchange, out-of-date methods or other complications that can

affect the outcome, such as system failure, interruption of analytical round is held the manually validation of the procedure. The results are interfaced or entered according to the brute data, by the analysis executor or routed to the Reports Editing Sector for typing. The Technical Director supports the decision-making actions in analysis performing and search needed external support with other laboratories or competent departments. In the case of changes in analytical procedures that result in changes in results or in clinical interpretation, customers are notified in advance personally or through the examination report.

3.2.3 Post-analytical Phase

- Issuance Process and Delivery of Reports: The procedures of the reports are reviewed, signed and released with electronic password by enabled expert who is assigned the role and is immediately available on a specific program and on the Internet, unless for blocked exams delivered only in the laboratory. The report contains the necessary items such as identification of the patient and the laboratory; Technical director; sample and its particularities; the test results and their measurement units; the reference values; interpretation of data where appropriate and others. Reports issued by support laboratory, when appropriate, are transcribed on the same computerized program of the requester and it is described the laboratory that has performed the analysis. The reliability of the transcripts or reports sent from support laboratory by computerized means, via laboratory program is provided by the expert before the report's release.
- Delivery method: The delivery of the report is performed by the receptionists. Other forms of delivery are carried out: delivery in companies, hospitals and clinics by staff of transport sector; by Internet; via fax to hospitals or prior agreement, for other clients; e-mail, mail, only with prior agreement with customers.
- Post Delivery: The laboratory maintains customer approach for report's post-delivery communication. In the case of detection of non-compliance in the report, after delivery, it is removed from the Internet, fixed by the expert, preferably by the same that released the mistaken report. Then the details of the complication are recorded in the historical data.

The lab monitors monthly information relating to customer's perception about their requirements, from the following sources: customer survey, including suggestions, complaints, compliments; customer complaints by phone, website or reports of employees; number of delays in the delivery of results; number of results released after the deadline; number of new collections for non-compliance; customer service time.

The customer satisfaction survey is planned for every two years. The data collected by the records above, entries as indicators. They are reviewed, leading, where necessary, to corrective or preventive actions seeking customer satisfaction.

The laboratory works in management of risk and client security in order to eliminate or minimize risks and comply with legal and regulatory requirements, through disseminated actions and trained those involved in laboratory activities. This action is reversed in operational benefits evidenced in documents such as work instructions, manuals and also in carrying out during educational campaigns as SIPAT (Work Accidents Prevention Internal Week Fair), training, guidance through communication channels.

3.3 Achieved Results

After understanding the process, it was necessary to build and analyze the Value Stream Mapping (VSM), and then to design a visualization of the improvements, the future process. The map, called the map of the current situation, portrays how is the value stream at first, in a first analysis.

The value stream is defined as a set of procedures needed to provide a product or service, covering from the supply of raw materials, manufacturing process and product delivery until customer satisfaction. It allows to identify how long each step of the process is completed and also facilitates the waste perception, especially when it comes from time, stock and handling.

During the VSM development, the necessary procedures in the process for the patient were initially modeled. It starts in the laboratory entrance, at reception, which leads to the waiting room, registration, authorization, and the room of blood collection. From this site, the patient is released from the laboratory and is advised to check the exam results online or return to the laboratory, after a certain time period. Although the analysis process has been monitored in place, actions to be initially implemented were presented to the laboratory senior management. This action encompass the customer service at the front desk, avoiding queues, long delays and reworks in the company's data system.

Then the VSM collaborated to identify possible problems encountered in these activities. The Appendix 1 shows the current VSM, especially the complications, according to the balloons which indicate problems (identifier number):

- *Pre-analytical Phase:* Inappropriate procedure: (1) The laboratory does not monitor the waiting time between getting the password and the first service by the receptionist; (2) Layout not well distributed, the reception that cannot stand the demand at peak times in contrast to the screening room underutilized with beyond necessary space; (3) System frequently out of the air; (4) release for the examination without authorization, causing delays in sending guides to health insurance. *Standby:* (5) Patient waiting time too long from his arriving to the moment to be called by the front desk service; (6) The reception has very small

space, which makes impossible the inclusion of more receptionists; (7) Idleness of the nurse who collects the sample due to the long time to complete the service at the reception, making it impossible the continuous flow process; (8) too long time for authorization of health insurance.

- *Analysis phase:* Rework/Defects: (9) Repeat tests with considerable frequency due to lack of standard of the repetition criteria.
- *Post-analytical Phase*: Inappropriate Process: (10) Errors in the delivery of the report due to exchange of patients' last names. It happens when the receptionist does not confirm the registration data.

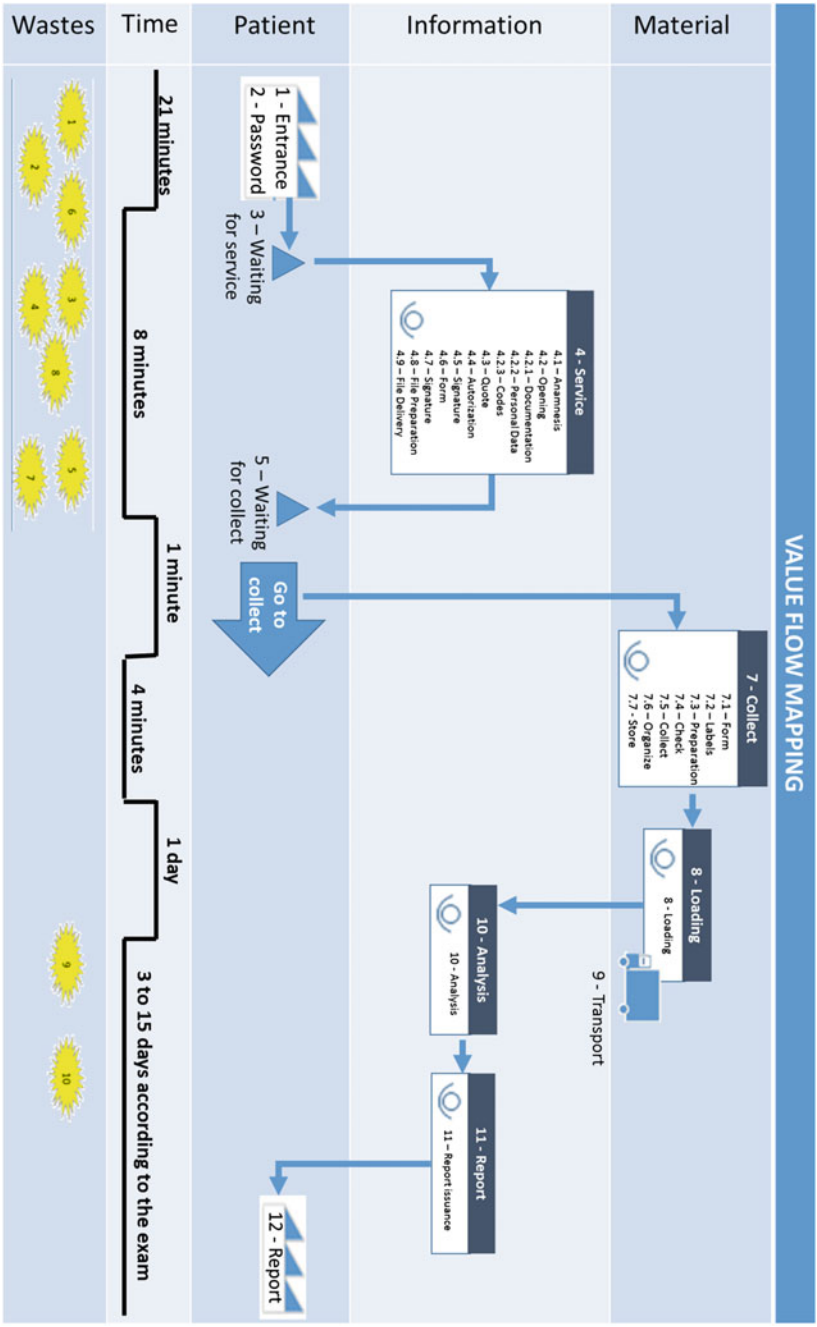
It is notable that from the monitoring of the process and subsequent time study, there are waste that significantly increase the time of the process as a whole. The waiting time at the reception was the main problem found by this study.

Using this information, the Improvement Plan was prepared as future value. It contains most changes that would optimize the processes: (1) Insert the time monitoring between getting password to the time of the first service by the receptionist; (2), (6) Change of lay out with new distribution of physical and functional capacity of the space; (3) find ways to improve the connection system with the supplier; (4) Standardization of release procedure for conducting examinations; (5) Levelling of reception workforce; (7) The improvements of previous steps to reduce nurse idle time; (8) Implement a support desk software to enable a pre-authorization; (9) Standardization of rework procedure; (10) Registration data confirmation at patient entry and at the time of report delivering.

4 Conclusion

During the development of the research, the importance of the value stream mapping utilization could be proved as well as the application of lean principles in the processes of the studied organization. The utilization of this philosophy would make possible an increase in added value in a future scenario to their services, reducing or eliminating waste in processes and increasing customer satisfaction, mainly by reducing the waiting time, which is extremely important when considering this branch. Thus, the aims of this work were achieved, considering it was allowed to study and apply the Lean concepts and to propound improvements from the identification of the application area, process monitoring and building of current value stream mappings. The suggestion of implementation of the project was presented to laboratory managers, who want to implement it in a close period, thus improving service quality to its customers.

Appendix: Value Stream Mapping Current Scenario



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Virtual Communities of Practice Success in Healthcare Sector: A Comparative Review

Haitham Alali

Abstract Many organizations including health care sector, have failed to attain the expected benefits from the knowledge management (KM) initiatives or projects. One of the KM initiatives in health care sector is virtual communities of practice (VCoPs), where practitioners conduct discussions and share experience online. Presently, there is no accepted or overall conceptual framework that addresses the important aspects of effective KM in a way to assist specifically the virtual communities in KM, reflecting the need to review the literature pertaining the VCoPs measurement in order to extract the main taxonomy from the literature. The review shows that research on VCoPs should take into account technical, social, semantic, human, and effectiveness dimensions in measuring the VCoPs success.

Keywords Virtual communities of practice · Success dimensions · Literature review · Leximancer · Healthcare · Knowledge management

1 Introduction and Background

Health care sector is vital component of any society in the world. Health care sector has many challenges in learning context, related to geographical distance and high cost of learning which represent the need for effective knowledge management (KM) initiatives to develop health practitioners' knowledge, instead of traditional and costly learning channels such as face-to-face learning. Realizing the need for effective KM initiatives, health care policy makers should provide suitable environment in order to enhance professionals' knowledge depending on updated health researches and professionals evidence-based practices. Consequently, the health care policy makers should implement successful knowledge management system (KMS) in order to improve health services quality and universal convergence. On

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the other hand, there remain recurrent concerns regarding the adequacy of knowledge resources and the way they are currently used.

Many researchers have claimed that managing knowledge through the organization has an enabling role to play in reducing operations costs and building a learning organization [1]. Those managing the knowledge functions in health care sector have not ignored such advice, and widespread use of KMS has occurred [2]. Yet, few organizations systematically attempt to measure the effectiveness of their information system (IS), or even know how to do so [3]. Consequently, KMS managers as well as IS researchers are stressing the need to better understand the factors that contribute to the success or otherwise of KM [4].

Teece [5] suggested that achieving the organizational overall objectives depends on their ability to create, transfer, utilize, knowledge. For this reason, many health care organizations are putting their organizational knowledge as the most important priority [6]. Unfortunately, several research undertaken revealed that many organizations have failed to attain the expected benefits from the KM initiatives or projects [2, 7, 8].

One of the KM initiatives in health care sector is virtual communities of practice (VCoPs). The virtual community of practice is new strong interactive channel that emerged in the last years in order to support all the characteristics to be used as a KMS, and as an enabler of knowledge creation, sharing, and utilization. According to Wenger and Snyder [9], VCoP is all about managing knowledge through capturing and sharing of members' expertise, spreading know-how, ideas, problems, innovations, talents, and experiences. They are held together by a common purpose and a need to know what the others know. VCoP is pushing medical practice into information supported, patient-centered and just-in time knowledge sharing environment. Moreover, VCoPs supports both synchronous and asynchronous communication [10].

VCoP offers unprecedented capacities and potentials for knowledge management. The enabling role of VCoP in support of knowledge management initiatives is generally accepted by both researchers and practitioners in the area of KM. However, some researchers and practitioners question the effectiveness of this contribution owing to the well-publicized failure of numerous KM initiatives [2, 11]. On the other hand, demand for useful measures for assessing the overall benefits of IS investments has long been acknowledged [3, 12, 13]. It is based on this background that this research will be discussed. The purpose of the literature review is to identify the most critical dimensions that constitute towards the success of VCoPs. This study extracted a theory based measures for the main concepts that were adopted by earlier research in measuring the VCoPs success.

2 The Concept, Nature, and Use of VCoPs

In recent years, knowledge has been increasingly recognized as one of the most important assets of organizations [5, 14, 15]. According to Davenport and Prusak [16: 5]:

> Knowledge is a fluid mix of framed experience, values, contextual information, and expert insight that provides a framework for evaluating and incorporating new experiences and information; it originates and is applied in the minds of the knower. In organizations, it often becomes embedded not only in documents or repositories, but also in organizational routines, processes, practices, and norms.

Research should explore the initiatives as to how organizations can manage what knowledge workers know and how their existing knowledge can be disseminated, transferred and shared to other individuals. KM is considered as a systematic process of managing knowledge assets, processes, and environment to facilitate the creation, organizing, sharing, utilization, and measurement of knowledge to achieve the strategic aims of an organization [7, 17, 18].

Poynard and his colleagues conducted a study on scientific evidences about cirrhosis and hepatitis in adults and they found 285 of 474 conclusions of original articles and meta-analysis published from 1945 to 1999. The study showed that only 60 % were still considered to be true medical practices, 19 % were considered to be obsolete medical practices, and 21 % were considered to be false medical practices about cirrhosis or hepatitis in adults [19]. Furthermore, the World Health Organization (WHO) mentioned in many reports and conferences, the failure of health organizations and professionals to translate research knowledge into action (Know-Do gap) in health care practices [20].

One of the key components of KM is the communities of practice (CoPs). The concept of CoPs has become increasingly apparent in the policy directives for healthcare continuing professional development and learning [21]. According to Lave and Wenger [22], CoPs consist of experts in specific area, with a common interest who interact to share skills and knowledge to solve problems in their area of expertise. The rapid diffusion of internet, growing internationalization of business, and distributed international environment generate technological and motivational bases for CoPs which takes the CoPs in virtual setting. VCoP is an emergent form of online collaboration and communication that utilize network and communication technologies which allow individuals to communicate and stay connected, even though they are separated by space and time i.e., geographic location and time zone [10, 23].

The WHO, National Health and Medical Research Council (NHMRC) and many other international health organizations have deployed global knowledge networks through using VCoPs in order to ensure that all people everywhere shall have an access to professional health workers' knowledge. Moreover, the updated knowledge and best practices through VCoPs could enhance health practitioners' knowledge at global level [24].

The purpose of focusing on VCoPs is to invite greater inquiring into such approach of knowledge management in the health care sector. There are also attempts to measure such KM initiatives success, to create, transfer, and utilize knowledge more effectively [25]. As a result, long-standing difficulties were encountered by many health systems in attracting or retaining trained staff, and the distances between professionals. Hence, new KM initiatives have emerged in some systems in order to increase knowledge creation and sharing among experts and practitioners. On this realization, the researchers propose VCoPs as the knowledge management system that will be linking new practitioners with other health professionals to explore and discuss topics of interest, share knowledge and best practices, as well as identify and address common health problems [22, 26]. Ultimately, VCoP is seen as a method of increasing knowledge capital for all urban and rural health care practitioners, which reflect the urgent need to address the main success factors that might sustain and enhance the VCoPs success [27, 28].

3 Method

In order to get a comprehensive review of the literature pertaining to VCoPs success, we searched the cited research from health informatics, information systems, and social science, databases including Pub Med, Science direct, Springer Link, Emerald, ProQuest, Wiley, Sage, EBSCO, Taylor, and the ACM. A total of 349 empirical studies are downloaded and categorized into health and general subsets, of which 88 studies remained after removing those are found to be irrelevant to the measurement of VCoPs, and studies that have not adopted the CoPs in virtual setting, and these were categorized as 23 studies related to health care VCoPs and 65 studies related to other domains.

The analysis of these studies conducted in two phases. In the first phase, the remaining 88 articles were employed to the Leximancer software. The Leximancer (Lexi-Portal Version 4) is a data mining tool used for qualitative data analysis and automatic extraction of the main concepts. The Leximancer offers a base for objective, unbiased and automatic discovery of the concepts. However, the abstracts of all 88 articles were employed to the software to disclose the key concept and themes. In the second phase, the main themes were further refined by applying deep content analysis for studies that were highly appreciated in the topic area. Twenty five empirical studies were randomly selected from the 88 articles to apply content analysis to extract and synthesis the main concepts/dimensions, theories, and research methods that were applied to measure the VCoPs success. Furthermore, the result from analysis was summarized and coded. The descriptive analysis was derived by using cross tabulation and simple descriptive analysis revealed by SPSS 12.0 software.

4 The Results

4.1 Content Analysis

Results illustrate the key concepts yielded from the content analysis of the 88 research papers. The number of times the concept was used in the paper is also included in the table. The information in the table indicates the frequency of the occurrences of the concept in literature. The relation between the concepts and the samples of this research is clearly established in the table. The thematic map of the literature was generated based on the Leximancer review (Fig. 1 for health literature and Fig. 2 for non health literature). The circles in the map indicate the theme and the dots indicate the concept.

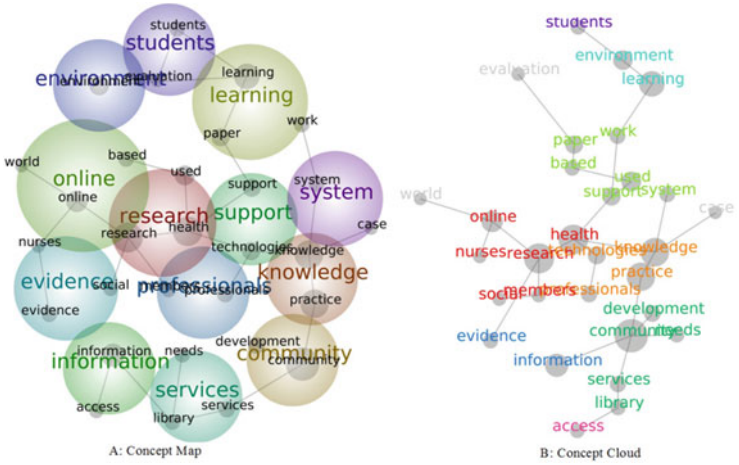

Fig. 1 Map of key themes and concepts in health literature on VCoPs success

Fig. 2 Map of key themes and concepts in non-health literature on VCoPs success

The data in the table and map recognize the central themes and concepts in the literature. The VCoPs literature in health care setting mainly adopted four themes: learning, research, online, and the evidence theme. However, the learning theme has intersection with students theme which reflects the relation between learning and the students, while the research, support, and professionals themes have intersection with each other. Moreover, the online, evidence, and research themes have intersection with each other which might indicate the role of web-based technologies to support the evidence-based practices mainly from nurse's perspective.

Health literature mostly assesses VCoPs in technical dimension which reflect their adoption of technical concepts such as: technologies, system, and access to the Internet. The social dimension as a second dimension, focusing on the community itself with its social relations. The human dimension focused on the interaction between students and professionals during the learning process and skills development. In addition, the semantic dimension exists by focusing on the knowledge including information and research resources availability as well as knowledge quality via sharing the evidence-based practices. The effectiveness dimension within health literature has not fully studied while the majority of the studies were descriptive research as shown in Table 2.

On the other hand, the non-health literature is more inclusive in measuring the VCoPs. However, it has revealed seven themes such as: research, knowledge, learning, implications, practice, social, and management themes. The social, behavior, and knowledge themes are interlinked with each other, while the management theme is intersect with practice and research themes but it does not join with other themes including social, learning, and knowledge themes which may reflect that the majority of successful VCoPs are stand-alone communities and not managed by organizations.

The social and semantic dimensions are the most studied aspects within non-health literature. The social dimension particularly focuses on interpersonal trust and social capital through knowledge sharing behavior. However, the semantic dimension mainly focuses on the knowledge and information characteristics during online learning process. The technical dimension is represented by the facilitating role of information technology with virtual context of CoPs. In addition, the effectiveness dimension is studied explicitly within non-health literature; particularly by focusing on the usage efficiency and the outcomes advantages from VCoPs mainly in organizational context.

Briefly, the literature of VCoPs within healthcare setting have paid more attention to the learning process for the staff and professionals via the social environment and technology as enabler, in order to increase the level of professionalism. The findings reflected that research on VCoPs should take into account technical, social, semantic, human, and effectiveness dimensions which makes balance between health and non-health research in measuring the VCoPs. Further analysis will be provided in the next section to compare between health and non-health literature and provide evidence on the main taxonomy of VCoPs success and acceptance.

4.2 Literature Review

As mentioned above, twenty-five studies were selected to be analyzed. In choosing, 23 articles from cited journals were surveyed in this study. In addition the ICIS and ACM Proceedings were added to the listed journals for their contribution in the VCoPs measurement research. Both of Tables 1 and 2 represent the list of the selected studies according to their authors and publication year. The sample separated into general (non-health) and health subsets; the largely studies from general subset (14 out of 25, 56 %); where health care subset studies are (11 out of 25, 44 %). The content analysis was conducted for all studies and the main concepts, dimensions, theories, and methodologies are extracted and presented in the following section.

Table 1 Selected non-health VCoPs studies: aspects of VcoPs

Author and year	Theory base	Approach	T	So	Se	H	E
Vavasseur and MacGregor (2008)	Professional development model that is situated in a community of practice	Mixed-method comparative case study/quantitative and qualitative approaches	✓	✓	✓	✓	
Zhang and Watts (2003)	Dual-process theories of information processing	Qualitative		✓	✓	✓	✓
Dubé et al. (2005)	–	Action research/qualitative	✓	✓	✓	✓	
Ackerman (1998)	–	Qualitative	✓	✓	✓	✓	✓
Rosenbaum and Shachaf (2010)	Integrate structuration theory, communities of practice framework	Case study/descriptive	✓	✓	✓	✓	
Fang and Chiu (2010)	Integrate three research streams—justice, trust, and organizational citizenship behaviors	Quantitative/survey		✓	✓	✓	✓
Yu et al. (2010)	–	Quantitative/survey		✓	✓	✓	✓

(continued)

Table 1 (continued)

Author and year	Theory base	Approach	T	So	Se	H	E
Lin et al. (2009) [38]	Social cognitive theory (SCT)	Quantitative/survey	✓	✓		✓	✓
Yang and Lai (2010) [39]	Motivation theory	Quantitative/survey		✓		✓	✓
Chiu et al. (2006) [40]	Integrate the social cognitive theory and the social capital theory	Quantitative/survey		✓	✓	✓	✓
Wasko et al. (2009) [41]	Social network theory	Quantitative and qualitative/questionnaire and massages content analysis		✓	✓	✓	✓
Urbach et al. (2010) [42]	D&M IS success model/IS success theories	Quantitative/survey	✓	✓	✓	✓	✓
Chen and Hung (2010) [43]	Social cognitive theory	Quantitative/online survey	✓	✓		✓	✓
Kuo et al. (2003) [44]	Theory of planned behavior	Quantitative/online survey	✓	✓		✓	✓

T technical, *So* social, *Se* semantic, *H* human, *E* effectiveness

The main dimensions yielded by the content analysis of the selected empirical studies were used in VCoPs measurement. The data in Tables 1 and 2 identify the central concepts, themes, theory base, and methodology in the literature. However, the main were classified into five main dimensions; technical, social, semantic, human, and effectiveness dimensions.

The main dimensions were extracted particularly focusing on; Social & Cultural dimension was applied in (21 out of 25, 84 %); followed by Human and effectiveness, both dimensions were applied in (20 out of 25, 80 %); Semantic dimension was applied in (18 out of 25, 72 %); and The Technical dimension applied in (17 out of 25, 68 %). However, all non-health studies applied the human dimension in their studies, but only 54 % (6 out of 11) within health studies, on the other hand all non-health studies applied social dimension, where only 63.6 % (7 out of 11) of health studies.

The review shows that 71.4 % (10 out of 14) of the non-health studies applied the semantic dimension which approximately similar to 72 % (8 out of 11) within health studies. Nevertheless, the majority of health studies as 81.8 % (9 out of 11) adopted the technical dimension, where only 57.1 % (8 out of 14) of non-health studies adopted this dimension.

Table 2 Selected health VCoPs studies: aspects of VCoPs

Author and year	Theory base	Approach	T	So	Se	H	E
Booth et al. (2003) [45]	–	Descriptive	✓		✓	✓	✓
Russell et al. (2004)	Ba model	Qualitative analysis/focus groups		✓	✓		✓
Armstrong and Kendall (2010)	Knowledge translation theory	Descriptive	✓	✓		✓	✓
Ho et al. (2010)	Wenger's CoPs framework	Descriptive	✓	✓		✓	✓
Brooks and Scott (2006b) [46]	Knowledge management theory	Qualitative/case study	✓		✓		✓
Clarke et al. (2005) [47]	–	Case study	✓	✓			✓
Brooks and Scott (2006a) [48]	Knowledge work theory	Qualitative/case study	✓	✓	✓	✓	✓
(Bertulis and Cheeseborough 2008)	–	Quantitative/Survey	✓	✓	✓	✓	
Docherty et al. (2005) [49]		Qualitative and quantitative	✓		✓	✓	✓
Stergiou et al. (2009)	Constructivist learning theory	Triangulation; (qualitative; questionnaire and quantitative; interview)	✓		✓		✓
Beer et al. (2005) [50]	–	Qualitative		✓	✓		

T technical, *So* social, *Se* semantic, *H* human, *E* effectiveness

Both health and non-health subsets studied the effectiveness dimension as 78.6 % (11 out of 14) for non-health studies and 81.8 % (9 out of 11) within health studies. However, the majority of research conducted within health care setting is qualitative research; only 1 study out of 11 is adopted quantitative research approach and 2 studies adopted mixed approach (quantitative and qualitative), unlike the non-health studies 8 out of 14 of studies have used the quantitative approach and 2 have used mixed method. While the non-health studies appear more relay on theoretical bases 78.6 % (11 out of 14) compare with the health studies 54.5 % (6 out of 11) only based on theories. Also research pertaining to VCoPs within health care context has no consensus on specific theories; research adopted diversity of theories as shown in Table 2 Russell et al. [29] adopted Ba model; Ho et al. [30] adopted Wenger's CoPs framework; Armstrong and Kendall [31] knowledge translation theory; and Stergiou et al. [32] adopted constructivist learning theory.

5 Discussion

In knowledge management research, success is defined as the improvement in organizational effectiveness that comes from reusing knowledge by providing the correct knowledge at the right time [33]. On the other hand, the knowledge management system success is defined as the impact of employment of KMS components effectively to increase or encourage the effective use of a knowledge management system [33]. The effective implementation of KMS processes and improvement in its usage will be reflected on KM success. KMS success in term of CoPs can be measured by various methods including achieving objectives of the CoPs and learning enrichment [34, 35].

The success of VCoPs is determined by measuring two levels. Firstly, measuring the effectiveness of knowledge creation, codification, sharing and use processes. This level can be achieved by determining the factors that affect KM processes in terms of VCoPs. This study argues that success factors for KM processes are a joint between technical, semantic, human, and social dimensions and their effectiveness in managing the knowledge within the VCoPs.

The technical and semantic dimensions in terms of perceived usefulness, perceived ease of use, system quality, knowledge content quality, and service quality [3]. Furthermore, the social and human factors are embedded in human behavior context in terms of attitude, subjective norms, perceived behavior control, motivations of individuals, knowledge sharing culture, trust, and leadership of health care practitioners.

Secondly, measuring the effectiveness of VCoPs can be achieved through measuring the output and value of KM processes. According to [36], KMS outcomes are mainly measured by financial evidence for example return on investment, return on asset, and performance indicators; such as organizational effectiveness and productivity [36]. Paying attention on the previous tangible outcomes help executives in order to justify an investment of millions of dollars in KM initiatives [25]. Furthermore, it is difficult to investigate KMS intangible outcomes such as skills of practitioners, best practices, commitment, intellectual property, and reputation. Nevertheless, many organizations currently considered the intangible outcomes that lead to achieving the competitive advantage. Thus, in recent time, the interests of the researchers have shifted to measure intangible outcomes of the KMS [36].

According to Wenger et al. [25], there are several benefits of CoPs to the organization in term of improve business outcomes such as arena for problem solving, quick answers to questions, reduced time and costs, improved quality of decisions, more perspectives on problems, coordination, standardization and synergies across units, resources for implementing strategies and strengthened quality assurance. On the other hand, there are several benefits to community members in term of improving the experience such as help with challenges, access to expertise, better able to contribute to the team, confidence in one's approach to problems, the fun of being with colleagues, more meaningful participation, and a sense of belonging [37].

6 Conclusion and Future Research

Currently, researches on the effectiveness and success of VCoPs in several areas including health care sector are limited. This research sheds light on the dimensions influencing the KM success in order to get adequate understanding and knowledge of factors that affect the success and effectiveness of VCoPs in the health care sector. The VCoPs concept is increasingly being considered and applied in empirical research in the health literature. This study summarized and synthesized the earlier studies pertaining to VCoPs measurement. The comparison between health and non-health literature regarding to the main dimensions were adopted in both subsets. However, health literature is sporadic, and numerous investigations are descriptive and centralized on one occupation or location. The generalisability of health research results is limited. Furthermore, the complexity with the research were conducted in health care context is due to the nature of descriptive studies. There is a need in the most of these studies for specificity in their claims, theory bases, and readability of developed instrument.

More empirical investigation within health care context is needed by integration between all dimensions that used and validated frequently in the literature in order to get the most comprehensive view to all measurements of the VCoPs success. The review shows that research on VCoPs mainly adopted technical, social, semantic, human, and effectiveness dimensions in measuring the VCoPs success. These dimensions need to be investigated through a preliminary study with health care practitioners and KM professionals in order to verify the validity of the dimensions found in the VCoPs literature.

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Overlook of Patient Time Log Entry Errors During Emergency Department Processes

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Abstract Patients visiting emergency departments need appropriate medical care on time from the point of arrival to discharge. Time logs are essential for keeping track of patient status during the visit. The accuracy of time logs is not supposed to be compromised to the speed of data entry. The objective of this study was to investigate how falsely patient time logs were entered during emergency department processes. Data omissions and false entries of time logs were considered to estimate the likelihood of data entry errors. Results showed that omission errors were occurred at the doctor's examination process and false entry errors at the registration process. The modality change of data entry from keying data to voice activated data entry would be a suggestion to reduce the false time log data entry at emergency department processes.

Keywords Emergency department · Time log · Omission error · False entry error

1 Introduction

Overcrowding in emergency departments (ED) have been issued continuously in the U.S. Many studies have reported negative effects of overcrowding patients in ED on quality of emergency care services [1–5]. The quality of healthcare in emergency departments depends on the effective management of ED resources and the integrity, reliability, and accuracy of patient medical information including patient time logs after arriving ED. One of the commitments that a hospital subjected to Emergency Medical Treatment Active Labor Act requirements must comply with is to keep a central log in hospital. Many hospitals have implemented electronic medical record systems by adopting health information technology. Most of studies [6–8] have focused on electronic health record systems that allow physicians to record patient medical data electronically rather than traditional paper

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data collection. The emergency of electronic health record systems have resulted in potential errors such as patient data being incorrectly entered, displayed, or transmitted. The risks associated potential errors can impact medical information integrity, quality of care, and safety of patients.

From the perspective of timely performing ED processes, it is essential to keep tracking patient time logs accurately during ED visits. However, working environments in ED are highly stressful and time intensive. Since keying in patient time logs accurately is much important than fast keying in under the peculiar circumstances of ED, errors of data entry is critical to quality and usefulness of electronic time logs. Inaccuracies of time logs at the roomed, examination, or discharge processes can put a patient early or late in a room or result in delay of transfer. In a worst case scenario, a physician may end up charting to a wrong patient. Or, there is a possibility that a new patient can be admitted to be placed in a room even though the current patient is still not discharged from the room. In order to prevent these kinds of mistakes from crowded emergency departments, the electronic time log system must catch up as hard as it can as to who's in the right place at the right time. Based on the author's knowledge, few studies on the keying errors of patient time logs in ED have been reported in the literature. The objective of this study was to investigate how correctly or falsely patient time logs were entered during the emergency department processes to evaluate the integrity of time records of medical care.

2 Methods

2.1 Patient Time Logs

An emergency department of a tertiary care teaching hospital in one county in North Carolina of the United States of America was selected to collect patient time log records. The ED had approximately 80,000 patient visits on average a year. The electronic time logs of patients during visits were recorded from arrival to discharge separated by six processes such as registration, triage, roomed, examination, discharge ordered, and discharge. Time logs for a year were examined. The annual time logs were recorded and kept for three month periods such as July 1 to September 30, October 1 to December 31, January 1 to March 31, and April 1 to June 30. The typical patient flow in this study was assumed (1) patient arrival the ED, (2) beginning a registration at admission desk, (3) being triaged by a nurse to determine the acuity level, (4) be roomed, (5) being examined by a physician, and (6) a discharge order is placed and patient being discharged. Electronic time logs were kept for the beginning and ending times of the ED processes except the roomed process. For instance, the registration process had the beginning time of registration and the ending time of that process. The roomed process had only the beginning time when patient actually roomed.

2.2 Time Log Entry Errors

Two types of time log entry errors such as omission errors and false entry errors were considered at the beginning and ending of each process. Omission errors were defined when there were no time logs for considered processes and false entry errors when time logs were not chronologically correct compared to time logs of the previous processes. For defining false entry errors, it was assumed that each patient's arrival was correct and set as a starting point of chronological event time horizon. A chronological comparison was used to check if time logs at the beginning and ending of each process were correct compared to the associated arrival time. If the beginning and ending times were correct, the ending time was compared to the beginning time. If it was chronological correct, it was counted as a correct time log for that event. Otherwise, it was considered false data entry error. For instance, a patient's registration beginning time was compared with the patient' arrival time to check the chronological order of the two events. If the registration beginning time was not later than the arrival time, it counted a false entry error. But, the false entry errors for registration ending time logs were examined by checking the correctness of registration ending time compared to the arrival time first. And then the correctness of registration ending time was checked by comparing it to the registration beginning time. The following examples of a patient's time logs for arrival time, registration begin time, and registration end time illustrate how to find false data entry errors.

For validating the registration begin time log, if we have

- arrival time: 8:00 am,
- registration begin time: 8:05 am,

the registration begin time log is correct.

If we have

- arrival time: 8:00 am,
- registration begin time: 7:45 am,

the registration begin time log is incorrect and it considers a false data entry error.

For validating the registration end time log, if we have

- arrival time: 8:00 am,
- registration begin time: 8:05 am,
- registration end time: 8:10 am,

first, the registration end time is validated with the arrival time and then the registration end time is validated with the begin time. The registration end time log is correct.

If we have

- arrival time: 8:00 am,
- registration begin time: 8:05 am,
- registration end time: 8:03 am,

the registration end time is validated compared to the arrival time. The registration end time is valid compared to the arrival time, but is not valid compared to the registration begin time. The registration end time log is a false entry error.

If we have

- arrival time: 8:00 am,
- registration begin time: 7:45 am,
- registration end time: 8:10 am,

the registration end time is valid compared to the arrival time and the registration begin time. The registration end time log is correct.

3 Results

The rates of omission errors, false entry errors, and correct data entries were summarized for each quarterly period over a year (Fig. 1).

The omission error rates were summarized for each process during each quarterly period over a year (Fig. 2).

The false entry error rates were summarized for each process during each quarterly period over a year (Fig. 3).

Analysis of variance was applied to test for equality of false data entry errors in different processes and quarterly periods. Table 1 shows the result.

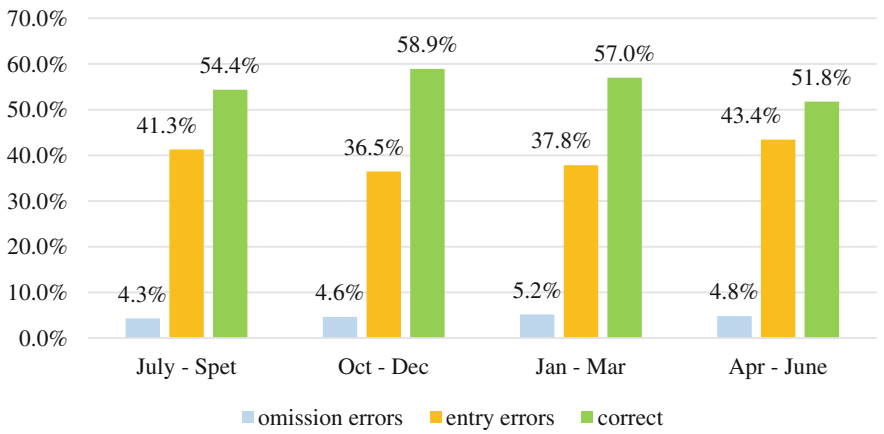

Fig. 1 Rates of omission errors, false entry errors, and correct entries for each quarterly period

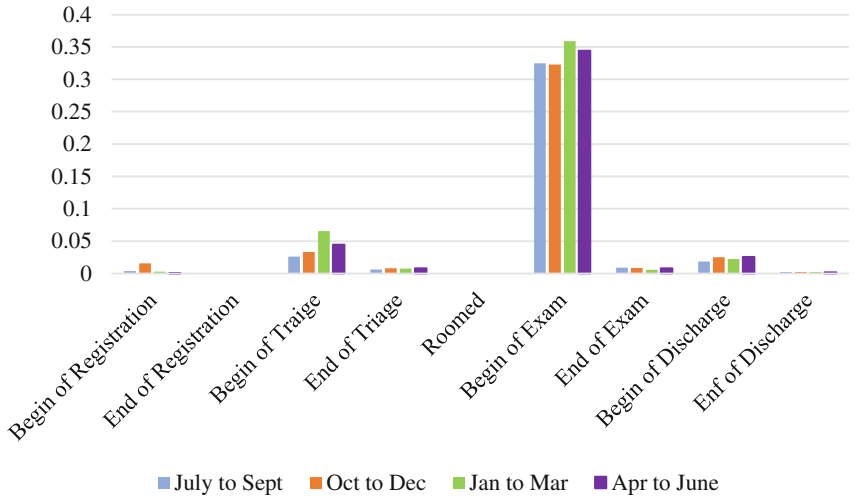

Fig. 2 Omission errors for each process during each quarterly period

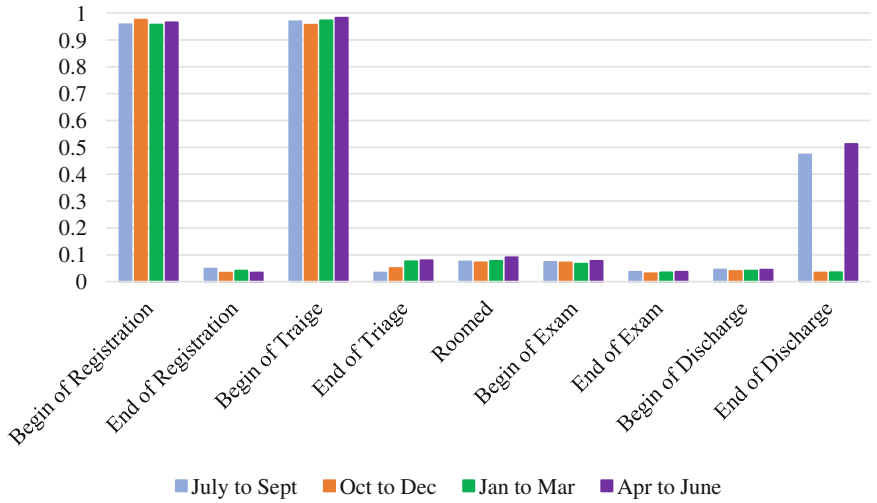

Fig. 3 False entry errors for each process during each quarterly period

Table 1 Analysis of variance for equality of false entry data errors in processes and periods*

Source	Sum of squares	Degrees of freedom	Mean square	F statistic	*P*-value
Processes	5.006	8	0.626	78.25	≈0
Periods	0.027	3	0.009	1.125	0.359
Error	0.187	24	0.008		
Total	5.220	35			

*Values were rounded to three decimal places

4 Discussions and Conclusions

The average rate of correct time log entry during the ED visit was less than 60 % for every quarter. The ED staffs were highly likely to forget to key in time logs at the points of triage and examination. The high omission rates at these two processes can be related to the characteristics of the processes such as urgency and time demand. When the ED staffs see patients in emergency first time, they may more focus on medical conditions of patients rather than managerial perspectives for patients. A significant difference of false data entry rate was found among the processes. The rates of false data entries were very high at the beginning of registration and triage. One of the possible reasons of the high rates was speculated that these first two processes would be more interrupt-driven steps due to patients flow-in. For the registration and triage processes, patients come to the resources for the service, which can be called a pushing system, while the resources of the rest of the processes come to patients, called a pulling system. When patients keep pushing into the registration and triage processes, more interruptions or breaks would be possible during the processes. A study [9] reported that a voice recognition data entry system would interrupt amount of workflow less than did the typed data entry. It would suggest that a voice recognition data entry system may reduce the rates of false data entries in Ed processes.

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Incentives for the Acceptance of Mobility Equipment by Elderly People on the Basis of the Kano Model: A Human Factors Perspective for Initial Contact with Healthcare Products

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Abstract Personal mobility, such as, for example, the ability to get up and sit down independently, decreases by age. In Germany, one out of ten people older than 75 years needs long-term care and thereby support in personal mobility. Within the age group of 80+ years this number increases even more. Personal immobility is one of the main reasons for the necessity of a caregiver. To improve older persons' independent mobility, supporting technical devices like walking sticks, walkers and wheel chairs established themselves. However, these devices can just be used after the patient gets up or sits down. For these special situations, technical solutions are also available. They are able to support a user even during situations in which he or she needs to be lifted. But they are not used frequently due to various reasons such as high costs and high stigmatization potential. In this

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study, the Kano model was used to analyze different customer requirements for initial contact with such a technical mobility aid. Investigated requirements were, for example, design, acceptance of mobility aids' sharing solutions, usability and usage sites of such aids. The study revealed individual design to be an attractive customer requirement whereas a pooling solution and hence sharing the mobility aid leads to a decreased customer value. All in all, this study stresses customers' acceptance of mobility aids and identifies several customer requirements for a positive initial contact.

Keywords Acceptance · Elderly · Human factors · Incentives · Initial contact · Kano model · Mobility equipment

1 Introduction

The performance and independence of people are both characterized by individual differences and intraindividual changes through life, occurring during the process of aging, illnesses or accidents. With regard to the musculoskeletal system, these changes may cause temporary or permanent limitations in terms of personal mobility (e.g. to get up and walk), resulting in an individual's need for support. This demand for compensation of limitations is mostly covered by caregivers or supporting techniques. Technical devices support independent mobility like walking sticks, walkers and wheel chairs have established themselves. Other devices which support the patient in situations where they need to be lifted to get up or sit down are not common in private households yet. However, they are already available within the health and care sector. Due to various reasons, such as high costs and high stigmatization potential, they are only conditionally accepted and therefore uncommon. Consequently, the corresponding potential is less exploited.

The present study was conducted in order to adequately react to the continuously increasing demand of target group specific assistance. As the decision of the future user is not voluntary but prescribed by their physician and the need for these systems often occurs at short notice, for example through accidents or diseases, the initial contact and certain incentives within this contact have a crucial significance in terms of long-term acceptance and adherence [1].

An analysis was conducted testing specific variables relevant for acceptance before and after the initial contact with a mobility aid in accordance with the supply offer for people with limitations in their individual mobility. Besides these variables for initial contact, we wanted to capture technical affinity and subjectively perceived added value. Due to the fact that about 65 % of all people in long-term care in Germany are female according the federal statistical office of Germany [2], this study focused primarily on the proposed customer requirements within an

exclusively female group of participants. According to technology acceptance theory, women are less attracted to technology than men [3]. The goal of this paper is to present obstacles and incentives for an initial contact of older female people with a mobility aid which could be used independently and is able to support the user in case of a necessary lift to get up or sit down.

2 Theoretical Background

The user acceptance has a great impact on the sustainable integration of technical systems in medical care, supply processes and patients' therapy adherence. However, user acceptance changes throughout the whole product lifecycle. Based on this knowledge, a model-based approach for empirical measurement of expectations of the elderly towards the initial contact with a mobility aid was applied. The approach bases on the Kano-Model, known from client oriented corporate management and product development [4]. Thus, this established construct to capture expectations was adapted to the context of patient research and can be used for formalization of satisfaction measurements [5].

2.1 Levels of Quality

The Kano-model is divided into five levels of quality:

- *Must-be Quality (M)*. These attributes are taken for granted when fulfilled but result in dissatisfaction if they are not fulfilled.
- *One-dimensional Quality (O)*. These attributes result in satisfaction when fulfilled and dissatisfaction when not fulfilled. These are attributes that are spoken and the ones in which companies compete.
- *Attractive Quality (A)*. These attributes provide satisfaction when achieved fully, but do not cause dissatisfaction when not fulfilled. These attributes are not expected by a normal customer and thereby have the potential to please the customer.
- *Indifferent Quality (I)*. These attributes refer to aspects that are neither good nor bad, and they do not result in either customer satisfaction or customer dissatisfaction.
- *Reverse Quality (R)*. These attributes refer to a high degree of achievement resulting in dissatisfaction and to the fact that not all customers are alike. For example, some customers prefer high-tech products, while others prefer the basic model of a product and will be dissatisfied if a product has too many extra features

- *Questionable (Q)*. Attributes in this category should be reviewed. It is most likely that the questions for this attribute were not appropriate for the application of the Kano model concept.

Therefore, the model represents an extension of Herzberg's Two-Factor-Theory, which was developed to measure and influence motivation during work. The basic attributes are in accordance with Herzberg's hygiene factors, while the performance attributes as well as the excitement attributes can be compared with Herzberg's motivational factors [6].

It has to be noted that the expectation towards a product attribute is not identical for individuals. For person A an attribute can be classified as an Attractive Quality attribute, whereas for person B it appears as a Must-be Quality attribute and person C classifies it as a Reverse Quality attribute.

The attributes change over time due to the development of a habituation effect. An excitement attribute may develop into a performance attribute and later into a basic attribute [7].

2.2 Satisfaction Measurement

This measurement is based on the assumption that satisfaction originates from two factors, namely:

- Expectations
- Perceived Quality/Performance

The Kano model can be used to measure expectations as an element of satisfaction measurement. Therefore, questions regarding assessment of concrete products or theoretical scenarios are asked. In this process axiomatic function are subordinated to Kano attributes, which describe the connection between assessment and satisfaction value.

3 Methodology

The measurement of expectations was carried out by means of a paper based survey using bipolar answer possibilities with regard to the evaluated product attributes. Each attribute was judged twice: first by a functional (positively formulated) and second by a dysfunctional (negatively formulated) question. Both questions were asked straight after each other. Five possible answers were available for both questions:

Customer Requirements		Dysfunctional				
		1. like	2. must-be	3. neutral	4. live with	5. dislike
Functional	1. like	Q	A	A	A	O
	2. must-be	R	I	I	I	M
	3. neutral	R	I	I	I	M
	4. live with	R	I	I	I	M
	5. dislike	R	R	R	R	Q

Customer Requirement is:

A: Attractive
M: Must-be
R: Reverse
O: One-dimensional
Q: Questionable
I: Indifferent

Fig. 1 Kano evaluation Table [4]

- I would be very happy
- I take that for granted
- I don't care
- I barely accept this
- That would annoy me

Through the combination of answers of the functional and dysfunctional question the classification was derived according to Fig. 1.

In case of single unanswered questions, the corresponding attribute was classified as Q (questionable) and thereby illogical answers were not taken into account during analysis. For the analysis of the results of this encoding Kano model provides different rules and methods.

1. *Evaluation rule M > O > A > I*. If the individual product attribute cannot be explicitly assigned to one single category, the evaluation rule "M > O > A > I" can be used to do so. When making decisions about product developments, mainly those features which show the greatest influence on the perceived product quality have to be taken into account. Therefore chose the category for which the rule is valid.
2. *Category strength*. If a dominant pattern does not appear, Lee and Newcomb [8] recommended that two additional measures, category strength, and total strength, may be used to define Kano categories. Category strength is the difference (in percentage) between the highest and the second highest categories. A value greater than 6 % for category strength would indicate a statistical difference between the highest and the second highest category. Total strength is

calculated as the total proportion of must-be (M), one-dimensional (O), and attractive (A) attributes. If the category strength of a product is lower than 6 % and the total strength exceeded 60 %, it is not possible to categorize the item; such an attribute would be assigned to the questionable (Q) category [8]. This method was used in the current study to categorize evaluated attributes.

3. *Customer satisfaction coefficient (CS coefficient)*. The customer satisfaction coefficient explains whether satisfaction can be increased by meeting a product requirement, or whether fulfilling the product requirement solely prevents the customer from being dissatisfied [9]. The CS-coefficient is an indicator for how strongly a product feature can influence satisfaction or customer dissatisfaction in case of its absence. Therefore the coefficient is divided into two components, first "Extent of satisfaction" (CS+) and second "Extent of dissatisfaction" (CS−).

$$CS+ = (A+O)/(A+O+I+M). \tag{1}$$

$$CS- = (O+M)/((-1)*(A+O+I+M)). \tag{2}$$

In case coefficients are greater in magnitude than 0.5, the variable is recommended to be significant in context of increasing or decreasing customers' satisfaction [9].

4. *Fong-test*. Fong stated in 1996 a different approach to determine the significance of the classification of an evaluated attribute [10]. Therefore the so-called Fong-Test as described in notation (3) was introduced.

$$|a-b| < 1.65 * \sqrt{(((a+b)*(2*n-a-b))/2*n)}. \tag{3}$$

'a' represents the absolute frequency of the response category with the largest number of entrants, 'b' the frequency of response category with the second largest number of entrants and 'n' indicates the total number of entries in all response categories. If the inequality is valid, the assignment of the attribute to the category is significant. This method was applied in case category and total strength method led to an indifferent result.

3.1 Dependent Variables

In this study 15 variables that were considered relevant for acceptance were investigated before and after the initial contact in accordance with the supply offer for people with limitations in their individual mobility (see Table 1).

Table 1 Dependent variables

Nr.	Description
K1	To ease the burden for relatives
K2	Noticeable design
K3	Space-saving design
K4	Be safe and look safe (design)
K5	Individual design
K6	Humanlike design
K7	Health insurance pays for aid
K8	Measuring vital signs to avoid a fall
K9	Easy usability
K10	Usability within all rooms of user's home
K11	Environmentally friendly product
K12	Sharing the mobility aid with others (pooling)
K13	Testing the product at home before purchase
K14	Detect a dizzy spell and react autonomously
K15	Doctor orders to use the mobility aid

3.2 Questionnaire

The questionnaire started by presenting a scenario of a mobility aid which supports personal mobility, designed especially for users that cannot get up, sit down or walk without assistance or only with great pain. For this purpose, 30 questions were developed, describing 15 attributes for the integration of technical systems, the social environment as well as medical care. According to the Kano-Model, the functional and dysfunctional questions for each attribute were asked one after another. Apart from these attributes, demographic data such as age, living situation, previous experience with mobility aid and limitations in personal mobility as well as any symptomatic pain in this context was also captured. Furthermore, the questionnaire asked the participants whether they would prefer that the mobility aid approaches from the front, back or from the side. They were also asked where they would like to have the mobility aid while they move with it: in front, by their side or behind them.

3.3 Participants

In total 72 women took part in this study, seven participants needed to be excluded for analysis due to incomplete answers. The mean age was 70.70 years (SD = 6.1086). All participants live autonomously in a flat or house. 15 % live together with their family. The level of education reaches from unskilled without an educational degree to post-secondary degree. All participants had no experience at

Table 2 Results

	Description	Category	Category strength (%)	Total strength (%)	Fong test
K01	To ease the burden for relatives	O	21.5	75.4	–
K02	Noticeable design	R	61.5	4.6	–
K03	Space-saving design	O	10.7	76.9	Sig.
K04	Be safe and look safe (design)	O	1.5[a]	60.0	Sig.
K05	Individual design	A	12.3	52.3	Sig.
K06	Humanlike design	I	20	36.9	–
K07	Health insurance pays for aid	O	20	78.5	–
K08	Measuring vital signs to avoid a fall	O	20	83.1	–
K09	Easy usability	O	4.6[a]	50.8	Sig.
K10	Usability within all rooms of user's home	O	20	81.5	–
K11	Environmentally friendly product	O	30.7	76.9	–
K12	Sharing the mobility aid with others (pooling)	R	67.7	6.2	–
K13	Testing the product at home before purchase	O	3.1[a]	70.8	Sig.
K14	Detect a dizzy spell and react autonomously	O	1.5[a]	55.4	Sig.
K15	Doctor orders to use the mobility aid	I	13.8	16.9	Sig.

[a]Category Strength greater than 6 % indicates a statistical difference

all with the investigated type of mobility aid or robotic systems. About 62 % of all participants suffer sometimes up to regularly from pain while moving (Table 2).

The recruitment of participants was carried out via several family physicians; thereby a representative sample for Germany is present, limited to the female gender. All women participated voluntarily. No financial compensation was given for participation.

4 Results

This section provides an overview about the results. Data was analyzed with SPSS 22 and Microsoft Excel 2010. 63 % of all participants reported to understand the described scenario before answering the Kano model questions, further 30 % reported they did not understand the scenario and 7 % did not answer this question.

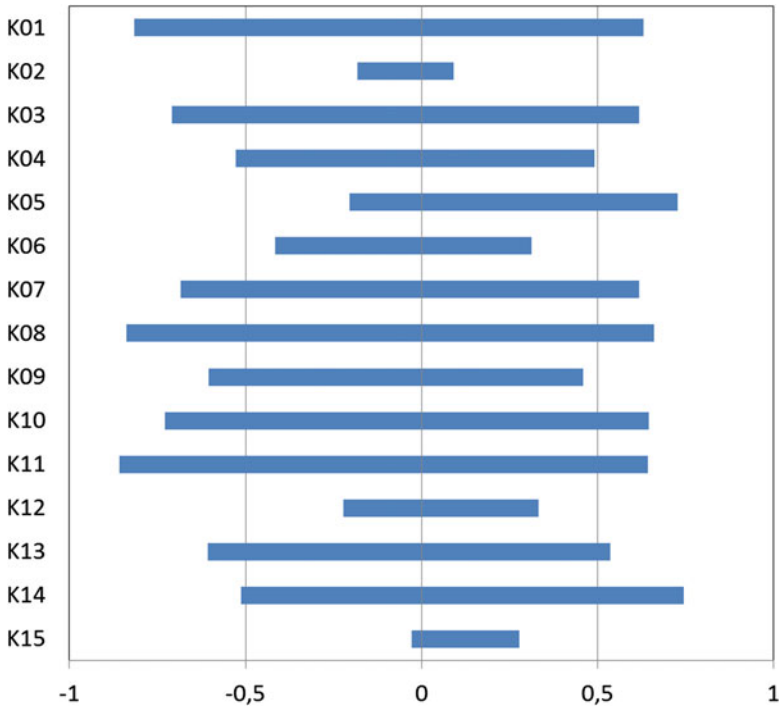

Fig. 2 Customer satisfaction coefficient

Table 2 presents the investigated attributes assigned to the corresponding category according the Kano Model. Furthermore, the category strength and total strength of each attribute are provided. The Fong-Test was performed in the cases of category strength as well as total strength and found no statistical difference. According to these tests all categorizations are valid and significant. Figure 2 provides customer satisfaction coefficients for each variable. For the questions about the preferred approach direction as well as position during movement most participants preferred the mobility aid to be in front as well as to them approach from the front (Fig. 2).

5 Conclusion

The results indicate that, despite individual preferences of the participants, specific requirements for the integration of technical support systems within health and care processes are present. These requirements have an above-average influence on the satisfaction of potential customers and users of the relevant support systems.

Independent from age in the group of older women, individual design turned out to be an excitement attribute of a mobility aid. Further, none of the investigated attributes was determined to be a "Must-Be-attribute". Although it was possible to identify two "Reverse attributes", these are requirements which decrease customer satisfaction if they are fulfilled. In this study 'noticeable design' as well as 'sharing the mobility aid' were determined to be reverse attributes. Participants were indifferent about whether or not the mobility aid should have a humanlike design. This corresponds with results of another recent study by Mertens et al. [11]. The requirement that a "Doctor orders to use the mobility aid" was also revealed to be an indifferent customer requirement.

'To ease burden for relatives' is a high significant attribute in terms of customer satisfaction, it increases as well as decreases customer satisfaction depending on if it is present or absent. The same can be said for 'space-saving design', 'health insurance pays for aid', 'measuring vital signs to avoid a fall', 'usability within all rooms of users home', 'environmentally friendly product', 'testing the product at home before purchase' and 'detect a dizzy spell and react autonomously'. In all these cases the customer satisfaction coefficients CS− and CS+ exceed −0.5 or +0.5. This is reasonable because all of these attributes were revealed to be one-dimensional attributes and thus these attributes result in satisfaction when fulfilled and dissatisfaction when not fulfilled.

6 Limitations and Outlook

Future research should investigate the presented attributes more deeply to develop best practice solutions for initial contact with innovative products in the context of the elderly. Further, the group of participants should be extended to male participants in order to identify gender differences. As described earlier, expectations change over time. This means that satisfaction decreases although service performance remains constant or increases—this happens when the user previously considered the examined service performance as excitement attributes, but currently as basic attributes. Therefore, future research should evaluate the same attributes again to investigate time related differences in customer requirements for an initial contact with innovative products like a mobility aid which is able to lift the user.

All in all, participants seem to have a performance-oriented positive view of the initial contact with a mobility aid as defined in the context of this study.

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Part IV
Human Factors and Ergonomics in Healthcare Safety

Engaging and Effective Staff Training to Improve Patient Safety and Satisfaction

Gregg Alexander and Patrick Baker

Abstract Improving patient safety and increasing patient satisfaction are top priority concerns for healthcare institutions. Alarm fatigue is also a key and very problematic issue. Developing programs to address these problems often involves making system-wide cultural changes, but changing institutional culture can be challenging. Use of animation and storytelling to inspire emotional "buy in" from staff, combined with an efficient and engaging multimedia training program, can allow for rapid and cost-effective cultural change. A "culture of safety" is established yielding improvements in patient safety and satisfaction while decreasing alarm fatigue for clinical staff.

Keywords Staff training · Patient safety · Patient satisfaction · Animation · Alarm fatigue · Patient call lights · Culture change

1 Introduction

Staff training at hospitals can be challenging. This is certainly true if the training involves a system-wide change in processes or procedures, and it is especially true if the training involves a cultural change.

One significant cultural change that healthcare facilities are beginning to focus upon is the response to patient call lights. Many hospitals and long-term care facilities have found that their approach to patient call light responses has been inadequate. Clinicians are often over-burdened with duties, and the seemingly never-ending increase in various alarms to which they must respond often leaves

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them struggling to respond to any alarm or call light in as timely a fashion as they, or their managers, might prefer.

An overwhelming majority of hospitals rank alarm fatigue as one of the top patient safety concerns [1]. According to a Joint Commission Sentinel Event Alert for 98 alarm-related incidents between January 2009 and June 2012, significant numbers of negative patient outcomes are attributable to alarm fatigue, including deaths, permanent loss of function, additional care requirements, and extended hospital stays [2]. In 2014, decreasing alarm fatigue became a Joint Commission National Patient Safety Goal [3].

While improved monitoring systems and better software algorithms can impact this in the long term, one fairly immediate solution to decreasing the alarm response demand upon clinical staff is to "share the load," so to speak. This can be done by training all staff—clinical and non-clinical alike—to respond to any and all patient call lights that they encounter. This improved culture of safety, variously titled, involves teaching and empowering non-clinical healthcare facility personnel; most, if not all, of them have never been told that responding to patient call lights was any part of their job duties.

One analogous situation often strikes a familiar chord with anyone working within a healthcare institution: imagine you were standing in line in the facility's gift shop and the person ahead of you suddenly fell to the floor clutching their chest with what appeared to be a heart attack. Would you simply ignore them and/or walk away?

Or, would you kneel down to try to help, perhaps yelling for others to summon medical personnel to come and assist? The unanimous response is that people would do what they could to help. Equating this to a patient call light where someone is in need of assistance and the appropriate response from any facility employee is to respond makes a very direct connection for most every healthcare worker, regardless of their job title or primary job duties. Most people can easily understand that to see what the need is and to do what they can—be it direct assistance or summoning others, such as clinically-trained staff—makes good sense, and is the "right thing to do."

The biggest roadblock for non-clinical staff is not only that they haven't been empowered previously to enter into the domain of "direct patient care," but that they have not been oriented as to what is clinically acceptable for them to do when responding to patient needs. They haven't been provided any guidance or guidelines to help them know when, how, and why to respond to patient calls for help.

This is important: non-clinical staff must be made fully aware that they are not being called upon to perform any clinically-related functions beyond their level of training or experience. They are merely being given "permission" to step up and ask, "I see your call light. How can I help you?" For something simple, such as refilling a water pitcher or handing the patient a book that has fallen, they should feel comfortable responding to such non-clinical patient needs. If, however, the patient has fallen, is in pain, or has some other medical need, non-clinical personnel are empowered to say, "Hold on… let me get someone here to assist you with that." They can then summon appropriate clinical staff without feeling they are being asked to go beyond their capabilities.

The upshots from such an approach are multiple:

- Patient needs are responded to more quickly.
- Patients feel more important, knowing that everyone in the institution considers their well-being to be of top concern.
- Patient safety is enhanced when long delays for critical issues are avoided.
- Patients feel greater satisfaction with the "total team care" they experience.
- Non-clinical staff feel less anxiety participating with patient care issues.
- Non-clinical staff develop a greater sense of being a part of the care team.
- Clinical staff will experience a decrease in alarm fatigue when this "share the load" patient call light response system is deployed and alarms are decreased [4].
- Clinical and non-clinical staff have increased interactions.
- Clinical staff develop a greater appreciation for their non-clinical co-workers.
- A more positive system-wide culture develops when all staff feel like "team-mates" working together in patient care.

2 Healthcare Facility Cultural Change

Making such a cultural change won't happen with a simple directive or memo. Non-clinical staff—be they facility managers, food service workers, or executives—must be trained, and their not-unexpected fears assuaged. They must be given support and be made to understand exactly what they should—and shouldn't—do in a variety of patient need encounters. Plus, it is important to make clear that the same expectations and responsibilities will be an across-the-board change, that they are an integral part of a system-wide change in patient care culture.

Facilitating that cultural change requires a training program that is effective, easily deployed, and preferably, cost efficient.

Such were the requirements at the University of Cincinnati Health's West Chester Hospital. They sought to adopt a complete program to train all staff: clinical and non-clinical, current and new hires, from executives to volunteers. But they wanted something more, something beyond team meetings and handouts. They sought a program that would reach people on an emotional level, knowing full well that change requires commitment, commitment requires motivation, and people are most effectively motivated when an effective emotional connection is inspired.

UC Health West Chester contacted Health Nuts Media, a unique company that creates animated content, games, and apps to connect stories and entertainment with often complex health and medical issues in simplified, easy-to-understand, and engaging ways. Working in co-production, UC Health West Chester and Health Nuts Media created an entire program entitled "The No Pass Zone," a complete multimedia training package centered around animated storytelling scenarios to train 100 % of West Chester Hospital associates and volunteers (Fig. 1).

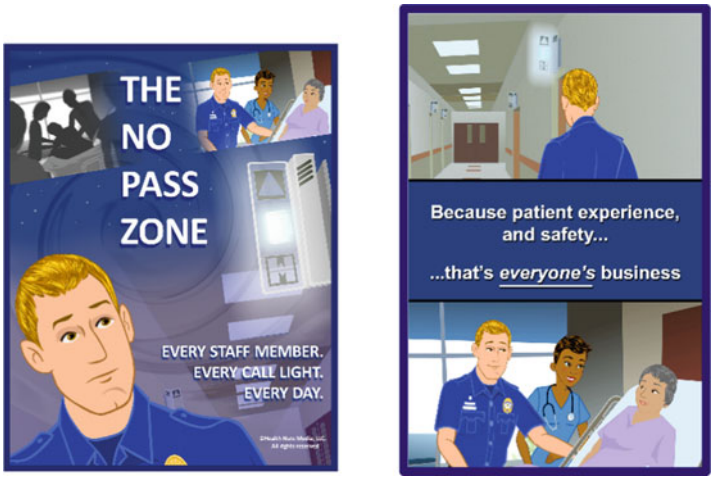

Fig. 1 The no pass zone multimedia staff training program

3 Why Animation?

The use of animation is a winning strategy for engaging audiences and simplifying messaging. Whether promoting breakfast cereal or auto insurance, an animated character has many advantages over a "real" spokesperson: (Fig. 2)

- *Versatility*: Animated characters can be stylized in any way to fit the product messaging and can say and do things that are difficult, if not impossible, for real people.
- *Low Cost*: Unlike a real actor, animated mascots do not need to be paid salaries or residuals.
- *Long Shelf Life*: Unlike real people who age over time, an animated character can remain the same forever.
- *Acceptability*: Audiences perceive animated characters in different ways than they perceive real people. Animation is typically perceived as less threatening and is more likely to be seen as endearing. This can help to overcome communication barriers and facilitate more receptiveness to messages.

Fig. 2 Animated characters are widely used and have numerous advantages

Fig. 3 Smokey

- *Scandal-Proof*: Unlike real actors, animated characters will not become involved in scandals. They won't get arrested or say something that could damage your brand.
- *Easy Scalability*: Animated characters can speak in many different languages. Their hair color, hair style, skin tone, clothing, and other elements can be adjusted to suit various audience segments, and they can be used for gaming, avatars, and other interactive media.

In education and public service, animation has also been a time-tested medium. Consider Smokey the Bear—the longest running PSA campaign in US history. Created in 1944, Smokey the Bear has educated generations of Americans about the dangers of forest fires. According to the Ad Council, Smokey the Bear and his message are recognized in the United States by 95 % of adults and 77 % of children [5]. The United Nations, American Diabetes Association, U.S. Department of Health and Human Services, Starlight Children's Foundation and UNICEF are all organizations that have utilized animation to communicate important messages (Fig. 3).

4 The Power of Animation

In response to the cholera epidemic that began in Haiti in late 2010, Global Health Media produced an award-winning animation, "The Story of Cholera." Designed to help affected populations around the world better understand cholera and how to prevent it, the film was produced in collaboration with internationally acclaimed animator Yoni Goodman.

"The story features a young boy who helps a health worker save his father and then guides his village in preventing cholera from spreading. By making the invisible cholera germs visible, this simple animated narrative brings to life the teaching points of cholera prevention" [6].

The power of this amazing animated short is that even without audio—in other words, regardless of a person's literacy level or language—the entire message is completely understandable. From how the germs are transmitted to the symptoms it causes to effective means for prevention, The Story of Cholera communicates its important concepts using delicate yet powerful imagery. (With vomiting and diarrhea as hallmark symptoms, the visual portrayal might be off-putting, but using

Fig. 4 Scenes from "The Story of Cholera"

animation and a high degree of sensitivity, even these are conveyed without being offensive or grotesque.) (Fig. 4).

Animation has the power to engage, inform, and enlighten with high conceptual impact.

5 Why Animation for Staff Training?

Animation applied to staff training has many powerful benefits. These include:

- *Engaging*: By using a unique attention-grabber, you help keep participants engaged and interested in the material being presented.
- *Entertaining*: Animated characters have a license to be a little silly and can perform superhuman and even impossible feats, which can help to break up lengthy training sessions with a bit of comedic relief.
- *Memorable*: When participants watch a unique animation, it helps put visual context to the concepts they're learning and makes them more likely to recall what they learned long after their training is complete. Plus, narrated information is remembered better than written information [7].
- *Eye-catching*: If participants have started to lose focus on their training, a catchy animation can help startle them back to task. Their attention will be renewed and they'll be more likely to process the information being presented.
- *Motivating*: Animation has attention-gaining and entertaining features, which helps to motivate learning.

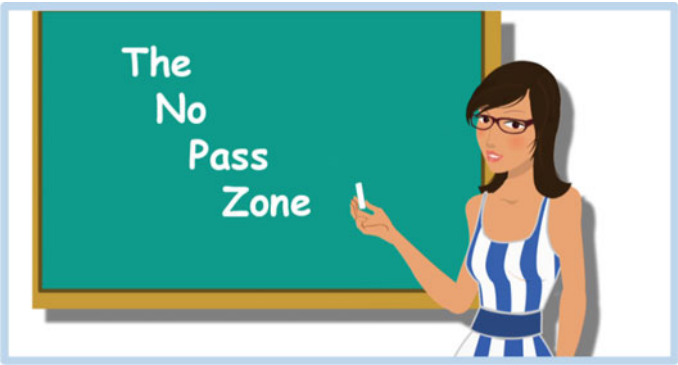

Fig. 5 Animation for staff training

- *Effective*: Animated graphics are also more effective compared with static graphics [8]. It has been shown there is a significant difference in learners' performance when taught using "cartoon-style" animated graphics versus conventional instruction [9] (Fig. 5).
- *Cross-literate*: Animation, especially when combined with spoken content, allows even those with low health literacy to understand and recall information on par with those with high health literacy. Further, animated content suits all level of health literacy equally well [10].
- *Sets the tone*: You don't want employees to dread training. A fun and engaging animation helps set the tone for how they should approach their time in training: with enthusiasm and an open mind. If leaders use animation to demonstrate a positive and enjoyable attitude about the process, staff will follow suit.
- *Makes learning more relatable*: It might sound somewhat counter-intuitive, but when employees have a character or visual to identify with, they're more likely to trust the information than if merely presented in written format. Animation can almost give the material a sense of human-like interaction, without being threatening. Plus, people are less defensive with animated characters than with live action videos or real life instructors.
- *Improves the attitude toward future training*: When employees know their training is engaging, they'll be more willing and ready to learn new concepts in the future. Animation can help improve the overall training experience, which will also make for better experiences down the line [11].

6 The Power of Story

People are storytellers, both individually and socially. The transference of human knowledge through thousands of years has depended upon story. Story helps humans contextualize knowledge, and increases long term recall. Storytelling helps

people navigate life's difficult social problems [12]. Our shared experiences help to ensure our basic survival by passing on acquired wisdom. Indeed, even species our Latin name, "Homo sapiens," literally means "wise man" [13].

Long written documents, spreadsheets, and prolonged PowerPoint slide decks may contain knowledge, but it is emotion that motivates people and empowers long term information retention. People aren't moved to action by large "data dumps" [14]. Not until the invention of printing did pure collections of data become prevalent. For the majority of human history, accumulated wisdom, knowledge, and experiences were shared by being incorporated into a storied narrative.

Story provides context. It affords the creation of "memory pegs" empowering the brain's ability to create neural connections and associations to enable recall and assist with future interpretations and information relationship awareness. Story adds power.

7 The No Pass Zone and UC Health West Chester Hospital

7.1 The Process

After reaching a collaborative co-production agreement,[1] UC Health West Chester and Health Nuts Media worked together to develop the requirements for the complete staff training program to instruct all UC Health West Chester staff—"associates" and volunteers—on the cultural change initiative entitled, "The No Pass Zone."

Program development included:

- *Conceptual Outline*: creative concepts were tied to the essential staff training requirements
- *Story Creation*: incorporating necessary elements of staff education into an engaging narrative (e.g., using an "Outer Limits" and Rod Serling-esque theme)
- *Vocal Recording*: professional voice actors record approved script
- *Animation*: full animation built around script and vocal recordings, multiple training scenarios
- *Ancillary Training Materials*: development of a complete package for staff training around the animated content including: PowerPoint presentation, instructor manual, staff manual, and questionnaire.

Approval of each step of the process was vital before proceeding to the next phase, as each phase builds upon the prior work. (e.g., Animation is much more difficult to change than are the script or vocal recordings, thus it is critical to "get it

[1]Via our collaborative co-production model, UC Health West Chester maintains in perpetuity rights to all content in "The No Pass Zone" training program, while Health Nuts Media retains all rights to white-labeled versions all materials for marketing and resale purposes.

right" during each phase of development to keep costs contained and timelines on track.)

The core animated content includes seven videos, one primary and six situational examples to highlight potential difficulties and solutions for key encounter problems. These include:

- "The No Pass Zone"—the importance and overview of the concept
- How to handle an upset patient
  - The encounter
  - The solution
- What to do if you notice a co-worker ignoring a call light
  - The encounter
  - The solution
- How to deal with bad attitudes by co-workers in response to call lights
  - The encounter
  - The solution

Breaking situational example videos into encounter example and solution example allows for Q&A with staff during training to discuss the situation, how it might best be handled, and then viewing a recommended solution example. Interactive small group training sessions allowed for staff interplay and reinforced learning methodologies.

7.2 The Results

Within mere months, UC Health West Chester achieved 100 % in-person education using the "The No Pass Zone" program. With current staff, they conducted 45 min interactive sessions with multidisciplinary groups of 20 associates and/or volunteers. To maintain 100 % compliance, they provide in-person training of "The No Pass Zone" program during new hire orientation.

Staff acceptance and response to "The No Pass Zone" content and training has been remarkable. Though no formal study has to date been performed upon the effectiveness and impact of this training, initial anecdotal comments are very encouraging. De-identified comments from UC Health West Chester staff include the following "lessons learned":

- Associates learned that The No Pass Zone is a patient safety initiative and all associates have the ability to help keep our patient's safe.
  - "*I can prevent an emergency.*"
  - "*Making sure that all patients are safe is every employee's responsibility.*"

- Non-clinical associates learned that they now have "permission" to enter a patient's room.
  - "*This training gives us permission to assist patients in their room, not just in public areas.*"
  - "*I was never sure if it was ok to enter a patient's room. Now I know it is ok.*"
- Clinical associates learned that not all associates feel comfortable entering a patient's room.
  - "*I now have a better perspective on the apprehension of non-clinical staff in answering call lights.*"
- Associates have learned the vitality of a patient's call light.
  - "*I will respond to call lights now that I know how important they can be!*"
- Associates learned what to say, do, and look for when entering a patient's room.
  - "*I now have more knowledge of what to do and look for when in a patient's room.*"
  - "*I would not have known what to do before this training*."
- Associates are now more comfortable and confident when entering a patient's room.
  - "*This training has made me less nervous to go into a patient's room.*"
  - "*I will now be more confident in helping.*"
  - "*Being new to this environment, I'm still getting used to everything that goes on here and this class has really helped me feel more comfortable with these experiences.*"
- Associates are working as a team to help each other keep our patients safe.
  - "*I will not pass a call light and will engage others to help me do the same.*"
  - "*I will remind others to stop.*"
- Management has noted the effectiveness and engaging nature of the training.
  - "*Frontline staff on every level have grasped the concepts of The No Pass Zone from these short videos. There isn't one person to whom I've shown these wonderful animated videos—from management to care providers to support staff—who hasn't said, 'Wow!'*"

Engaging and effective training to improve patient safety and satisfaction appears to also have improved staff attitudes and their approach to total team patient care. Patient reports have been similarly positive, and data collection is in progress.

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Methodology of Care Humanitude in Promoting Self-care in Dependent People: An Integrative Review

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Abstract The aging of the population has led to an increase in the prevalence of chronic degenerative diseases and dependence. We need to implement humanized health care that will improve the quality of life and well-being of these people and help maintain their autonomy and self-care.: To identify the implications of the caring in Humanitude in promoting self-care in the dependent person. Integrative review of the literature of the period between 2007 and 2015, using the databases Medline, EBSCO and Google Scholar. In using the PI[C]OD methodology and criteria for inclusion and exclusion, we obtained 54 items where 7 were selected for analysis. There are several health benefits in the promotion of self-care, by applying the Humanitude caring philosophy, mainly regarding the relationship between the nurse and the patient. It is essential to develop further studies focused on the implications of caring in Humanitude in self-care in the dependent person.

Keywords Caring humanitude · Methodology of care humanitude · Self-care

1 Introduction

The growing number of elderly people with Dementia, Behavioral and Psychological Symptoms of Dementia (BPSD) (agitation, aggression, disorientation, refusal of care, opposing force), poly-medicated and with complications resulting from being bed-ridden, has become one of the major challenges of the health care system for which neither the institutions nor the caregivers are prepared.

To respond to this challenge, in 2006, the National Network for Integrated Continuous Care (RNCCI) was created to provide support to dependent people, aiming at maintaining or improving their autonomy and independence. However, the average length of hospital stay has increased, 50 % of inpatients show no

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positive developments in their overall physical autonomy and 79 % are discharged with support needs.

These units are mainly used by elderly people with dementia who begin losing their autonomy and whose physical and cognitive condition is aggravated. They show neuropsychiatric symptoms, especially agitation, and they do not collaborate, or even hamper or refuse care. This situation often results in poly-medication, institutionalization, bed confinement and immobilization complications (reduced autonomy, increased risk of pressure ulcers, loss of balance and increased risk of falls). The situation is aggravated by the caregivers' difficulties to provide care due to lack of training, consuming more time, physical and mental energy, leading to burnout and turnover. This strongly contributes to an increase in the operating expenses per bed and the length of hospital stay.

The Methodology of Care Humanitude by Gineste and Marescotti (MGM) was developed over 35 years time period and has led to remarkable changes in the institutions where it was implemented with very significant health benefits, particularly in terms of the well-being of the patient, as he/she is being cared for, and the caregiver, as he/she is providing high-quality care [1, 2].

This methodology is based on four key pillars: eye contact, speech, touch and verticality including 150 techniques that promote verticality, operative humanization, professionalize the relationship between the caregiver and the person cared for. By focusing primarily on the patients' potential, encouraging them to actively participate in all types of care, it produces important benefits in terms of the patient's autonomy and independence [1, 2].

This innovative and low-cost methodology with scientifically validated benefits at both national and international levels emerges as one of the main solutions for the current major challenges in health, such as the increased dependence of the elderly with dementia, the complexity of their care and consequent operational costs, thus contributing to the sustainability of the National Health System.

2 Methodology

The elaboration of this integrative literature review has the primary objective of identifying the health benefits, namely in promoting self-care, by utilizing caring Humanitude in dependent people.

Keeping this in mind, and according to the PI[C]OD method, we defined the following question for our investigation: "What are the implications of caring in Humanitude in promoting self-care in dependent people?".

For the development of integrative literature review, in order to direct our study towards the goal we set for ourselves, the inclusion and exclusion criteria were defined and presented in Table 1.

The pursuit of scientific evidence was based on the formulation of the research question and subsequent enumeration of keywords to be researched in the defined time period (2007–2015).

Table 1 Inclusion and exclusion criteria

Selection criteria	Inclusion criteria	Exclusion criteria
Participants	Age >18 years of age Male and female gender People with a high level of dependency/vulnerability	Age <18 years of age Independent people
Interventions	Relationship with nurses The pillars of humanitude® Promotion of human dignity Relationship skills help	Relationship with other professionals
Research design	Quantitative studies; Qualitative studies; Systematic reviews of the literature	

The survey was conducted in August 2015 in the EBSCO, MEDLINE and Google Scholar online databases, using both Portuguese and English languages with publications limited to the period from 2007 to 2015.

Due to the scarcity of articles related to the topic, researching by title and/or summary, available articles with an integral text were selected so that important data would not be left out of this revision.

When searching in multiple databases common items were found within the selected research codes. So, and after a fine analysis and taking into account the criteria of inclusion and exclusion and the goal of the review, we reached a total of 7 articles for analysis.

3 Presentation and Discussion of Results

Following the methods previously described, we had access to 54 scientific studies. After applying the inclusion and exclusion criteria, 7 articles were selected.

As for the methodologies of these 7 articles, 4 resulted from research studies conducted in clinical settings. Two are a systematic review of literature and the other is a descriptive study.

The studies analyzed in this review, and presented in Table 2, emphasizing the importance of Humanitude philosophy in the promotion of care [3], the meaning of the Humanitude philosophy in the care context [4], the importance of Humanitude in interpersonal relationships [5] and the contribution of the Humanitude pillars in the promotion of personal autonomy [2, 6–8].

The care provided through Humanitude approach promotes the psychological balance and preservation of capabilities allowing greater well-being and increased autonomy [2, 8].

To deprive a human being of the Humanitude pillars can promote behavior changes, such as pathological agitation, loss of autonomy and the deterioration of

Table 2 Scientific study analyzed

Authors	Methods	Objective	Participants	Interventions	Outcomes
Simões et al. [5]	Descriptive article	To know the importance of humanitude in interpersonal relationships and care	Not considered	Analysis of selected documentation	The nurses assigned great importance to humanitude, as well as they perceived its applicability in their care practice
Simões et al. [5]	Systematic literature review	To identify scientific evidence on the contribution of the humanitude implementation in dependent people	6 studies published focused in humanitude	Analysis of selected studies about the meaning of humanitude in nursing care	The care humanitude by focusing primarily on the patients' potential, encouraging them to actively participate in all types of care, produces important gains of the patient's autonomy and independence
Simões et al. [5]	Descriptive study	To know the importance that nurses give to care based on the philosophy of humanitude	160 nurses with 2 or more years of professional experience in Portugal	Online survey with data collection instrument with 28 items	The detailed description of the gestures that nurses execute helps people with cognitive difficulties to perceive the body schema. The techniques of care humanitude are determinant to the evolution of patient's health
Phaneuf [8]	Descriptive article	To identify what are the health gains by applying the care based on the humanitude philosophy	Not considered	Analysis of selected documentation	The care based on the humanitude philosophy allows the preservation of human capacities. The verticality allows visual

(continued)

Table 2 (continued)

Authors	Methods	Objective	Participants	Interventions	Outcomes
					contact, facilitates the functioning of the heart and circulation, promotes bone metabolism, the perception of body schema and autonomy
Simões et al. [5]	Descriptive study	To develop the skills of caregivers in the application of MGM, and to evaluate the responses of patients cared	A team of caregivers and a population of elderly dependents	Application of perception scales in the applicability of MGM, and an observation grid	The implementation of MGM showed effectiveness particularly in decreasing the agitation states, and increasing the care participation and collaborators' satisfaction
Araújo et al. [6]	Descriptive and longitudinal study	To evaluate the self-care in dependent persons using MGM for 3 months	3 people with dementia and dependent on self-care	Application of MGM	The people cared for increased their will to live and their autonomy
Albuquerque et al. [7]	Systematic literature review	To identify studies on the contribution of humanitude care and self-care	6 published studies about humanitude and self-care	Analysis of studies pertaining to the contribution of humanitude care in the promotion of self-care	The implementation of MGM promotes the autonomy and self-care of the dependent person

the physical and cognitive condition. This situation often results in poly-medication, institutionalization, bed confinement and immobilization complications (reduced autonomy, increased risk of pressure ulcers, loss of balance and increased risk of falls) [2]. The situation is aggravated by the caregivers' difficulties making it necessary that caregivers have specific training on caring with Humanitude [6].

When careers fail to promote autonomy, they lead to the destruction of the remaining capacities. Careers should stimulate the person's abilities, increasing their autonomy and independence [6]. When nurses give the patient the opportunity to take the initiative and make their own decisions about the care process, they promote the dignity of the person cared for [6]. In this case, we are acting and observing patients as human beings. The nurse has an important role maximizing the skills of the dependent person aiming towards the promotion of autonomy, thus creating a relationship of equality [2, 6].

Overall, it is demonstrated that nurses can protect or violate the dignity of patients by their attitudes, showing violations in their ethical approach and behavior towards the patient [4].

The verticality is a sign of our species and our dignity as human beings and therefore it is considered one of the main pillars of Humanitude. By leaving someone bedridden, its verticality can be severely and irreparably damaged. A better verticality promotion contradicts a spondylitis posture and the sense of futility and defeat [8]. This pillar is essentially tactile, visual and postural. It stands as a constant referral in our relation with space, time and surrounding environment. The verticality allows visual contact with each other, becoming a source of respect and encouragement to the development of intelligence. This Humanitude pillar facilitates the functioning of the heart and circulation, stimulates the appetite, promotes digestion, the urinary and intestinal elimination, it also promotes bone metabolism, the perception of the body schema and increases muscle tone [8]. Standing, marching and other various exercises are beneficial to their health in an overall manner and have advantages in diverse human functions: physical, physiological and social [8]. From a physiological view, several systems are affected. Therefore, mobilizing patients in relation to their necessities is not only vital to their health, but also intrinsic to what we need to fully live out our Humanitude [8]. Being bedridden causes symptoms of immobility with disastrous repercussions to the vital systems. The person progressively loses the corporal scheme and the sensory-motor intelligence [2, 8].

The gentle caring touch and soft mobilizations awaken feelings of tenderness and communicate nonverbally with the body awakening their life strength. The tenderness of touching with softness, allows the effective connection with the dependent person [5, 8].

The eyes of the caregiver captivate the attention and confirm the dignity of the patient as a human being. The look is also an appeal to the Humanitude and a stimulation to evolve, to regain balance, both physical and psychological, because it is in the eyes of others that we realize what we are and what we are worth [2, 8]. These authors [2, 8] consider that this look allows for captivating attention and maintaining focus.

The conjugation of the Humanitude pillars enables an approach to good affective memories in sick and vulnerable people, as well as the appeasement, leading to the approximation of intimacy of the person [2, 7, 8] and self-care benefits [6] (Table 2).

4 Conclusion

According to the results obtained, we can conclude the Methodology of Care Humanitude by Gineste and Marescotti (MGM) has led to remarkable changes in the institutions where it was implemented, and very significant health benefits were obtained, particularly in terms of the well-being of the patient, as he/she is being cared for, and the caregiver, as he/she is providing high-quality care.

This methodology focuses primarily on the patients' potential, encouraging them to actively participate in all types of care. The MGM promotes the verticality, therefore promoting self-care and producing important benefits in terms of the patient's autonomy and independence.

It is demonstrated that there is a scarce number of studies on the implications of Humanitude in promoting self-care. In this sense, it is concluded there should be more studies on this theme in order to disseminate and implement the use of this philosophy in nursing care practice.

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Application of User Experience Map and Safety Map to Design Healthcare Service

Jinhua Li, Long Liu and Yayan Zheng

Abstract Design for healthcare service involves two critical issues: imbed safety and expected user experience. Many researches have already been conducted in this area but mostly consider these two issues separately. This paper described a study in 2015 with Chinese designers who work on healthcare service design, to find out the advantage and disadvantage of the methods they used. Obvious unbalanced consideration between safety and experience has been found in their design process. Based on this result, through case study and theoretical analysis, a possibility to combine the experience map of EBD and safety map of FMEA to help designers coping with healthcare service design issues efficiently is proposed. The initial model of this method is discussed and presented in this paper.

Keywords User experience · Safety · Healthcare service · Design

1 Introduction

In order to provide expected healthcare service, two critical issues should be taken into consideration in the healthcare service design: imbed safety and expected user experience. Although many researches have been conducted to propose methods to cope with the healthcare service design issues, previous reports revealed that safety design methods and experience design methods are usually separated. For safety design, the Failure Mode and Effects Analysis (FMEA) is a quite common method to help explore and control potential risks. For user experience design [1], the Experience-based Co-Design (EBCD) method is applied with the goal of improving

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the subjective user experience [2]. By now, few studies focus on combining safety design and experience design together. As the consequence, the service designers are usually not well supported by effective method that could help them cope with design issues in real healthcare settings with safety and experience consideration together.

Especially in china, with the limitation in healthcare resource, experience design is unlikely to be practiced while safety design is by now the generally well recognized requirement in practice [3]. This would significantly influence the quality improvement of healthcare industry.

In this paper, we would at first have a review on the popular methods used in healthcare service design, and then investigate 14 designers' work process and design methods when they are conducting a healthcare service design project. The specific objectives of this paper are:

1. To explore the methods used in healthcare service design to search improvement potentials of these methods.
2. To investigate the designers' work in a practical healthcare service design project to understand some facts of their application of some methods.
3. To explore a way to combine safety design and experience design together to provide the service designers with a tool to apply in the healthcare service design area.

2 The Challenge for Healthcare Service Design

Service design is nowadays increasingly accepted in various industries due to its effect to improve the service quality through application of a system perspective to observe products, users, information, working process and other elements related to the service provision. In the past decades, service design has been developed with concrete methods to help designers achieve improving service experience in many industries. However, this practice is not well implemented in the Chinese healthcare industry where few projects have been conducted to demonstrate the benefit and improvement service design approach can bring.

It is obvious that healthcare service has its unique features as it is a highly professional and critical area with extremely high requirement on safety. Healthcare service would connect quite diverse parties like patients, their relatives, caregivers, and technicians, etc. [2]. During the service provision, different parties have varied experience when they communication each other or interact with the environment and medical equipment. In this process, complex factors, e.g. the surrounding environment with specific facilities, the communication and the physical and emotional status of the patients, would have significant impacts on user experience and the treatment effect. On the other hand, healthcare service is highly specialized and normalized. It is closely related to life of people, therefore the requirements on safety are strict [4]. The device characteristics, the information accuracy, the process efficiency, etc. should be well considered, with the intention to integrating requirements regarding two critical issues: expected user experience and imbed safety.

3 Previous Research of Healthcare Service Design

In recent years, the healthcare industry has made a lot of progress, with the focus on not only the innovation of medical devices, but also the improvement of service quality in healthcare institutions. Many theoretical researches and practical explorations have been conducted in healthcare service design, with the development and application of different approaches aiming to promote the healthcare service design.

3.1 Service Design Approach

Service design should adopt interdisciplinary approaches that combine different methods and tools from various disciplines. There is no common definition or clearly articulated language of service design [5]. Published service design methodologies include a wide array of user experience and adapted design methods [6]. They aim to improve consumer's experience and satisfy business benefit, involving physical products, service process, and information dissemination etc. (Fig. 1) [7]. The commonly used tools in service design include personas, customer journey map, service blueprint, system map and so on. They have been widely applied in practical designs in many industries, and have achieved many successes by now.

The introduction of service design into healthcare area began in UK with its reform on the National Health Service (NHS) around 2000 which emphasized on patient experience in care. There are many examples of the service design in healthcare industry. The approach described in Fig. 1 is a very good framework of methods for healthcare service design, with which those complex details occurring in medical process could be analyzed from a systematic view. The benefits of both the healthcare givers and patients could be taken into consideration. With some visualization tools, the real users, include doctors, nurses, patients and others, could

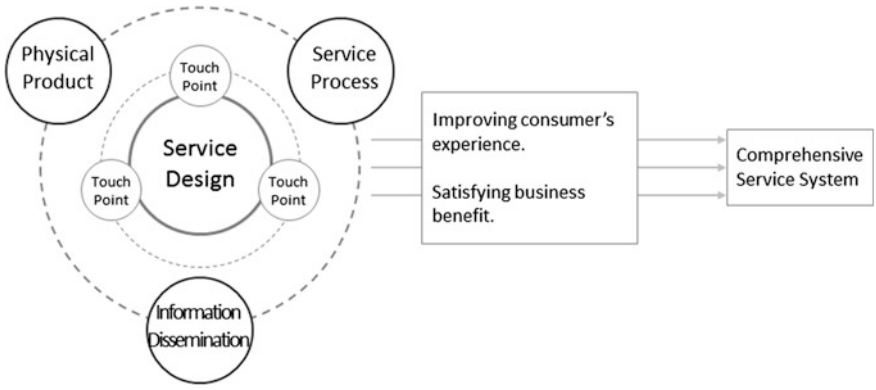

Fig. 1 Framework of service design [7]

be involved in design process. With a open and user-centred design process, the improvement of the user experience could be realized.

However, as healthcare service is closely related to life and health of people, it is neither benefit-oriented nor consumer-oriented [6]. Some special requirements especially the consideration on safety should be well included. In china, healthcare service is now facing up to huge challenge induced by large population and restricted resource, and is still in development. The quality assurance closely related to safety is still the main concern of the majority of the public healthcare institutions. How to well adopt mature service design methods with the suitable adaptation to Chinese applications is still struggling in healthcare service design to satisfy requirement of the society to ensure adequate healthcare provision.

3.2 *Experience-Based Co-design (EBCD)*

The EBCD approach, originally called 'Experience Based Design' (EBD), has been published by the NHS Institute for Innovation and Improvement (Fig 2). It is a method of using the experience of patients, care givers and staff to design better healthcare services. The approach involves looking at the care journey and in addition the emotional journey people experience when they come into contact with a particular pathway or part of the service [2].

EBCD emphasizes improving user experience, with the consideration of emotion as a significant evaluation factor. From the EBD viewpoint, users are considered co-designers of the services as they join and even integrate in the whole service improvement and innovation process [8]. Co-design process could fully utilize user's knowledge and experience to find improvement suggestions. Many practical cases already prove that EDCD could promote user's service experience; however, this method does not well integrate objective standards and regulations, and could not be applied to evaluate the healthcare safety.

3.3 *Failure Mode and Effects Analysis (FMEA)*

FMEA is a widely used risk assessment tool for defining, identifying, and eliminating potential failures or problems in products, process, designs, and services (Fig 3) [9]. Application of FMEA in healthcare environment can discover potential loopholes in

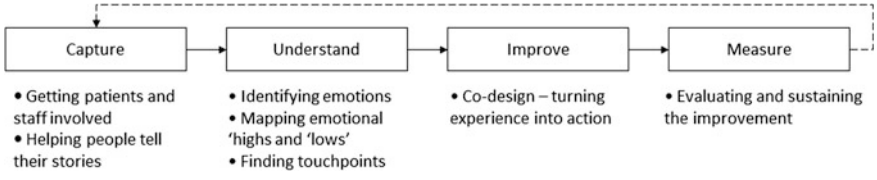

Fig. 2 EBD method process

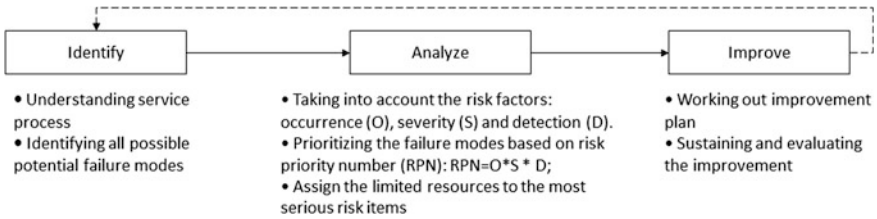

Fig. 3 FMEA method process [9]

the flow-sheet prospectively. Therefore, healthcare organization can adopt corresponding measures and make full use of systematic defense for potential defects [10].

FMEA is a method with obvious advantages in healthcare safety design [11]. By using the quantitative analysis with the RPN (Risk Priority Number), risk rank can be clearly shown and resource allocation to cope with higher risks to ensure safety can be made more rationally [9]. However, FMEA almost pays no attention on user experience. It is a management method rather than a user-oriented method. Healthcare professionals and expert dominant the design process, while real users, especially patients, and end operator of the service like nurse, are in many cases excluded.

Although service design usually applied multiple methods, one common fact is that almost all these methods regard service as a whole system, including product, information, people, etc. However, previous reports revealed that safety design methods and experience design methods are usually divided. Few studies combine safety design and experience design together. While EBCD emphasizes on user experience, FMEA focuses on risk management. It seems that service designers usually face up to healthcare service design without efficient methods coping with safety and user experience issues conjunctly.

4 Case Study

In order to figure out the methods used in healthcare service design, recently, the authors researched on the working process of several designers when they were doing healthcare service design. The research involved 14 graduate students from College of Design & Innovation, Tongji University. They already have fundamental knowledge on user study and have basic understanding on service design, and are familiar with mainstream design methods such as design thinking, user-centered design, etc. They have experience in several kinds of design projects but are not experienced in healthcare service design area.

Within two months, the students were assigned a task to improve a local hospital's service including registration, physical therapy, transfusion, inpatient care, etc. Each student focused on an individual project with research and design, and they shared their progress regularly. The authors studied their design process by observation and interview.

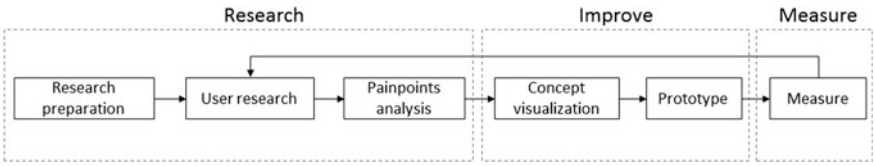

Fig. 4 Students followed three stages, which can be divided into five steps, in there design work

In general, the design students applied service design method in their working process, with three stages of work: research, improve and measure (Fig. 4). More specifically, the process can be divided into five steps: research preparation, user study, pain-points analysis, concept visualization, prototype and measure. This process fits the basic framework of service design well and the existent service design tools can be used.

4.1 Research

The stage of research includes research preparation, user study and pain-points analysis. The design methods used are field observation, desk research, interview, questionnaire and brainstorming.

In the research preparation phase, the initial focus of most students was the experience of patients, while 4 of them paid attention to that of the doctors and staff more at the beginning. Only one student considered the safety standard. During the investigation to find out valuable research questions, almost all designers met the problem that the doctors and staff were not ready to cooperate. One reason might be that they were too busy at work and had no time of break. Another more probable reason might be that they did not value the designers' work with professional outcomes.

For user study and pain-points analysis, designers mostly used storyboard and journey map to find out and organize touch points and pain-points. But they did not have effective method to analyze and filter pain-points which were meaningful for further design improvement. Most of the designers would rely on their personal experience and some benefit comparison to decide on the main direction of design, or discuss with more experienced designers for help. The analysis and selection of pain-points are important but are not well handled in the service design process.

4.2 Improve

In this phase, the designers were trying to integrate users into design with the intension of co-design by referring to the experience of doctors and patients because the designers usually lack knowledge on healthcare practice. Common methods are

user interview, expert interview, brainstorming, etc. They also use visualization tools such as blueprint, system map, to communicate with users. The authors found that about a half of the designers were using non-medical products and service as their design object, probably because of their unfamiliarity with requirements on healthcare design, with too much concern on some unnecessary entertainments. For example, one designer tried to introduce a high-end customization and gamification to physical examination, which might be an inacceptable solution due to the limited resources. Still worse in this case was, this idea destroyed the doctors' trust in design and made the cooperation even harder.

4.3 Measure

As a continuous optimization approach, service design is open with measure to evaluate the design outcomes to find improvement potentials for furthering in the next stage.

In this case, designers made a rough evaluation through experts' feedback and interview responses many times during the design (Fig. 5). However, as there were no existent clear criteria for the evaluation, the evaluation could hardly have expected objective results to provide solid support for the designers to go on the next steps. Also, the hospital could not make some changes in its routine activities without evidences to show the service improvement based on comparison between the existing design and the designers' work finished. This is surely not acceptable for the implementation and promotion of healthcare service design in practice.

Fig. 5 In this case, designers made a rough evaluation with experts' feedback and interview responses

Through the research on designers' work and methods they used for the healthcare service design, the authors found that the main methods are from service design sector and is EBCD alike. No designer used the FMEA method to analyze and evaluate the design issues related to safety. According to the interview with these designers, they almost all think that FMEA could be applied in the user-oriented design process. They even had the thought that the FMEA was against the way of design thinking with the limitation of the open mind to a very specific design issue. However, they also thought that it would be valuable for designers to adopt the FMEA as a reference for them to handle some critical issues in healthcare service design process.

5 Discussion

From our point of view, mitigating risk and improving user experience should not be divided in healthcare service design. However, the current practice shows that safety design and experience design is clearly separated. For the use of those widely applied methods in service design, designers always focus on user experience improvement, but pay little attention on safety standard in healthcare environment. The FMEA, as a quantitative and function-oriented method, is unfamiliar for the designers, therefore is not applied by now in most cases. As a consequence, the design solutions proposed by service designers' would often be evaluated as irrational or even could destroy the belief of healthcare industry in design. The development of healthcare service in this area might be hindered too.

Based on this understanding, in order to improve healthcare service design, the authors propose a possibility that combining safety map based on FMEA and experience map from EBCD to create a new tool. The tool is intended to be used mainly to support touch-point exploration and evaluation. The steps are:

- *Step 1*. Observe the service system from a holistic view. Draw a care journey map with the information of touch-points and relevant users. The first line of the map is about touch-points in care service, and the second line is about users who involved in the corresponding touch-points (Fig. 6). This map could not only show the whole service process but also show the activity of different user

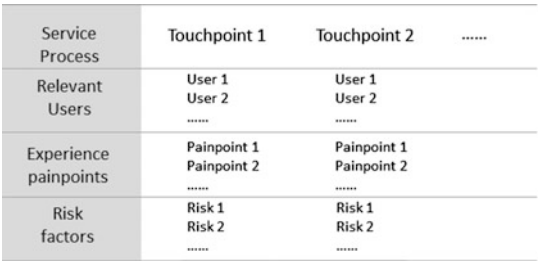

Fig. 6 Care journey map integrated with risk analysis

Fig. 7 Designers are using storyboard and journey map to organize touch points and pain-points

groups. This step could help designer understand the complex and professional service from a whole perspective, and plan next working steps rationally.

- *Step 2*. Do users study to explore pain-points on experience, and interview experts to identify potential risk factors involved. List this information on the care journey map (Fig. 7). This step could help collecting and showing various factors in one map clearly.
- *Step 3*. Evaluate user emotion and risk factors of each touch-point by using methods from EBCD and FMEA. Show the results in a coordinate axis, which abscissa is intended to show risk and ordinate is to show experience (Fig. 8). With this tool the touch-points distributed in first quadrant with the highest priority tasks could be clearly shown. Secondary priority tasks are those touch-points distributed in second quadrant and fourth quadrant. Touch-points

Fig. 8 Coordinate system to show risk and experience issues together

in third quadrant are in current way relatively good enough therefore do not need immediate concern when resource is limited.

- *Step 4*. Designers, users and experts could discuss this map and make improvement plan easily and rationally. Meanwhile, this tool also could be applied in design measure to help evaluating the improvement of each touch-point.

The tool combining safety map and experience map might have several advantages. At first, it could help designers recognize the importance of balancing user experience and safety requirement in healthcare service design. Secondly, the tool could collect complex and detailed factors in service design more efficiently. It evaluates priority of touch-points based on user experience and safety analysis, and visualizing the priority in a coordinate axis. With this way, it might help designers to communicate with other healthcare staffs and users effectively and efficiently, which is very important to form an efficient cooperation environment in design.

By now, this tool has been under refinement to plan to use in practical projects by designers at D&I of Tongji University. It provides very good basis for designers to further the service design in a more rational way. After improvement, the tool is definitely very useful in future research.

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An Assessment on the Level of Knowledge of Biosecurity Measures in the Academic Environment

Berla Moreira de Moraes, Adílio Moreira de Moraes, Betanea Moreira de Moraes and Vanessa Mesquita Ramos

Abstract Students are susceptible to a number of risks of illness and accidents during the professional learning process. This study had as objective to assess the level of knowledge of biosecurity protection measures of students at an occupational therapy course. Using the field research method, data were collected by means of a questionnaire on biosecurity, means of protection and immunization. The sample consisted of 62 students. We obtained the following results: 64 % knew the term 'biosecurity'; 43.55 % reported hand hygiene as a means of protection; 37.1 % used personal protective equipment (PPE), and only 16.13 % reported immunization as a means of protection. With this study, it became evident that adhesion fell short of the measures necessary to protect the student, and the need for the inclusion of the biosafety topic in the professional training process.

Keywords Biosecurity · Preventive measures · Occupational therapy

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1 Introduction

Biosecurity is an area of knowledge, which is understood today in two manners: first, concerning genetic material handling processes and the possible consequences to human and environmental health, and research on embryonic stem cells [1]; and the latter, to the events generated by chemical, physical, biological, ergonomic and psychosocial agents in the occupational health field, and laboratory environments in general [2].

Our focus is emphasized on the second manner of contemplating biosecurity. With the evolution of medicine and workplace safety agreed upon in the Occupational Health Protection Standards, undoubtedly, biosecurity becomes a basic discipline in the academic environment, which suggests a broader approach to overall security for students, teachers, and technical or administrative staff, since they are all involved in university work, teaching and research, as well as providing health services. In this context, the term 'biosecurity' is adopted as the science aimed at controlling and minimizing the risk arising from the practice of different technologies, whether in the laboratory or in the environment [3].

This prerogative is strengthened with the Regulatory Standard 32 (NR32) from the Ministry of Labor and Employment, establishing guidelines for the implementation of measures to protect the health and safety of workers and specifying what is understood as health services:

> Establish basic guidelines for the implementation of safety and health protection measures for health service workers, as well as those in positions of health promotion and care activities in general (…) For the purpose of this NR, health services are understood as any building for the provision of health care to the population, and all actions of promotion, recovery, care, research and teaching in health at any level of complexity [4] (Our translation).

Protected by the referred regulatory standard and recognized as a health category, the training of occupational therapists follows the parameters of the curriculum guidelines proposed by the National Council of Education, and the Ministry of Education and Culture; Paragraph 5, item III highlights that one of the responsibilities of the occupational therapist is:

> to recognize health as a right and act to ensure comprehensive care, understood as an articulated and continuous set of actions and preventive and curative services, individual and collective, required for each case in all levels of complexity of the system [5] (Our translation).

By being involved in several contexts of complexity in health and direct contact with the patient, the professional and the occupational therapy student are exposed to variable levels of risk, especially biological risk, which is inherent to all health professionals. For biological risk, the transmission of infectious diseases of microorganisms to patients and professionals is through direct contact between the patient and the professional [6].

Another important source of contamination refers to direct contact with body fluids while performing non-invasive procedures (during training activities of daily living) or through manipulating items, clothes, garbage and even contaminated surfaces, without the use of biosecurity measures [7]. Hence, the importance of biosecurity, which applied in the academic environment, corresponds to the adoption of standards and safe and adequate procedures to maintain the health of patients, professionals, students and visitors.

With occupational therapy students/professionals being susceptible to various risks of illness and accidents, the most effective mechanism of protection is offered by personal protective equipment (PPE). These are made up of cap, goggles, mask, apron, shoes and/or sneakers for the entire work team. For infection control to be more effective, the entire group must interact and be duly informed and vested, so that the aseptic chain is not interrupted at any time [8–10].

As with PPE, vaccination is considered one of the most important measures to prevent the acquisition of infection. Vaccination against hepatitis B (HBV), rubella, mumps, tetanus and influenza has been recommended for all health professionals, as well as students, who should preferably be immunized before their first contact with risks, in other words, at the beginning of the course [11].

The academic environment, either in the teaching or research laboratory or in the hospital or other medical facilities, is a place of constant learning for both teachers and students. Being in harmony with the work environment is essential. Prevention or reduction of risk of occupational disease through exposure to various agents, present in the academic laboratory environment, can be achieved by means of safe practices and measures that seek to preserve health and the environment.

The objective of this study is to analyze the level of knowledge of occupational therapy students with regards to biosecurity, and to identify their main demands in relation to knowledge on prevention and health protection in academia: hand hygiene, the use of PPE, and immunization.

2 Methodological Description

This paper presents part of the results of the research activities from the Extension Project: Biosecurity at the Department of Occupational Therapy and other areas of health. The rationale for the study consisted of literature review and field research with a defined universe. Data were collected by means of a self-complete questionnaire with 14 questions (open and closed), on biosecurity/prevention measures answered by students from occupational therapy degree course (Chart 1).

2.1 Sample and Bioethical Control

The sample consisted of 62 students from the 1st, 2nd, 3rd and 4th semesters, corresponding to the first two years of the graduation program. To start collecting data, the students were properly instructed on the objective of this study and appropriate ethical clarifications, ensuring anonymity; they were requested to sign the free, prior and informed consent, and then to respond the questionnaire on the concept, level of knowledge and biosecurity-related risks, as well as means of prevention related to biosecurity: hand hygiene, use of PPE, and immunization.

2.2 Data Collection Procedures

The questionnaire was applied in written form by 06 students linked to the referred extension project, properly guided by the coordinating teacher of the project, in the classrooms of the 04 occupational therapy graduation course classes without any interference from the applicants, with a time of 15 min to answer the questions. The questionnaire was applied in 04 days, one day for each graduation course class. Data were tabulated in Excel spreadsheets and the results analyzed with emphasis on the theoretical framework of biosecurity and prevention measures. As this course was in the implantation phase, it was not possible at the time, to conduct a comparative study of students in the last two years of the course, as they did not exist (Table 1).

3 Results

Results presented according to data obtained from questionnaires given to 62 students attending the first two years of the graduation program in occupational therapy, which represents 74.8 % of all students enrolled.

Of the students participating in the study, 25 % belong to the first semester, 25 % to the second semester, 25 % to the third semester, and 25 % to the fourth semester.

The predominant age group of occupational therapy students was 18–21 years, representing 73 % of the entire sample, followed by the 22–30 year age group (13 %). The less than 17 year age group accounted for 5 %, while the 31–40 year, the 41–50 year, and the 51–60 year age groups accounted for 3 % each.

Of the 62 participating students, 90 % are female, while 10 % are male.

Table 1 Questionnaire used in the study, addressing knowledge of biosecurity, means of protection: hand hygiene, personal protective equipment and immunization

1. Do you know the term 'Biosecurity'? ( ) yes ( ) no
2. Biosecurity aims to:
   ( ) Minimize risks
   ( ) Eliminate risks
   ( ) Prevent risks
   ( ) Preserve the environment
   ( ) Preserve the health of people/animals
3. What risks is biosecurity related to? ( ) Biological ( ) Chemical ( ) Ionizing radiation ( ) Physical ( ) Ergonomic ( ) Waste ( ) Accidental
4. Where did you acquire knowledge about biosecurity? ( ) workplace ( ) school ( ) faculty ( ) other: _____
5. How did you acquire knowledge about biosecurity? ( ) training ( ) lecture ( ) book ( ) magazine ( ) Internet ( ) others: _____
6. What means of protection do you use in your practice at work/in your studies? ( ) hand hygiene ( ) use of personal protective equipment ( ) immunization

With regards to hand hygiene:

7. You practice hand hygiene: ( ) before your practice at work/in your studies ( ) after your practice at work/in your studies
8. What do you use to perform hand hygiene? ( ) water ( ) soap ( ) alcohol

Use of personal protective equipment (PPE):

9. Do you use PPE? ( ) yes ( ) no
10. Which PPE?
11. How often do you use PPE? ( ) never ( ) sometimes ( ) always

Immunization

12. Are you up-to-date with your vaccinations? ( ) Yes ( ) No ( ) Do not remember
13. For your work/studies, what is the importance of vaccination? ( ) Important ( ) Little importance ( ) Not important
14. Cite which vaccines you consider important:

3.1 Knowledge of Term 'Biosecurity'

When asked about knowledge of the term 'biosecurity', 64 % said they knew the term, while 36 % stated that they did not know it. Biosecurity is inserted into graduation programs in the areas of health as a proposal to change the paradigm facing the need to adapt to health and safety questions in the workplace, according to Regulatory Standard 32. Although the course of Occupational Therapy in UFPB is in its fourth semester, and it does not have a specific discipline on the subject in its course curriculum, the results obtained here are considered satisfactory.

Biosecurity Objectives according to Students' Knowledge. When asked about the objectives of biosecurity, 51 % of students reported risk prevention, followed by 28 % for risk minimization, 11 % for the elimination of risk, 6 % for

environmental preservation, and the other 4 % of students for human and animal health. Given these data, the priority association between biosecurity and risk prevention is considered important since the course curriculum contains no specific discipline on the subject; the student probably makes this association due to the fact that the occupational therapist in his/her practice evaluates, prevents and treats individuals who through dysfunction of physical origin, and/or mental, and/or social, and/or developmental present alterations in their functions, with the goal of promoting health and quality of life.

Students' Level of Knowledge Level on Biosecurity Goals. Of the students interviewed, 81 % had an insufficient level of knowledge on the objectives of biosecurity, while 18 % had a regular level, and only 1 % presented good knowledge. Although most students knew the term 'biosecurity', these data show that their level of knowledge is insufficient, showing the need for a systematic approach to the subject in the course curriculum, as well as offering an elective discipline.

Risks Addressed by Biosecurity according to the Students and the Level of Familiarity of Those Risks. With regards to biosecurity-related risks, 20 % of students characterize the risks as accidental, 18 % as chemical, 17 % as biological, 15 % as physical, 12 % as ergonomic, and the other 9 % with waste and ionizing radiation. Analyzing the results, although there is a relatively equal distribution, 50 % of respondents had an insufficient level of knowledge of the risks addressed by biosecurity, while 23 % had regular levels and 27 % presented good knowledge, which reinforces the need for theoretical and practical deepening of the theme.

Where and How the Students Acquired Knowledge of Biosecurity. When asked where knowledge about biosecurity was acquired, 62 % reported in college, 16 % elsewhere, 15 % at school, and 7 % acquired their knowledge in the workplace. And when they were asked how the knowledge about biosecurity was acquired, 31 % reported it getting over the Internet, 31 % in other manners (such as in the classroom), 21 % in lectures, 9 % in books, 7 % in magazines, and 1 % from training. This result warns that while the primary place of learning of biosecurity is the college, this number is considered small, with regards to the role of the institution in training professionals that will be directly in touch with risks in their work practice.

3.2 Means of Protection Used in Practice

Of the students interviewed, 43.55 % answered that they sanitize their hands in their practice at work/in their studies, 37.1 % use PPE, 16.13 % considered immunization as a form protection, and 3.23 % did not respond. This result shows that most of the students associated protection to hand washing, as it is probably the most widespread method. A large percentage also considered the use of PPE as a method of protection, probably because such practice is already part of the daily lives of students, who already use PPE in the laboratory as of the first semester of

the course. But only a small portion considered immunization as a protective measure, which demonstrates a lack of knowledge on the issue, thus requiring additional information that can be incorporated through lectures and vaccination campaigns together with these students.

Hand Hygiene. Of the students interviewed, 48.39 % said they performed hand asepsis before and after their practice at work/in their studies, 40.32 % after their work/or studies, 6.45 % before their work/or studies, and 6.45 % chose not to answer the question. This result showed that most of the students knew the hand washing procedure, as well as the need for this measure to be performed before and after the practice of teaching and research, but a considerable percentage only referred to the importance of hand washing after activities, which does not demonstrate a lack of knowledge, but a situation of neglect regarding this procedure.

Hand Hygiene Procedure. With regard to the products used for hand hygiene, 45 % said they used soap and water, followed by 26 % who used water, soap and alcohol, and 15 % who used water, soap, alcohol and a degerming solution. We have also obtained as results that 8 % of students reported using only water and 6 % used only alcohol in the hand hygiene procedure. This result showed that most of the students used cleaning products to wash and disinfect their hands, but a small percentage used only water or alcohol demonstrating neglect in the use of products, which was not caused through a lack of knowledge.

Personal Protective Equipment Used in the Academic Environment. Regarding the use of PPE, 75.81 % chose to use PPE, 19.35 % do not use any equipment, and 4.84 % did not to answer the question. Among the personal protective equipment commonly used in the academic environment, the following were cited: gloves and mask (16 %), lab coat, gloves and mask (11 %), gloves and lab coat (11 %), gloves, mask and closed shoes (6 %); it is important to point out that 52 % did not express their opinion. This result showed that although most students reported using PPE, it suggests that most students do not consider the lab coat as protective equipment, but just as common laboratory clothing. The use of the gloves and the mask was remembered because these students, as of the first semester, have been studying disciplines that require their use (in the anatomy laboratory). However, equipment such as cap and goggles were not among the most frequently cited, since they were not part of the routine of these students or they had not been informed on their importance during academic activities in the laboratory and/or clinical visits.

Frequency of Use of Personal Protective Equipment. When asked about the frequency of use of PPE, 30.6 % answered that they always use them, 33.8 % sometimes use them, 22.5 % said they never use them, and 12.9 % did not express an opinion. This result demonstrates that the frequency of use of PPE is reduced, which may suggest insufficient knowledge on the safety standards and the risk of contamination in the academic environment.

Student Immunization as a Protective Action. When asked if they were up-to-date with their vaccinations, 61 % of the students reported that they were, 23 % could not remember, and 16 % said that they were not. From these data the

number of students not immunized is considered worrying, since from the first semester of the course, they are inserted in laboratory practices in disciplines such as anatomy and histology, and they visit such places as hospitals, clinics, and out-patient centers, and therefore they are exposed to risks.

Importance of Immunization in the Academic Environment. When asked about the importance of vaccination in their study environment, 88 % responded that it was an important means of protection, while 8 % said it had little importance, 2 % answered that it was not important, and 2 % did not express their opinion. A small portion of students considered that vaccination had little/no importance in their study environment, which demonstrates a lack of information on the risks that they may be exposed to, thus requiring additional instruction that might be incorporated through lectures and vaccination campaigns together with these students.

Which Vaccines Should be Taken during the Graduation Course. Among the vaccines considered most important for the students, 18 % reported tetanus and hepatitis, 56 % mentioned other vaccines such as H1N1, measles, rubella, rabies, triple, among others, and 26 % did not express their opinions. This result shows that only part of the students associated tetanus and hepatitis as the most important vaccines, although they are among the most cited in the area of health and news media.

3.3 Accidents and Risk of Accidents in the Academic Environment

When asked about involvement in accidents in study environment and if they knew how to proceed in one, 11 % reported that they had been involved in accidents (slipping on stairs, tripping over wires in the room) and they knew how to proceed, 71 % had no involvement in accidents and 18 % did express their opinion. The accidents the students were involved in derived from accidental risks which may be present in the study environment. As well as accidental risk, other risks may be present in the academic environment of occupational therapy students such as biological, chemical, physical and ergonomic risks; in this manner, they are exposed to possible accidents and/or illnesses if there is no further instruction on them, and ways to prevent them, as well as, how to act in case of an accident or illness in the course curriculum.

4 Conclusions

In this study, it was evident that adhesion, by the students of occupational therapy graduation program, falls short of the necessary health protection measures, as recommended by the biosecurity laws.

In general, the students of the occupational therapy course have demonstrated insufficient knowledge on biosecurity, since it was observed that of the 3 protective measures that were assessed, the practice of hand hygiene was the most adopted by students, probably due to the fact that it is the most disclosed in academia.

The application of biosecurity protection measures requires the adoption of instructions recommended by law and the scientific body of knowledge, adopting adequate habits in the academic routine, which is favorable for this course.

However, there are still few data in the literature on the issue discussed here, we hope to contribute to the dissemination of knowledge on this topic and encourage the formation of a consciousness in biosecurity practices, so that the use of universal standards becomes habit in the academic/professional routine of occupational therapy.

Finally, this study suggests the inclusion of the biosecurity topic in the training process of students in order to keep them informed and warned against the various risks inherent in the exercise of their academic and future professional activities.

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Methods to Characterize Operating Room Variables in Robotic Surgery to Enhance Patient Safety

Anthony M. Composto, Luke A. Reisner, Abhilash K. Pandya, David A. Edelman, Katrina L. Jacobs and Tandi M. Bagian

Abstract Surgical team experience is an important determinant of operative outcome. However, even the most experienced team will not be familiar with all potential variability that could be encountered during a surgical procedure. Robotic surgery adds further complexity through advanced technology, additional equipment, intricate process steps, etc. One method that is crucial to understanding a robotic procedure is surgical observation, which can be used to identify the process flow and involved objects. Another method is task excursion analysis, a proactive approach to understanding system variability and key factors that may affect system performance and patient safety. Finally, a method must be used to efficiently present the gathered information to surgical teams. As rapidly evolving technology is introduced into health care systems, the adoption of these types of methods is necessary to ensure patient safety. This paper describes the proposed methodology for analyzing robotic surgery variability and provides some example data.

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Keywords Task analysis · Robotic surgery · Patient safety · Clinical teams · Veterans health administration · Best practices

1 Introduction

Robotic surgery is an advancing technology that has the potential to significantly improve surgical outcomes. However, there are concerns based on outcomes, cost, and utilization. Yu et al. report that high-volume hospitals have better outcomes in terms of fewer complications as well as lower costs for robotic or laparoscopic cases [1]. Chang et al. report that high-volume surgeons were more likely to successfully adopt the technology [2]. It has also been reported that robotic surgery, which may add time and cost to the surgery, has outcomes that are comparable to or better than (shorter stays, less blood loss, lower overall costs, and fewer readmissions) more traditional techniques [3, 4].

There are barriers to the successful use of robotic technology in surgery. Among other factors, there is a learning curve for novice surgical teams. Is it possible to translate the expertise of proficient, high-volume surgical teams to novice teams in a systematic and easily distributable manner? This would effect the safer adoption of robotic surgery, ultimately leading to improved patient safety and efficacy.

This paper outlines a methodology (Fig. 1) for understanding the variability of robotic surgery, creating a common framework through which experienced clinicians can capture and communicate what they have learned. This will help less experienced medical professionals anticipate and detect emerging situations so they are better prepared to provide the patient with critical care. The proposed methods are intended to be broadly applicable to different parts of a robotic (or even non-robotic) procedure. For this paper, we focus on the setup of the robot with respect to the patient. A long-term objective of our research is to create tools that can be used by clinicians for better training and real-time access to best-practice guidelines within the operating room for improved patient safety and surgical outcomes.

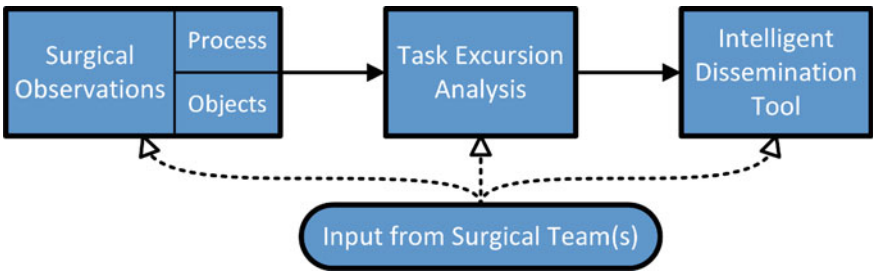

Fig. 1 The proposed methodology for identifying, analyzing, and disseminating guidelines for the variations that may occur during surgical procedures

1.1 Background and Significance

Task excursion analysis (TEA) is a proactive approach developed by the U.S. Department of Veterans Affairs (VA) National Center for Patient Safety (NCPS). The goal is to understand task/system variability and create a framework for capturing information [5]. This method enables the identification and analysis of key factors that have the potential to influence overall task/system performance and patient safety. TEA can be applied to organize surgical observations and to help create a framework that for knowledge documentation and transfer.

Surgeon experience is an important determinant of operative outcome [6]. Similarly, this can apply to the entire surgical team. An experienced operating room (OR) team will have a knowledge of proper room configuration that enables a procedure to flow with a minimum amount of interruptions and the lowest risk to the patient. The added complexity of robotic surgical cases can further confound this issue, especially for teams with less experience [7]. Even if a surgical team has experience with a particular procedure, mitigating factors (such as patient gender, size, weight, or injuries that restrict joint movement) can alter the optimal parameters of the setup for that particular case, potentially causing interruptions or non-ideal robot setups.

It has been suggested that this information can be disseminated through training libraries that identify challenges that can be encountered during a surgery [8]. However, it is also suggested that even the most complete training cannot cover all possible scenarios. Therefore, training should be augmented with tools that allow information to be obtained in real-time as challenges occur [7].

Quality by design, fault tree analysis, hazard analysis and critical control points, prevention through design, and hierarchy of controls are just a few of the tools used in other industries for proactive handling and prevention of undesirable events. These tools have proven so effective in their fields that the U.S. Food and Drug Administration (FDA) has incorporated them into a recent guidance document for both industry and their staff [9].

In comparison to other fields that use these methods, the present level of proactive identification/analysis of preventative measures within the field of robotic surgery is minimal. Currently, there is no organized, effective method of capturing and disseminating this information throughout the health care industry.

The information captured through the proposed methodology will provide a foundation for training and helpful advice for new robotic surgical teams and serve as a useful guide for experienced teams. For example, it has been suggested that the involvement of human error in undesirable anesthetic incidents is between 70 and 80 % and that 60 % of anesthetists do no not follow the recommended check procedure for the equipment [10]. To at least some extent, one can expect similar undesirable practices to exist in other areas. Therefore, creating tools to help reduce preventable harm should have a positive impact on patient safety and overall

surgical outcomes. It has been shown that a system of checks (e.g., checklists) can help reduce variability, errors, and other undesirable events, even for the most knowledgeable of experts [11].

2 Methods

The first steps of the proposed methodology (Fig. 1) are to capture large amounts of data through observations within the OR environment during a wide variety of robotic surgical procedures. Next, the gathered data is grouped into relevant categories and analyzed using task excursion analysis [5]. Finally, the results of the analysis are presented to clinicians in an efficient manner. Each of these methods is described in the sections below. For this paper, our descriptions focus on an example sub-process of robotic surgery: the setup of the robot with respect to the patient.

2.1 Observation of Robotic Surgical Cases

Observing and consulting with experienced robotic surgical teams creates the initial foundation for the proposed methodology. During the observations, information should be captured on OR processes (such as robot setup) and OR object relations (such as tools for the procedure and their locations in the room). In addition, the surgical team as a whole should be observed to learn what they do and how they prepare for a procedure. This should be complemented by interviewing the surgical team to capture their knowledge as well as any thoughts or ideas they have to help further improve the dissemination of the knowledge.

Document the Process Flow of the Procedure (Task Identification). Identifying the process flow of a robotic surgical case is crucial to understanding the steps involved in the entire procedure. At a minimum, the procedures from the time the patient enters the OR to the time the patient exits the room should be documented. The relationships among the processes should also be captured. A partial example is shown in Fig. 2. This data will help identify the possible variations in a procedure so their ranges can be analyzed.

Document the Objects in the Operating Room and Their Relationships. We define the objects in the room as anything physical, such as people, the robot, tables, tools, cables, etc. The objects and their relationships to each other should be documented (Fig. 3). This will help in the identification of the overall layout of the room (Figs. 4 and 5) and the variables that should be examined. Understanding the objects and their physical limits will also ensure that their recommended configurations are physically obtainable by the available equipment.

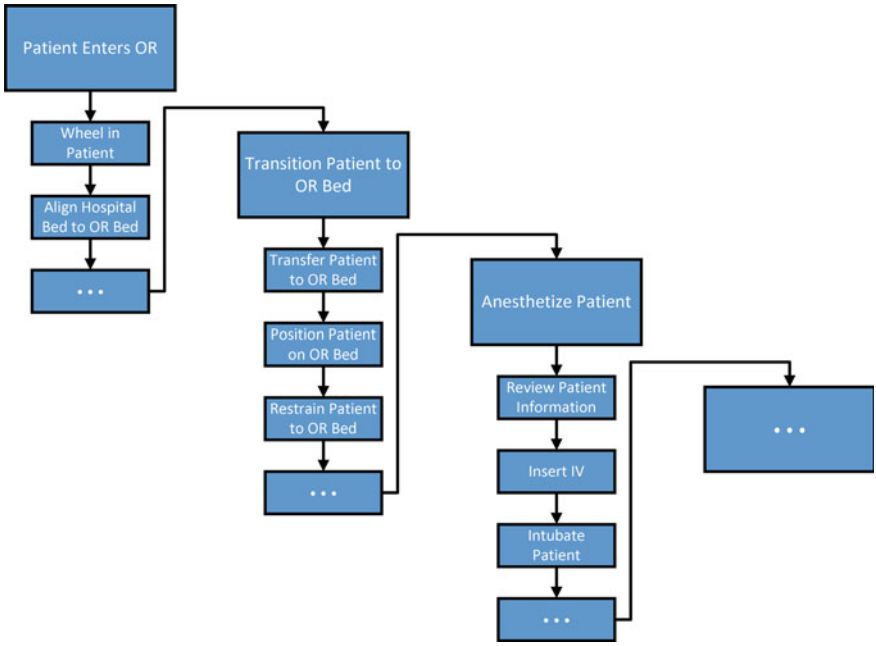

Fig. 2 A partial process flow diagram for a surgical procedure

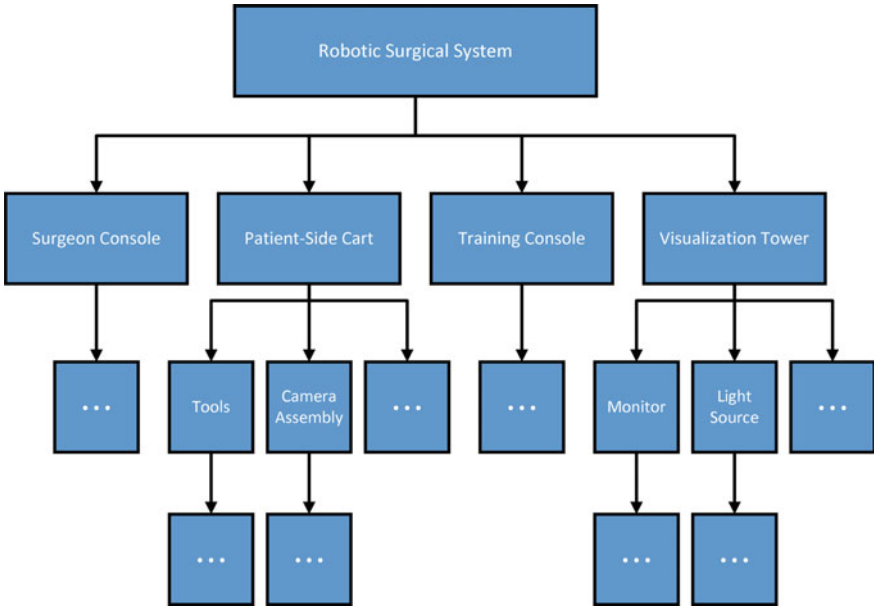

Fig. 3 A partial object relationship diagram for an operating room

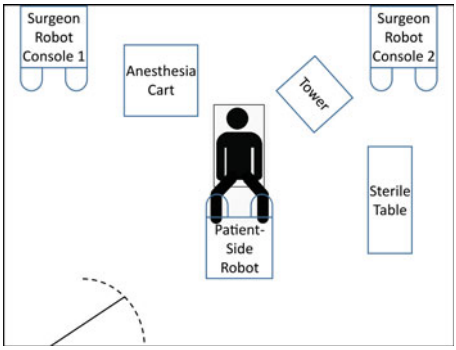

Fig. 4 Surgical robot in the lithotomy position between the patient's legs

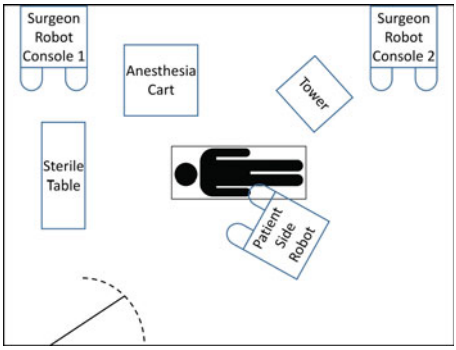

Fig. 5 Surgical robot docked to the side of the patient

2.2 Task Excursion Analysis

TEA [5] strives to combine the human factors technique of task analysis with a formal recognition of the range of interfaces between: (a) the person doing the task; (b) the environment in which the task is being performed; and, (c) the aspects of the task itself. In a task analysis, one divides a process into a discrete sequence of tasks and then analyzes each task for factors of interest. These factors could include potential errors, causes of those errors, the harm associated with each error, or ways to reduce the likelihood or impact of each error.

For individuals unfamiliar with a process, these analyses may be difficult to perform. One might not have the experience to imagine what could go wrong with a step in a process. Consequently, TEA provides a structured approach that focuses on what could **change** for each task element. Some examples include ranges of people (size, strength, training, etc.), ranges of environments (lighting, noise, room size, distractions, etc.), and ranges related to the procedure (size and shape of patient, kinds of tools/equipment, team members, etc.).

The TEA is driven by the information gathered through the surgical observations described in the previous sections. While observing surgical procedures and performing the TEA, it is helpful to have questions in mind that focus the analysis.

For our example sub-process of robotic surgery (the setup of the robot with respect to the patient), we considered the following questions:

- What are the relevant characteristics of the user/environment/task and their expected ranges?
- What are the interactions between user/environment/task characteristics?
- How do the characteristics of the tool/setup align with the user/environment/task requirements?
- Is a tool/setup appropriate for the task goal?
- What use errors might occur?

Identify the Level(s) that TEA Analyses Should Be Performed. A failure mode and effects analysis (FMEA) can be performed on multiple levels of a process/design to capture additional details for a more complete evaluation [9]. There may be a FMEA performed on a component and then another on an assembly that contains that same component. This may also be necessary with task excursion analysis. Therefore, an evaluation of each process, sub-process, or assembly and its objects should be evaluated to determine if a TEA is required. If there is sufficient variability within that area, a TEA should be performed on it.

2.3 Disseminate Results to Surgical Teams

Once the information is captured and organized, it needs to be presented to the OR staff in a meaningful way. A well-designed system will: (a) help facilitate the transfer of knowledge from skilled OR teams to novice teams; (b) accelerate the adoption of safer and efficacious techniques/technologies; and, (c) inform system designers of the challenges and preferences of surgical teams. The authors envision that this will take the form of process-specific training and a real-time OR reference system for best-practice guidelines.

For less experienced robotic surgical staff, the OR reference system should provide guidelines for generic room configuration parameters. On the other hand, experienced team members should not be forced to review what they already know. Instead, only specific case parameters that deviate from the "normal" parameters should be displayed to ensure that they are not overlooked. This can be achieved, for example, by creating a computer program. The program would allow the user to manually input patient data or possibly retrieve it from an electronic medical record (EMR) database. Then the program would provide specific recommendations for the particular patient and procedure.

The proposed system should also allow experts to interact with it to add new knowledge to the system. This would expedite knowledge transfer to other teams with a level of efficiency that is not currently available.

3 Example Use Case

The following is an example of how variations in aspects of a patient's health can lead to differences in the setup of a case. The proposed methodology could be used to analyze such a case so the variables could be anticipated and handled efficiently and safely for the patient. It is hoped that every surgical team can benefit from the lessons already discovered by others.

A 60-year-old male arrives for a scheduled elective inguinal hernia repair. He has a past medical history of hypertension and severe knee and hip arthritis. His past surgical history is negative. He is brought into the operating room and placed on the operating room table. General anesthesia is administered without difficulty. A Foley catheter is placed, and the stirrups are attached to the OR table. When performing a robotic inguinal surgery, the surgeon's preference is to dock the robot in the lithotomy position between the patient's legs (Fig. 4). However, because of the severe arthritis, the patient's hips and knees cannot accommodate this surgical position. Although the lithotomy position is preferred, the OR staff knows that the operation can also proceed with the robot docked to the side of the patient (Fig. 5). The staff now transitions the room to the side-docking setup. This new arrangement has implications with respect to access, anesthesia, sterile-side positioning, and robot positioning, all of which have implications for the surgery.

4 Discussion

Based on the success of proactive quality and safety analysis tools in other non-medical domains, it is anticipated that an appropriately designed and executed system could have the same level of success in robotic surgery. The benefits should include more streamlined room setup and configuration, reduced time to bring novice teams up to expert-level performance, and the ability to share knowledge across the health care industry more efficiently. Each of these benefits alone is notable, but together they have the potential to improve patient safety by preventing undesirable events instead of merely reacting to them [12].

The Computer-Assisted Robot-Enhanced Systems (CARES) research group at Wayne State University is working in collaboration with the VA NCPS to develop a knowledge system for adoption within the VA hospital system. A series of robotic surgical cases have been observed by the group, and the OR processes and objects have been documented. The next steps will be to develop tools for (a) identifying areas in which a TEA analysis would be beneficial and (b) organizing the performance of a TEA. The CARES group and the VA NCPS are leveraging an ongoing relationship with surgeons at the Detroit Medical Center to complete this work. These relationships will allow a comprehensive analysis of robotic procedures and the identification of areas where this system will have the most benefit.

The extensive VA health care system and their participation in this project provide a unique opportunity for initial testing, proof-of-concept development, and potential

future adoption. For this work, preliminary testing of the knowledge system can be conducted at local VA medical centers. Once validated, the system can be expanded throughout the rest of the VA. After being thoroughly scrutinized within this larger environment, there can be efforts to expand beyond the VA network.

Some of the potential obstacles for implementing this type of knowledge system could include resistance from surgical teams, resistance from hospitals, and conflicting information within the database. However, none of the obstacles should prevent the development and testing of the system. If the system is proven to be effective, much of the resistance should subside.

Tools that have been developed to prevent undesirable events (rather than simply reacting to them) have been widely adopted in other fields with great success. We anticipate that a similar methodology of proactive efforts to increase safety and quality should be effective in the field of robotic surgery. In a domain that has the potential to cause such harm to a patient, the adoption of these types of tools could lead to significant improvements in patient care.

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Low-Fidelity Simulation Versus Live Human Arms for Intravenous Cannulation Training: A Qualitative Assessment

Gary L. Boykin Sr.

Abstract In the military, as well as in civilian medical settings, the question of whether to use simulation versus live tissue remains in debate. The purpose of this paper is to examine qualitative data provided by students (n = 260) attending the Army's Licensed Practical Nurse (LPN) program who completed peripheral intravenous cannulation (PIVC) training using either a Simulated Human Arm (SHA) (n = 135) or a Live Human Arm (LHA) (n = 124). Students provided subjective responses in a written format pertaining to their PIVC training method. Data patterns were assessed using Spradley's semantic relationship approach. Results reveal that both those using a SHA and a LHA reported feeling confident following training, however the reasons for their confidence differed. Those using a SHA felt confident due to the opportunity to repeatedly practice on a simulated arm, while those learning on a LHA felt assured knowing they had performed PIVC successfully on a live human during LPN training.

Keywords Simulation · Intravenous infusion · Nursing · Training

1 Introduction

Today's war fighting efforts often occur in highly populated communities where the injured consist of both war fighters and noncombatants. Skilled first responders provide lifesaving medical interventions, stabilize, and evacuate the sick and injured persons to safe zones. Military students preparing to become Licensed Practical Nurses (LPN) are trained in lifesaving techniques for clinical and combat environments. Peripheral intravenous cannulation (PIVC) for intravenous (IV) therapy is a signature skill for military nursing students. However, training to proficiency can pose challenges. Historically, this invasive procedure has been taught using live anatomy via peer-on-peer training methods (R. Jones, personal communication,

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May 10, 2010). Such training can be costly due to materials being contaminated after each use e.g., needles. In addition, peer-on-peer training methods can cause bruising, possible infection, or a stress related reaction among students [1, 2]. An alternative training method is the use of a simulator that reflects the characteristics of human arm anatomy. PIVC training effects using simulation among 260 Army LPN students were examined by Jones and colleagues [3], with results indicating no significant performance differences for first attempts between PIVC training using low fidelity simulation versus the use of a human arm [3]. That is, either method was equally effective in preparing LPN students to transition to real-world medical scenarios. However using a Simulated Human Arm (SHA) for training PIVC may reduce adverse incidences that could occur when performing the procedure on a Live Human Arm (LHA). The focus of this report is to evaluate students' self-reports of their learning experiences with a LHA or a Simulated Human Arm SHA. The prior findings (no difference in instructor ratings of student performance following training using the two techniques) may be further examined and explained by evaluating students' training insight.

2 Literature Review

Recent studies have shown how simulation has been used for numerous occupational specialties in both military and civilian sectors as an augmentation to live training [4, 5]. Notably, simulation is used for training in operating rooms and emergency and trauma departments [6–8], and its use has been shown to be an effective method for assessing training, practicing, and learning medical skills [9–11]. Functionally, in medical settings, simulation allows students and practitioners to perform routine and life threating procedural skills using creative training scenarios without causing risk or injury [9, 12, 13]. Low fidelity simulation has less exactness, while high fidelity simulation is closer to the real thing [9, 14]. Determining the level of fidelity to use is often based upon the skill and level of the training task [14]. The realism of simulation has shown to improve cognitive responsibility among medical practitioners [15], as advanced simulation devices, such as virtual reality (VR) mimic live anatomy and physiological functions [9, 16]. In addition, VR training for PIVC has been shown to reduce time and errors [17]. Savage and colleagues [18] reported no significant performance difference between high fidelity simulators and live tissue among military medical technicians. Lower fidelity medical simulation is believed to be less engaging to the end user because, proportionately, it lacks realism [5]. Nevertheless, frequently, low fidelity anatomical arms are used to train medical students to perform PIVC [13]. In fact, one study found no PIVC performance differences for training medical students using a plastic arm versus a high fidelity virtual reality (VR) simulator [13]. Similarly, de Giovanni et al. [19] examined the effectiveness of using low versus high fidelity simulation (CD recording versus heart sound simulator, "Harvey simulation", respectively) to evaluate students' ability to distinguish heart sound. They concluded no significant difference between the

training groups ("CD group = 48 %, Harvey group = 44 %; F = 0.05, P = 0.82"). In general, the U.S. Military uses new and improved medical simulation for training service members to performed routine and advanced medical tasks in mock combat environments [20, 21]. It is believed that simulations will be much more advanced in healthcare in the years to come [16]. However, currently, there is little information reported on how military LPN students perceive the use of low fidelity simulation for PIVC. The use of survey response data can provide an abundance of information concerning students' level of knowledge and personal feedback during medical training [12]. A study conducted in 2011 by Carr et al. [22], evaluated medical students' (interns) aptitudes and attitudes related to peripheral intravenous cannulation. Their research identified through student survey responses to fill-in the blank and closed questions, significant information about students' vein puncture, anatomy, and procedural task knowledge. They were also able to determine levels of confidence for performing PIVC by asking students a scaled confidence question. They reported significant results for students' confidence in performing IV cannulation versus the number of PIVCs performed ("$p = 0.002$"). These findings are important, as they provide meaningful insight for clinical instructors and program developers. The purpose of this paper is to examine Army LPN students' open responses regarding their PIVC training experience using a LHA or a SHA.

3 Methods

3.1 Procedures

Two hundred and sixty students (5 classes) attending the U.S. Army's Licensed Practical Nurse course were randomly assigned to train PIVC procedures on either a LHA (group 1, n = 124) or SHA (group 2, n = 135). All students received instructions and training according to their randomly assigned group. First, they watched a PIVC instructional video lasting approximately 12 min that offered detailed information on how to properly perform PIVC procedures (step-by-step). The video was projected on a large screen ($\sim 10' \times 8'$) in a pre-designated classroom ($\sim 42' \times 30'$) with all students seated in chairs and facing towards the screen. Any student identified as having a visual impairment due to their distance from the screen was allowed to move closer. A live certified nursing instructor was present to answer questions and to provide clarity to any ambiguous information rendered in the video. Second, after viewing the training video, and in the presence of a nursing instructor (1 to 1 ratio), students were allowed to practice the PIVC procedure for one hour using another student's arm (LHA) or a Laerdal® SHA, depending on

their assigned training group. The instructor then guided the students through the PIVC procedures and again answered any questions regarding the task.

Following training, all students independent of training group, were tested and graded on PIVC procedures using a LHA. Testing was based on pass/fail standards. The training instructors scored each procedural task using a 14-point evaluation form. Students were allowed up to three attempts to successfully complete the critical PIVC tasks (some tasks were not critical), for example, securing the IV tubing. However, in order to receive a passing score, nine of the fourteen tasks had to be completed in accordance with the training standard. Figure 1 shows a PIVC training and testing station with the SHA. As previously mentioned, the results presented in this paper are the qualitative feedback responses from the students received as a part of a larger study [3], where there was found to be no significant difference between students training with a LHA or SHA ($p < 0.05$).

3.2 Instrumentation

Survey: Students completed a basic demographic questionnaire including gender, race, education, and military enlistment status. In addition, a section of the survey allowed students to openly describe their personal perspectives relative to post training and testing with either the LHA or the SHA ("please indicate below additional comments").

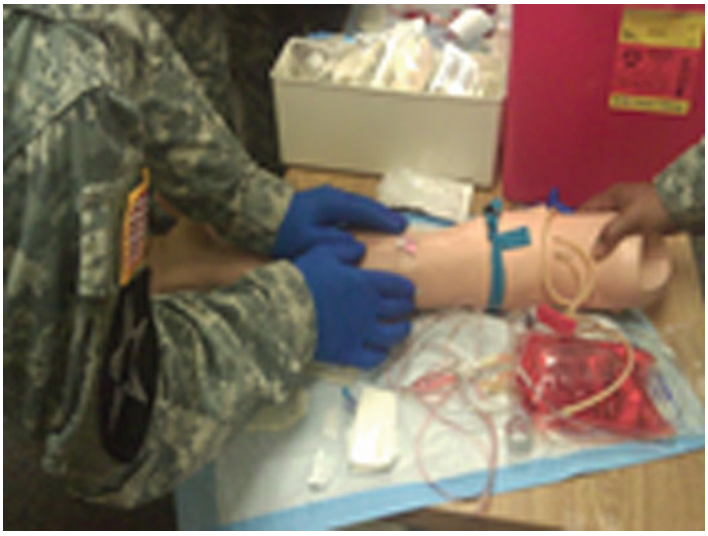

Fig. 1 PIVC training and testing station with simulated human arm (SHA)

3.3 Software

For this report, Microsoft Excel 2013 was used to prepare and manage demographic and student response data, construct categories and pinpoint trends.

3.4 Data Analysis

Qualitative analyses and taxonomy categories were obtained using Spradley's (1979) semantic relationship. Spradley's approach to qualitative content establishes rules to identify patterns of likeness [23]. Items that are similar in nature are applied to a standardized rule. For example, X is a reason for Y (classification). Students' written responses (sentence or paragraphs) were entered verbatim into a Microsoft Excel 2013 database and specific words or phrases were identified e.g., "ability to practice" or "very good for equipment familiarization on live patients", thus developing specific subcategories. Once the subcategories were established, words or phrases were then coded with a number one and tallied to gain a response percentage. Aggregate subcategories were used to establish taxonomies.

4 Results

Students (n = 260) in this cohort were largely male (n = 85, 61 %) and on active duty (n = 71, 52 %). Table 1 provides more detailed demographic information. Although there were a large number of participants that completed the study, less than half of the students (41 %) provided open responses (n = 58 SHA, 47 LHA). The data analysis led to two taxonomies: (1) Confidence and (2) Competence for each training group. Tables 2, 3, 4 and 5 show individual items and taxonomies. Benefits of simulation and live training for PIVC skills between both groups

Table 1 Demographic information

Demographic category	Frequency	Percent[a] (%)
Mean age and standard deviation: 27.86 (6.47)		
Gender		
Male	85	63
Female	50	37
Military status		
Active	71	52
Reserve	64	47
International	01	0.7

[a]Due to rounding, not all percentages will add up to 100 %

Table 2 Confidence taxonomy items for students in SHA group (using X is a reason of Y)

Individual items (X's)	Percent of comments
Ability to learn new equipment	29%
Ability to practice	63%
Prior medical experience	9%
Training environment Task repetition	18%

Table 3 Confidence taxonomy items for students in LHA group (using X is a reason of Y)

Individual items (X's)	Percent of comments
Ability to learn new equipment	35%
Ability to practice	46%
Prior medical experience	12%
Use of live anatomy[a] Human responses[a] Task completion satisfaction	42%

[a]denotes categories unique to this group

appeared to offer a sense of reassured confidence and competence. The reasons stated for their confidence and competence had similar, as well as differing rationale.

Twenty-nine percent of the SHA group responses were related to equipment familiarization and 63 % were related to the ability to practice. For the LHA group, equipment familiarization responses equaled 35 %, and 46 % of the responses were geared toward practicing. A participant in the SHA stated "Practicing always build my confidence". Eighteen percent of the participants receiving training in the SHA appreciated the opportunity to make mistakes and correct training deficiencies (repetitiously) in a less stressful environment and without causing pain to the recipient. One student commented the SHA was "a good training method for those with less experience." However, 12 % of the participants in the SHA mentioned the LHA might have been a better choice for training PIVC due to the live anatomy.

Table 4 Competence taxonomy for students in SHA group (using X is a reason of Y)

Individual items (X's)	Percent of comments
Equipment familiarization	29%
Ability to practice	63%
Task completion satisfaction	18%
Prior medical	9%
Combat tour of duty	

Table 5 Competence taxonomy for students in LHA group (using X is a reason of Y)

Individual items (X's)	Percent of comments
Equipment familiarization	35%
Ability to practice	46%
Task completion satisfaction	18%
Prior medical	12%
Combat tour of duty	

Participants in both groups that had greater command of the PIVC tasks via prior combat or clinical medical experience (9 % SHA and 12 % LHA respectively), also appeared to have improved confidence and competence after completing the PIVC testing. A participant in the LHA group commented, "Multiple combat tours made this too easy, but it would be helpful to the new nursing students". A student in the SHA with prior clinical experience stated "very good for familiarization".

Completing the PIVC training on a live human increased student confidence in that human reactions and emotions of the 'patient' could be gauged (42 %), whereas this was not applicable to the SHA group. Participants who were less

experienced or did not completely understand how to perform each step of the PIVC task mentioned that the simulated arm made them feel more comfortable in performing the skill (17 %). "I believe using the simulated arm is a good tool for first time users," a student remarked.

Some responses were not categorized for example "Hooah," "Super," or "Thanks." Therefore, only comments that fit a specific theme were tallied. There were several negative comments such as "The training video was outdated", "instructions were too easy to follow" or "The needle design was not good", etc. These comments were categorized as "other" and equaled less than 3 % of the total responses.

5 Discussion

Live tissue training is often considered optimal for training medical students. However, an established alternative is to train with simulation that offers the look and feel of real anatomy. Thus, simulation is an invaluable training adjutant. In many instances, Army nursing students are receiving medical training for the first time. Therefore, training with live human subjects may be an intimidating experience, especially when invasive procedures are required. These results support that premise, noting students' comments on their ability to repeat their practice without concern about another human and their 'practice peer-patient'. Fears can emanate from thoughts of making procedural mistakes or causing pain during peer-to-peer PIVC training. Moreover, those fears could alter their performance (i.e. hands shaking) and lead to personal injury. However, the need to train on live patients is conceivably necessary for nursing students before interfacing with real world patients. Therefore, it is a reasonable assumption that the need for training with live humans is an appropriate confidence builder as military war fighters train as they fight. This was demonstrated from student comments in the LHA group mentioning the use and feel of live anatomy, receiving feedback from their 'practice peer-patient', and their increased confidence. It should be noted that receiving feedback from their peers who are acting as a patient is quite valuable, as they will assuredly receive feedback from their future patients. Knowing how to respond to these comments and expressions of pain or fear is a skill in itself. Time to training completion of PIVC tasks for students that have difficulties grasping the concept or needing to refresh diminished skills is an important factor and could benefit from using the SHA first, before live PIVC attempts. Students that do not require such (those with prior experience), may still benefit through familiarization of newly developed medical equipment.

Both training methods were effective [3] and both instilled confidence and feelings of competence. These results reveal additional information not gained during the effectiveness study. The SHA group had a greater percent of their comments revealing their feeling competent and LHA group had a greater percent of their comments revealing feeling confident. The SHA group gained confidence and competence through their ability to repeatedly practice without concern for

hurting another person, while the LHA group gained confidence and competence using live human anatomy and the feedback from their peer-patient. In both cases, students learned the task.

Therefore, the question of use may reduce to 'cost'; both material and training costs. That is, simulation use embraces a training environment in which repetition of practical application is used in conjunction with the same equipment (used repeatedly by many students), thus diminishing the cost of equipment and the potential cost of injury or infection. Conversely, training with live patients requires the expenditure of equipment and supplies after each training episode (ex. needle replacement). However, this method may decrease possible fear-induced poor performance the first time a student performs the task on a live patient, and affords the student a better repertoire for responding to patient comments. A reasonable approach would be to use simulation training up to the point where students are confident in performing the procedure and are less apprehensive in terms of performing the procedure on a live human. At that time, LHA training may be introduced. It would be expected that this would take fewer attempts to achieve the task, thus reducing equipment costs and the possibility of bruising or infection due to their prior simulation practice.

6 Limitations

The primary limitations for this study was that not all students responded to the section of the questionnaire pertaining to the open responses. Future studies might emphasize the importance of student's completing the qualitative (personal experience) portion of the survey.

7 Conclusions

The intent of this paper was to acquire students' perceptions of using a simulated human arm and live human arm for training and testing PIVC. While the results show benefits of each, perhaps the answer is not "either/or". The optimal training method may be a combination of the two training methods to yield the most positive results for students and their patients. Students could practice repeatedly, without fear of hurting another person, using the simulator and once they feel competent and confident of their abilities, they could then practice on one another to get the feel for doing the procedure on live human tissue. They were also able to receive the verbal and non-verbal feedback from their 'peer-patient' that is also important preparation for their working with future patients. In addition, this alternative appears to be cost effective, as the live tissue training would be expected to be shorter in duration, thus reducing the expendable supplies used.

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Part V
Medical Device Design

Improving the User Experience of Medical Devices with Comparative Usability Testing

Anneliis Tosine and Hala Al-Jaber

Abstract A comparative usability test is an evaluation that helps to determine how a particular product performs in relation to similar products by having end users attempt to complete the same set of tasks for each product. This type of usability test assesses if a product is better or worse than others from a usability perspective and reveals relative strengths and weaknesses. When conducting a comparative usability test, a number of variables make the execution more complicated than a standalone usability test. This paper identifies variables to consider, based on a recent comparative test involving three ultrasound systems. Some variables that need to be considered are defining and recruiting appropriate test participants, selecting a suitable test environment, preparing and executing training, creating consent forms, applying a proper test methodology, selecting usability metrics to capture, and analyzing data. This paper identifies what a comparative usability test can offer and the latest techniques of executing such a test.

Keywords Usability test · User experience · Comparative · Ultrasound

1 Introduction

A comparative usability test can help gauge the position of a company's product in comparison to indirect and direct competitors. It can identify each product's strengths and weaknesses from an end user's point of view. The comparison can be made through ranking products by overall usability metrics or can be quite focused on comparing features, functions, or content. A comparative usability test provides product management, research, and development teams with information about what works and what does not from an end user's perspective, by having a group of

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representative users perform the same set of tasks with each product. The results from these tests can help form baseline performance metrics and identify areas for improvement. Product teams can use this information to create and improve upon strategies for upcoming product release cycles.

When planning for and conducting a comparative usability test, a number of variables make the execution more complicated than a standalone, more traditional, usability test.

This paper suggests some variables to consider and will highlight a best practices approach to conducting a comparative usability test. By identifying variables to consider, this paper should help teams plan and execute a comparative usability test more successfully. The paper also provides specific examples based on a recent comparative usability test that was conducted involving three premium ultrasound systems.

2 Case Study

The subject vendor had made a concerted effort to improve the overall usability of its premium ultrasound system. While the vendor felt confident that it had achieved its goals through a user-centered design approach for the new system, it needed to be able to measure the outcomes of its efforts in an objective way.

The authors conducted a comprehensive comparative usability test of the subject vendor's beta system and two other similar premium ultrasound systems from two other vendors. The goal of the test was to compare the effectiveness, efficiency and satisfaction of the three different ultrasound systems using standard usability metrics and methodologies.

Eleven common tasks in abdominal sonography were utilized to assess ease of use, task completion, number of errors and deviations, and overall assessment of usability. Twenty practicing sonographers with a specialty in abdominal sonography were recruited to participate in the test.

3 Best Practices

3.1 Defining and Recruiting Participants

For a traditional usability test that focuses on evaluating one product, selecting participants is a primary challenge because the right participants need to be recruited in an efficient manner. Variables that need to be considered during recruitment may include age, gender, attitude, computer and web experience, and professional and academic backgrounds. For a comparative usability test that focuses on evaluating two or more products, selecting participants can be even

more of a challenge because there are additional variables to consider. Three additional variables to consider are prior experience, brand and product attitude, and domain skills and frequency of using those skills.

One of the easiest and most intuitive approaches to handle these additional variables is to balance them across participants (i.e. ensuring that an equal percentage of participants with particular types of variables are involved). This approach is one of the easiest and most intuitive but it comes at a price, as it takes more time and could cost more to recruit these proportionally equal percentages of participants.

Paying close attention to the following performance-affecting variables is key when recruiting participants.

Prior Experience Prior experience with the product being tested has a direct impact on performance success in a usability test. Tasks may have higher completion rates and take less time to complete for participants with more experience. Prior experience also affects the participants' attitudes towards the product and experienced participants typically have more favorable attitudinal data [1].

In the subject comparative usability test, one new ultrasound system was compared alongside two other existing systems from different vendors. Test participants were to be current users of one of the two existing systems. Therefore, during recruitment, prior experience with certain brands of ultrasound systems was key to selecting test participants. This identification meant that each participant would be a first-time user of the two ultrasound systems s/he would evaluate during his/her usability session (e.g. current users of one system evaluated the other existing system and the new beta system).

Brand and Product Attitude Brand and product attitude affect usability test data so measures of favorability towards the products under evaluation are important to capture during the recruitment process [1]. To avoid existing bias towards a brand or product, screening potential participants at either ends of the favorability spectrum regarding a particular brand or product is a selection consideration.

It may also be interesting to manage and examine the differences of favorability. Ideally, the favorability responses should be relatively equal across participants.

For the subject comparative usability test, a Likert scale question was included during the recruitment process so that potential participants could rate their favorability towards each of the three brands. Participants were asked to rate their overall opinion of each brand on a scale from 1 to 5, where 1 represented 'very unfavorable' and 5 represented 'very favorable'. Participants that rated any of the three brands with a '1' were not included in the test. This approached helped to screen out individuals who really disliked a particular brand, as this feeling or attitude may have prejudiced the reliability of their data. This test included an equal number of participants for whom each brand was 'very favorable'. 'Very favorable' reflects a positive direction and strong intensity of feelings toward a brand. For this test's twenty participants, the favorability ratings for the three brands were within a point difference, based on the 5-point scale.

Domain Knowledge and Skills and Frequency of Use Domain knowledge and skills and frequency of use affect performance in a usability test. Specific domain knowledge or specialized skills usually have more impact on performance than differences in interface or design elements [1]. Domain knowledge refers to a set of concepts and terminology understood by practitioners in that domain and domain skills are specific skills useful only for that certain area of expertise [2].

During the recruitment process for the subject comparative usability test, professional demographics and sonography expertise were collected in order to determine the selection of participants. Information such as number of years worked as a sonographer, specialty, work environment, and academic background were collected. Effort was made to have an equal amount of sonography experience in the whole group of test participants.

During the recruitment process, another selection criterion was the participant's frequency of using certain skills, knowledge and brands of systems. For example, only full-time sonographers who regularly scanned patients were considered; students or part-time sonographers were not considered.

Participants with the same skill set were recruited to ensure that their skills would support them during the usability test, as these skills were related to what was being evaluated in the usability test (i.e. only participants with a specialty in abdominal sonography were recruited in order to complete tasks for a typical abdominal exam).

Defining soft and hard metrics for recruitment can allow for adjustments to be made along the way, as the success of the process is examined. For example, demographic information such as participants' sex and age were soft metrics for the subject usability test because they were deemed less impactful to the data as opposed to sonography expertise.

3.2 Training Researchers

In some instances, the user experience (UX) researchers who are conducting the comparative usability test also need product training before planning and executing the test.

For the subject comparative test, experienced end users of the three ultrasound systems were contacted to train the researchers and help them better understand typical workflows, features, terminology, etc. even for those aspects that were not considered a focus area of the test. This helped the researchers in a variety of ways such as documenting when test participants went off the ideal path or did an irreversible error while trying to complete a task. Documenting deviations from an ideal path is often used to measure product efficiency and errors to measure effective product design. The ideal path is considered the intended navigation route to complete a particular task. In some instances, there may be multiple ideal paths.

3.3 Usability Test Location and Space

For a comparative usability test, it is advisable to try to use a lab space that is in a neutral, third party location. This helps encourage participants to provide their honest opinions and feedback during the evaluation.

Comparative usability test sessions can be long because more than one product is being evaluated. Therefore, researchers need to incorporate breaks for the participants between evaluating one product and the next and to consider providing a lounge space and refreshments for participants so as to mitigate fatigue.

Client or stakeholder participation and collaboration during all user research phases has many benefits. The more researchers share, listen, accept and learn from clients or stakeholders, the higher the chances are that they will act upon test findings when they become available [3]. One way to involve a client or stakeholders is to have them observe the usability test sessions. However, to ensure that client or stakeholder participation does not affect the usability test data, ensure that test participants remain unaware of any direct connection that observers may have to any one of the products under evaluation.

When evaluating multiple brands of products, the sponsoring vendor's name must not be evident on any materials in the lab space (e.g. test protocols), as this may impact data as well.

During comparative usability tests, it is best to remove from view the product(s) that is/are not being used in the current usability test session. In the case of the subject test, participants could have become distracted by the third system in the lab space, as that was the brand of system they currently use for their job, so it was removed from the space. The participants' attention needs to be directed to the tasks at hand so that the test session can be kept on schedule.

3.4 Training Test Participants

In some instances, participants need to be trained before they begin a usability test (e.g. providing participants with training on the primary functions, interaction mechanisms, and associated domain knowledge of the device) [4]. Providing effective training should not be taken casually. Training participants should be formal, structured, and given to each participant so as to remain consistent. A standard means of training participants will ensure consistency from one session to the next. Then every test participant begins their usability session with the same skills and exposure to the system(s) or product(s) being tested.

For training to be effective, identify:

- The purpose of the training,
- What skills and knowledge participants are to learn, and
- How the training will be conducted [5].

For the subject comparison test of three ultrasound systems, each participant had to know how to perform some basic tasks with the systems s/he would be evaluating.

Creating training videos for each system, covering the same types of tasks and features in the same detail, was essential to ensuring that the test was not biased towards any of the systems. It addition, it freed the test facilitator from having to train each participant in the exact same manner.

Besides this standardized training, a set time was given for each participant to further familiarize themselves with the systems and for the researcher to observe first impressions. No additional assistance was given at this time in order to avoid swaying results.

The same overall time for training was allowed for each participant and each was encouraged to use the full time available to him or her. Access to user manuals, if available, is an additional construct to consider.

3.5 Waiver and Consent Forms

Typically, test participants are required to sign a waiver or consent form to participate in a test, especially if any parts of the usability test are being recording with notes or video/audio. They may also need to sign a non-disclosure agreement (NDA) form.

If a NDA is needed for a test, consider combining it with the consent form so that participants can sign one form at the beginning of the test instead of two. Since summative usability tests, such as the subject comparative usability test, require a large number of participants and may take a long time to complete, ensure that the consent form explicitly includes a statement requesting that participants not discuss the details about the test with others.

In the subject comparative usability test, the sponsoring ultrasound vendor wanted participant approval to share favorable findings and video recordings for promoting and marketing the new system. This approach required a consent and release form for marketing purposes.

The UX researchers advised the vendor that the most important part of the subject test was to conduct it in an efficient manner with the correct participants; the 'nice to have' addition was acquiring participants' permission for subsequent marketing. Prior agreement on this principle allowed the researchers to keep the two different consent forms separate and have the test participants review them at different times during their usability test session.

Each participant was required to sign the consent form detailing his or her participation and acknowledging the reason for recording the test. Participants did not have to sign the consent and release form for subsequent marketing.

The participants reviewed the consent and release form for marketing at the end of their test session so as to better differentiate what would and would not be shared from their session, if they chose to sign it. Signing the marketing release form at the end of the session helped to keep participants focused on providing honest feedback during the test instead of worrying or becoming distracted by the matter of releasing their views for marketing purposes. Copies of the forms were provided to participants, if they wanted to keep any for their own records.

3.6 Methodology for Executing Test Sessions

For a traditional usability test that focuses on evaluating one product, the approach is rather straightforward and well documented. For a comparative usability test that focuses on evaluating two or more products, conducting the test is more of a challenge because there are more variables to consider.

The following six aspects are ones to pay closest attention to when conducting a comparative usability test.

Product Order If the same group of participants evaluates two or more products in the usability test sessions (called a "within-subjects" test), then it is important to alternate the order in which the participants evaluate the products. This technique is used to avoid the introduction of confounding variables and ensures that the same percentage of participants is exposed to each product first. A confounding variable is a variable, other than the independent variable, that may affect the dependent variable [6]. Variables that can be affected by the order could include practice or learning effect as users get "warmed-up" and/or participants becoming fatigued. By counterbalancing the order of exposure, one can ensure that these unwanted effects are uniformly spread among all the products being evaluated [1]. This approach should be used for any training sessions as well.

Types of Tasks Selecting the test tasks to be included in a usability test is based on the key goals that end users of the product under evaluation are trying to accomplish with it. For a comparative usability test, it may not be that straightforward, as competing products may not help users achieve all of the same goals. Therefore, test tasks for a comparative usability test need to be selected based on the participants that are involved (i.e. abdominal sonographers evaluating abdominal exam scanning tasks) and tasks that can be done on each of the systems or products. Since there will be a learning effect in comparative tests, consideration should be given to multiple test tasks that evaluate the same functions or features with each system or product. In order to compare usability metrics, keep tasks specific instead of open (e.g. "explore the homepage" would be considered an open task) so that the same task can be repeated in the same way on each of the other systems or products and can then be more easily compared.

Test Task Phrasing In most situations, the UX researchers conducting the test are not themselves expert users of the products or systems under evaluation so it is important to get some external help for phrasing the test tasks. For the subject comparative usability test, prior assistance was sought from a clinical team and practicing sonographers in phrasing the test tasks. The improved task phrasing helped to convey the same message and a clear goal for participants to accomplish so they could have the same baseline understanding for each task. Different products or systems often use different words to mean the same things (e.g. 'Erase', 'Clear' and 'Delete'); therefore, tasks need to be worded similarly for each system or product. Be aware of your target audience and pose tasks to usability test participants in a manner that naturally resonates with them. Participants can take tasks very literally so it could be helpful to use plain English and no slang or product-specific language. Every participant needs to interpret the tasks the same way.

Realistic Testing Environment As in traditional usability tests, try and simulate the lab space as closely as possible to a typical work environment. For comparative usability tests it is also important to keep the environment as consistent as possible from test session-to-test session and product-to-product so that the environment does not impact the test's data.

Usability Metrics A research goal and purpose of a usability test determine the usability metrics and data to be collected during test sessions. For a comparative test, the collection of quantitative data is highly recommended as it allows for direct product comparisons to be made and statistical significance calculated.

If well-presented, quantitative results can be very meaningful, easy for stakeholders to understand, and straightforward to market and promote. For example, completion rates provide a simple metric of success and system effectiveness and the rates are easy to collect. Qualitative data is also important to collect, as it provides details about human behavior, emotion, and personality characteristics. The tradeoff for a test could be to collect think-aloud comments over task times. For example, qualitative data provides an understanding of participant attitudes by observing them directly and helps answer questions about 'why' or 'how to fix' a problem. Task times provide researchers with a glimpse into understanding system or product efficiency.

It is also very useful to debrief after each participant's test session and flag 'gold moments' to revisit at the end of the test. This helps keep the initial feedback and findings for the different products clear and organized.

Usability Test Wrap-Up Traditionally, a wrap-up session follows the completion of the test tasks and it is a great chance to ask follow-up questions based on what occurred during the usability test. It also gives a chance for participants to complete standardized questions or questionnaires such as the System Usability Scale questionnaire (SUS) [7]. For a comparative usability test, try going one step further

during the test wrap up. For example, follow-up on the SUS responses by calculating the SUS score for each system or product immediately after the test and further probe about the reasons why participants provided their ratings. The wrap up is also a great chance to ask a product preference question to get a 'bottom-line' response from all participants. Also, consider at this point breaking down the product preference question further to address finer variables that lead to the choice.

3.7 Analysis

The type of analysis performed on comparative usability test data depends on the data collected and who was involved in the test.

For most usability tests, quantitative data is a combination of completion rates, errors, deviations, task times, task-level satisfaction, help access, and lists of usability problems (typically including frequency and severity) [8]. As mentioned in the previous section, qualitative data provides details about human behavior, emotion, and personality characteristics in the form of think-aloud comments and responses to test questions.

When calculating test results, it is helpful for readers to understand how precise the estimates are, as compared to the unknown population value. Try to report results with confidence intervals around any mean to provide readers with the most likely range of the unknown population mean or proportion.

For comparative usability tests, test participants can attempt similar tasks on all products (within-subjects design) or different sets of users can evaluate each product (between-subjects design).

For a comparative test, it is necessary to compare results to a specific benchmark or goal in order to determine whether the difference between products, designs, versions, etc. is greater than what would be expected from chance [8]. From calculating confidence intervals, the boundaries of the interval can be used to determine whether a product or system has met or exceeded a goal. Keep in mind that the test design, within-subjects or between-subjects, impacts the calculations that determine if the difference is statistically significant or not.

For the subject comparative usability test, there was great value in conducting a within-subjects design. Besides benefits such as conducting the usability test in the same period of time and with the same recruitment effort and lab space, a major source of variation between sets of data could be removed because of the involvement of the same participants in each test group. Another fundamental advantage of a within-subjects design is statistical power because in effect, the number of subjects has been increased relative to a between-subjects design.

In order to keep the analysis as straightforward as possible, a carefully planned master spreadsheet of all the data to be collected often works best. One spreadsheet tab per product works well with each participant's data de-identified. Using one

program to document the data and complete calculations saves time as opposed to copying data from one program to another. Spreadsheet software applications often have many built-in functions that will help with analysis such as t-tests calculations to acquire precise *p*-values.

4 Summary

Comparative usability testing provides product management, research, design, and development teams with a wealth of data and a glimpse into how a product sizes up to its competitors. Since results from these tests provide baseline performance metrics and comparative data to use for claims of product successes, it is important to collect and analyze the data accurately.

In general, planning and executing a comparative usability test is more challenging than a traditional usability test because of a number of variables that make it more difficult.

Test Planning Stage During the planning stage, it is important to define and recruit test participants by focusing on prior experience, brand and product attitude, and domain skills and knowledge and frequency of use. When training the UX researchers who will facilitate the test, experienced end users of the products under evaluation can help the researchers better understand typical workflows, features, terminology, etc. For an in-person usability test evaluating products from multiple vendors, a test location outside of one of vendor's locations helps to make participants feel more comfortable so that they can better provide honest opinions and feedback during the test. At the test location, a break area with refreshments for participants is a consideration. Observations by clients or stakeholders may be permitted but their connection to the product(s) or system(s) must not be obvious to participants.

Test Execution Stage During the execution stage, decisions about participant training that need to be made are: the purpose of the training, what skills and knowledge the participants should learn, and how the training will be conducted. When using a waiver and consent forms, a combined consent and NDA form leaves just one form for participants to sign at the beginning of a test session. Also, if a separate release form for any marketing purposes is needed, consideration should be given to include it at the end of each test session. In order to execute a successful test, careful selection of the product order, types of test tasks, task phrasing, and usability metrics is essential. Additionally, the usability test space should provide a realistic testing environment and there should be ample time to conduct a meaningful test wrap-up session.

Test Analysis Stage When calculating test results, include confidence intervals around any means, compare results to specific benchmarks or goals, and compare results to the other products to determine if a significant difference exists.

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&You: Design of a Sensor-Based Wearable Device for Use in Cognitive Behavioral Therapy

Aaron McEuen, John Proffitt, Jorge D. Camba and EunSook Kwon

Abstract Cognitive Behavioral Therapy (CBT) is a psychotherapy treatment that trains an individual to adjust negative patterns of thinking and behavior associated with their disorder. In this paper, we present *&You*, a low-cost nonintrusive wearable device for use in CBT to assist patients with anxiety disorders. Our device reinforces habit forming processes by passively detecting measurable stress symptoms and notifying the user before a stimulus elicits a severe anxiety attack. Notifications are delivered as a series of brief vibrating pulses that can be stopped by tapping the device, which is strategically placed at the nape of the user's neck. The gesture of deactivating the notification forces the wearer into a body position that naturally expands their chest and increases lung capacity, which directly calms the user and disrupts the user's negative thought pattern.

Keywords Wearable devices · Cognitive behavioral therapy · Medical device design

1 Introduction

In recent years, the topic of mental health has gained considerable attention in the research community. Studies by the World Health Organization have reported substantial increases in the occurrence of mental disorders worldwide [1], which in

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many cases can have tragic consequences not only for the affected individuals, but also for their families, communities, and society in general [2]. In some instances, mental disorders can have a greater impact on quality of life than certain chronic medical disorders [3].

The development and delivery of effective treatments, therapies, and medication for mental illnesses can often be hindered by social stigma, high costs, and difficulties in adhering to treatment and/or accessing mental healthcare services [4, 5]. For this reason, researchers are now beginning to study how the fields of computer technology, engineering, and human-computer interaction can contribute to facilitate access to and improve the outcomes of therapeutic treatment [6].

Cognitive Behavioral Therapy (CBT) is a well-established and effective treatment applicable to an increasing number of psychological disorders including but not limited to, general anxiety disorder, obsessive compulsive disorder, and post-traumatic stress disorder [7, 8]. CBT is a psychotherapy treatment that trains individuals to adjust negative patterns of thinking and behavior associated with their disorder. In this context, recent advances in computer and information technology are creating new opportunities for supporting CBT and other treatments to ultimately develop more effective and scalable interventions targeting health behavior [9].

In this paper, we describe the development of *&You*, a low-cost nonintrusive wearable device aimed at assisting patients with anxiety disorders by passively detecting measurable stress symptoms and notifying the user before a stimulus elicits a severe anxiety attack.

2 Background

Cognitive Behavioral Therapy (CBT) is a goal-based therapy intended to deliberately alter the behaviors and thinking patterns behind issues that psychotherapy patients face. Sufferers of these disorders experience acute rises in stress when confronted with specific stimuli. To a certain extent, CBT takes the most hands-on approach to therapy compared to conventional methodology.

In the 1960s, psychiatrist A. Beck coined the term "Automatic Thoughts" to describe emotive thoughts that occur naturally in one's internal dialogue [10]. He considered these thoughts to be distinguishable by relative positivity vs. negativity and suggested that negative thoughts might perpetuate negative feelings. As such, training thoughts and behaviors would effectively assist the patient in overcoming difficulties.

As a participatory treatment, CBT requires the individual to habitualize behavioral and thought awareness by recognizing triggers to consciously modify the resulting negative response. Burdensome thoughts and emotive grievances are addressed first by patient's voluntary self-identification of negative cognitive tendencies and second by prompting introspective consideration of how those tendencies are emotively limiting. The structured nature of Cognitive Behavioral

Therapy facilitates long-term habitual perspective of "containment of affect" and an enhanced ability to tolerate often intense emotions [11]. To do this, CBT participants must be abstractly aware of their thought patterns while in a state of increased stress.

While the triggering stimulus varies depending on the disorder and individual, sufferers will experience consistent physiological responses. Common physiological responses include increased respiration, perspiration, and heart rate [12]. A number of physiological markers can be used for assessment, including: galvanic skin response, heartbeat patterns, blood pressure, and respiratory activity [13].

CBT techniques include the questioning of automatic thoughts; relaxation strategies; and the self-monitoring of events to help the patient identify factors that may be influencing his or her mood or actions and develop self-control mechanisms [14]. The inherent difficulty of forming habitual mindfulness can be inhibitory for patients seeking a non-medicated therapy type.

Research shows that digital technologies such as mobile applications, sensors, and wearable devices have the potential to improve the delivery of health interventions. By monitoring and measuring health behaviors and habits, and collecting patient data in real time, these technologies can facilitate faster, more reliable and immediate clinical interventions [15].

In the context of CBT, digital technology has been successfully used to automatically interpret physiological data in the delivery of e-therapy content [16], make therapies for depression and other mental health problems more personalized, and self-monitor certain health aspects such as insomnia, sleep quality and mood states [17, 18].

A significant amount of research has been devoted to replicating traditional therapeutic strategies with the aim to enhancing available services. Online-based treatments, for example, have been used to supplement face-to-face therapy sessions [19, 20]. Wearable and mobile devices have been utilized for the real-time self-monitoring and self-assessment of thoughts, feelings or behaviors [21, 22]. Advanced graphic technologies such as serious games and virtual and augmented reality have also been employed as therapy tools [23, 24].

The research and financial efforts devoted to sensor technology in the past few years as well as the miniaturization and affordability of the devices have led to the development of a large number of products that are ready to be used in clinical and health-related applications. These products typically take the form of an item that can be worn, such as a ring or bracelet, and a unit that can temporarily store physiological data and/or periodically upload it to a server via a wireless or Bluetooth connection for later processing [25, 26].

In this paper, we introduce a wearable device intended to assist in the recognizable physical manifest of negative cognition. Our design takes an active approach to behavior modification and CBT by forcing the user to reach the back of the neck when a stress symptom is detected and before it evolves into a more severe anxiety or attack. This gesture is intended to naturally stretch the abdomen, expand the lungs, and thus relieve stress. In the next sections, we describe the technical aspects of our system and provide examples of the use cycle.

3 Design and Operation

&You is a wearable device that utilizes an optical heart rate monitor and a Galvanic Skin Response (GSR) sensor to detect heart rate and perspiration spikes associated with stress responses. The detection of sudden spikes, as opposed to the continuous monitoring of heart rate and perspiration levels, eliminates false positives that could be caused by physically strenuous activity.

Optical heart rate monitors use a small LED pressed against the surface of the skin and paired with a photo-sensor to measure an individual's blood flow. This type of sensor is used in a variety of fitness tracking products and provides reasonably accurate results depending on where the sensor is placed on the body. Optical heart rate monitors are noninvasive, i.e. they simply need to be in contact with the surface of the skin to obtain a reading.

A GSR sensor measures the electrical resistance of the skin's surface by running a low voltage current through two metal leads placed on the skin, where any decrease in resistance indicates an increase in perspiration. The higher the measured voltage, the higher the perspiration present on the skin. GSR's are used in devices such as polygraphs as a physiological indicator of psychological stress, and can be highly responsive to emotions such as fear and anger.

Patients with common stress disorders regularly experience acute, measurable spikes in anxiety levels. Because these spikes are dramatic and episodic, the proposed device is programmed to recognize a stress spike beyond a particular threshold. Subsequently, the noise from generalized and less exaggerated anxiety fluctuations can be filtered out. These less exaggerated fluctuations are regular and otherwise normalized over a period of time (e.g., an individual walking up a flight of stairs causing a gradual increase in heart rate, or stepping outside on a hot day causing a noticeable increase in skin conductivity).

In situations where a wearer exhibits a measurable response to stimuli that affects one or both sensor types over an extended period of time, the device renders no response. Rather, the device's reaction is limited to specifically manifest at the point of a triggering stimuli for the wearer (as triggers vary between disorders and between sufferers). While triggers are irregular and difficult to detect and predict across all disorders, the response elicited in patients is quantifiable. In the case of a patient suffering from Obsessive Compulsive Disorder (OCD), a measurable trigger might be a repeated, highly specific, and disturbing thought about a certain individual. This type of negative stimuli can affect the sufferer in any context.

Our original prototype was designed as a simple U-shaped device that can be securely attached to the back of the user's neck (see Fig. 1). The device consists of three injection-molded plastic parts: two long arms and a middle segment, where the main electronic components are enclosed. A foam rubber bushing inserted at each joint acts as a spring, enabling a firm and adjustable grasp. A strip of hypoallergenic moleskin fabric lines the inner face of the device to provide grip to the neck as well as comfort for the wearer.

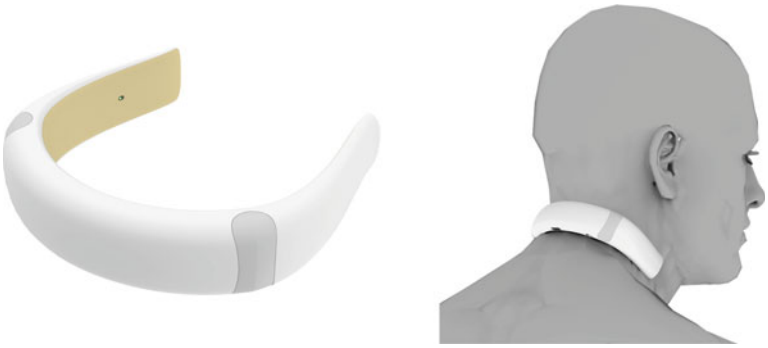

Fig. 1 Device and location on the user

Internally, our system uses an Arduino microcontroller, a polymer lithium ion battery, vibration motors to notify the user, and a switch used as a dismissal button. The device can be charged via a micro USB port. The GSR and heart rate sensors are mounted on the right and left arms of the device, respectively, and connected to the main board (see Fig. 2). An early prototype of *&You* is shown in Fig. 3.

The pseudo-code of the main algorithm implemented in our prototype is provided:

```
Program &You {
  while (device_state = on){
    ReadGSR(); //Galvanic Skin Response
    ReadBPM(); //Beats per minute

    //If spikes are detected
    if ((GSR>threshold_GSR) && (BPM>threshold_BPM)) {
      //Notify user
      vibrateMotors();

      //Check dismissal button until pressed
      while (not_dismissed){
        ReadDismissalButtonState();
      }

      //When button is pressed, stop motors
      stopMotors();}
  }
}
```

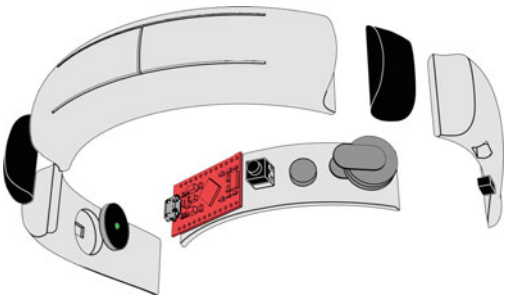

Fig. 2 Internal components

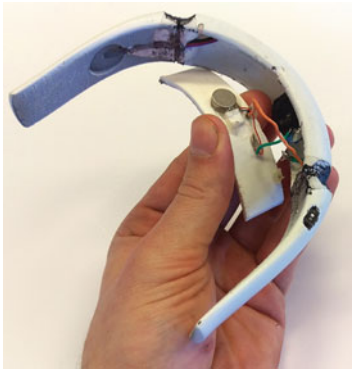

Fig. 3 Early prototype

3.1 Use Cycle

The proposed device constantly monitors input from the GSR and Heart rate sensors. When the wearer is triggered by a stressing stimulus (e.g. obsessive thoughts, compulsions, particular noises, etc.), spikes in beats per minute and skin conductivity are detected. The device then immediately alerts the wearer, breaking his/her negative thought cycle enabling them to better practice thought awareness. Furthermore, the deactivation of the vibration alert results in the wearer naturally assuming a posture that facilitates calming breathing exercises by expanding the lungs and enlarging the abdomen (see Fig. 4).

The interaction cycle of stimulus-notification-deactivation described above can occur between the wearer and device many times in the course of a day. However, after each interaction cycle, the device will fall into a relative rest cycle for a set duration (between 5 and 10 min) to allow the wearer to practice the mental coping methods associated with CBT.

The use cycle of the device is illustrated in Fig. 5 and described in Table 1.

Fig. 4 Dismissal gestures

Fig. 5 Use cycle of the device

4 Discussion and Future Work

Patients with stress disorders participating in Cognitive Behavioral Therapy are taught to practice thought awareness and recognize negative thoughts and behaviors. We could speculate a worst case scenario in which the obsessive compulsive patient is having a reoccurring disturbing thought while sitting in the passenger side of a vehicle, car-pooling with the subject of their unwanted obsession. At this point,

Table 1 Sequence of stages and actions in the use cycle of *&You*

Stage	Action	Description
1	Monitoring	Device monitors heart rate and perspiration spikes
2	User is triggered	Stressful stimuli trigger physical symptoms of stress
3	Spike detection	Device detects spike in heart rate and perspiration
4	User notification	Soft pulsing vibrations notify the user about the thought that is causing stress
5	Recognition of source of stress	User draws from their CBT training to recognize the thought to be unwanted, and the current reaction to be irrational
6	Dismissal gesture	User dismisses the notification by reaching to the back of the neck and pressing on the back of the device. This gesture is intended to stretch the body and expand the lungs, which helps reduce stress [27, 28]. It also applies light pressure on the back of the neck, which also contributes to stress relief [29]. The dismissal gesture is a physical parallel to the mental action of dismissing the thought after it is recognized as unwanted
7	Reset	Device returns to monitoring stage

the thinking becomes cyclical, alternating between the obsessive thought and subsequent guilt. Unless the patient has habitualized thought awareness, this obsessive thought cycle will continue.

The stress and discomfiture of the previous situation will cause a measurable spike in both skin conductivity and heart-rate over a brief period of time that can be detected by our proposed device. Immediately, the device will register a subtle, inaudible vibration to the nape of the wearer's neck. The brief pulsing identifies the stress spike to the wearer affording them a physical manifest of their otherwise irrational and dismissible thought cycle. Without causing noticeable disturbance to the wearer's surroundings, the device will continue until it is deactivated with the dismissal gesture.

Because cognitive behavioral therapy is a participatory process, patients would need to be inclined towards proactive self improvement and would have sought help already. As current CBT techniques require professional guidance, expert reviews suggested that *&You* would be useful not only as an outpatient therapy aid, but also in guided sessions of exposure therapy. These sessions would follow the existing precedent with the addition of *&You* to inform future use for the patient as well as real-time relative stress response levels. The use of the device in these sessions would allow greater mobility for more realistic exposure to triggering stimuli.

Although preliminary evaluations and expert reviews suggest *&You* might be an effective tool to use in CBT patients, the device remains untested with large sample sizes. Future testing will include a wider range of anxiety disorders across a broad demographic. Participants will be evaluated based on severity of response to triggering stimuli and tested against their own improvement over time.

In terms of hardware, the device would benefit from more accurate sensors that yield greater precision. Future developments will explore higher-end components to provide more comprehensive stress threshold recognition. Similarly, these components may be smaller in size to fit in the body of the device, resulting in an even more modest visual mass. To some extent, this reduction could be achieved by a more efficient arrangement of the internal components or a reduction in material wall thickness of the housing.

Finally, while the overall stylization of the device should remain largely ubiquitous, in its current state, the prototype is suitable to comfortably fit an average sized neck. However, the targeted CBT participants present significant variance in both age and size. In order to accommodate all possible users, the shape and connection between the adjustable armatures and main body must be further evaluated.

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Framework Proposal Including HFE in Product Development Process: A Suitable Approach for the Brazilian Medical Equipment Industry

Ana Paula Almeida, Rodrigo Almeida, Renata Custódio, Clarissa Trzesniak and Carlos Mello

Abstract Brazilian Medical Industry is mostly comprised of small to medium-sized manufactures Small changes on requirements can pose a big challenge on their process. From December 2015 the IEC 60601-1-6 has become mandatory for all new medical equipment registration in Brazilian market. These two facts led to the development of this research, aimed at provide a framework to include HFE methods inside the product development process, while confirming with the standards. The framework should be simple to implement and provide practical information showing which tool to use at the right time, considering a device in development. The methods were selected based on previous Brazilian experiences and literature review. The final framework is constituted of 4 steps using 6 HFE methods, linked in such way that the information generated by one method can be used as input to the other method, minimizing work overhead, and documentation to the standard requirements.

Keywords Human factors · Usability · Medical equipment · Product development process

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1 Introduction

Brazil ranks as the fifth most attractive market in the Americas region for Medical Devices (MD) commercialization. Although the country presently runs a negative balance of trade in medical equipment and supplies [1], Brazil has a Unified Healthcare System (SUS), created in 1993, providing healthcare services to 75 % of the population. All medical equipment used in the SUS is purchased by the Government by public bid, mostly by the lowest prices. The purchased is generally restricted to companies that have a local representation.

Brazilian Medical Industry are mostly comprised of small to medium-sized manufactures producing low cost products for the local market. They are required to comply with a set of regulatory requirements set by the Brazilian Health Surveillance Agency (ANVISA). The Brazilian government also has specific programs to prepare Brazilian companies to export, providing training and expertise on regulatory matters such as ISO certification, CE mark approval, FDA submission and the ANVISA Good Manufacturing Practices certification.

Even with the ANVISA and Ministry of Health efforts to help and establishing the requirements for product approval, the Brazilian Medical Industry is still struggling with the costs and time-consuming process to include the HFE process in their product development. The ANVISA has released a new list of mandatory requirements, which includes the Usability Engineering Process standard IEC 60601-1-6 for medical electrical devices. This standard points to the IEC 62366, which was internalized in Brazil only in 2010 (comprised with the international version of 2007).

The motivation of this research is to help the Brazilian medical equipment industry on how to apply Human Factors Engineering (HFE) methods in the Product Development Process (PDP), in the way to be compliant with the IEC standards and ANVISA requirements. As the demands on efficiency, effectiveness and satisfaction in the use of MD influence the care and patient safety, the inclusion of HFE is needed from the beginning within the PDP.

The proposed model intends to serve as a base framework focused on both regulations and Brazilian industries characteristics. The first part of the research aims to provide knowledge on HFE methods, other frameworks and models from the literature and from HFE-IEC standards. The second part will describe the Brazilian regulation process and its particularities that are faced by the industry. The last part will present the proposed framework that can be used as a guideline for product development. Although the goal of this model is to help Brazilian industries, it could be also used as a reference for others developing countries, and small-median size medical equipment companies.

2 Literature Review

The Product Development Process (PDP) refers to the steps, activities, tasks, stages and decisions involving the development project of a new product or an improvement on an existing one. It covers from the initial idea until the discontinuation of the product. This process identifies the customer's needs and translates them into specifications to be developed, generating a technical and commercial solution. All this linked to the strategy, restrictions and operational possibilities of the company [2–5].

The particularities of a medical equipment development are related to characteristics of it industry and government standards, resembling more processes and requirements related to safety than other industries. It can be similar in the level of complexity to automobile and aerospace industries, but both are more experienced and sediment type of development. In these areas, industries have PDP tailored to its needs, which concerns the standards and requirements specifics to its areas. As those requirements may change from country to country, some changes may be necessary. The same idea can be applied to MD.

There are some proposed PDP frameworks for MD. Medina et al. [6] compared five PDP models showing their differences and similarities. Figure 1 shows the mains summarized steps of a Medical Device Development Process (MDDP) in five broad steps.

Santos et al. [7] show that there are many guides in literature and standards for developing a medical equipment, but most of the does not cover all topics in a PDP, especially health technology assessment, standards, regulations, and HFE.

Silva [8] presents a guide aimed at identify usability issues with MD. It uses only three methods: task analysis, heuristic evaluation and usability test. The author links one method output as input for the next. This sequencing of the methods helps to improve their overall efficiency while ensuring that no gap or problem will be left in the process.

Van der Peijl et al. [9] point out that a great deal of work in usability should be done at the beginning or before the development, while there are still a great freedom regarding the change of the product design. Money et al. [10] features a PDP script for medical equipment and point out which usability engineering methods could be applied at each stage. The article, however, focus only on the stage of designing the product, not the whole PDP.

Another problem on designing a MDDP including HFE methods in the process, at least for manufactures without previous experience with HFE, is the huge amount of tools and methods available. Selecting the right tool, alone, is complex task. Defining a MDDP with the right tools on each stage can be a cumbersome and error prone process.

The IEC standard 62366 [11] presents some HFE methods that can be used throughout the PDP. However, it does not provide details on how many or when use each one, leaving it open to the development team. It also mentions that the list of methods presented is not exclusive or final, and that additional methods may be

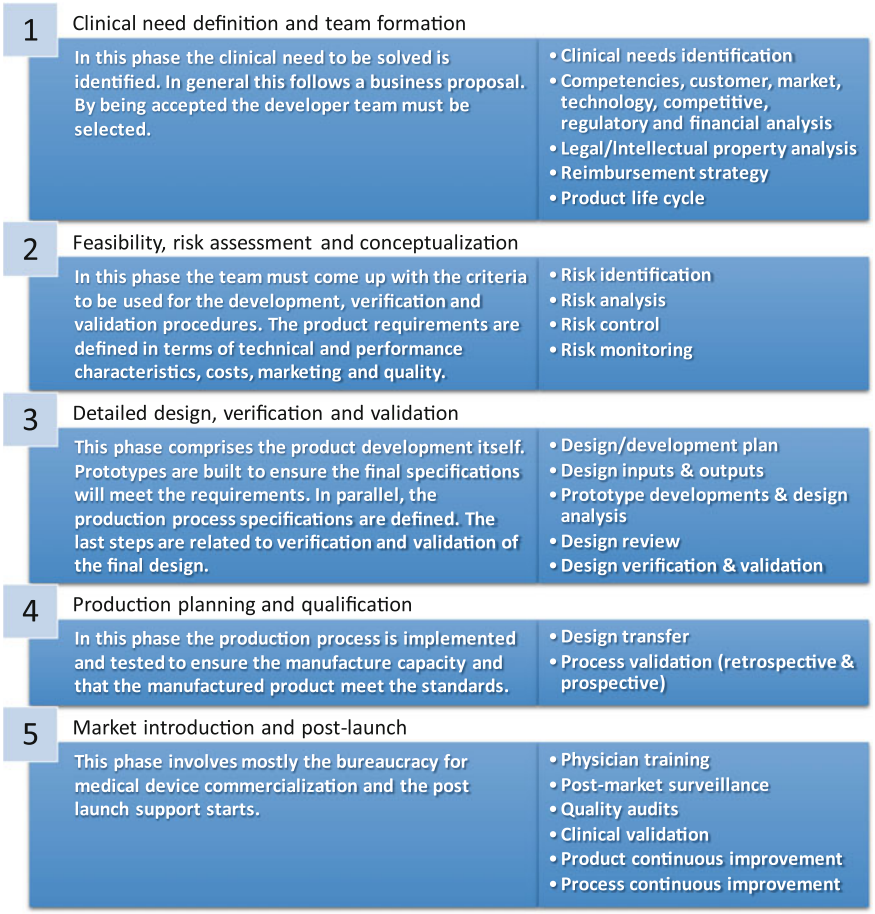

Fig. 1 Phases of MDDP as presented by Medina et al. [6] (adapted)

used. The standard also makes it clear that it is not necessary to apply all methods, but also states that none of them covers all needs analysis, verification and validation of the usability of a MD. It is necessary to use a suitable combination of methods for each step of the product development.

Some authors tried to compiled information on HFE tools selection. For Catecati et al. [12], for example, there is no clear systematic way of saying or indicating the most suitable method for each situation. The same authors say there are at least two important factors to consider in selecting methods in the process: the type of product being evaluated and their context of use. Martin et al. [13] presents a comparative table on 7 different methods to assist manufacturers in the selection.

Stanton [14] presents 107 different methods classified in 11 groups. They also suggested a guideline with a rough estimative on when use each group within a PDP. Although it was designed for a general product, it can be easily adapted for a

MD. Early in the process, he suggests methods to survey and model the characteristics of the solution, focusing on users, behavior (expected and unexpected), environment, requirements and restrictions. The analysis progresses to understand the product in its use, possible use errors, risk factors, interfaces and the device relationship with the user. At the end of the process, the author suggests methods that can be applied for verification and validation of the interfaces directly with users, demonstrating the usability achieved levels. They provide a small example with some of the HFE methods applied in a PDP.

Shah et al. [15] present a script for the involvement of users in the MDDP. According to the authors, the stages of development of medical equipment can be divided into in four steps: concept phase; development phase; testing stage; production and deployment phase. These steps can be directly mapped to the steps 2 to 5 in the Medina [6] MDDP. For each phase, they present which methods can be used, from a total of 15 different methods. However, they do not prioritize the methods nor give suggestions on how to cope with the standards requirements. According to the authors, the selection of the adequate method will depend on the available resource, in time and money, and the development team experience [15].

Almeida [16] presents an extensive model inserting HFE methods throughout all stages of the MDDP. The model is based on a Brazilian manufacturer case study. The manufacturer model was tuned with recommendations of other studies found the literature, specifically the references: [8–11, 13, 17–21]. The company did not know any specific PDP model for MD and had to create one by adapting a PDP from the automobile industry. They opt for this model because some people from the team had had previous experiences.

The IEC standard 62366 [11] divides the equipment design cycle in four elements: user research/conceptual design, requirement and criteria development, detailed design/specification and evaluation. It also provides a list of 16 tools/methods that can be used to assess the usability of the product. The standard does not provide when, on the development process, each tool should be used or how many different tools the company should adopt. It only states that the development team must critically analyses the product complexity to assure the correct use of the HFE methods.

Table 1 presents the comparison on the three proposed PDP from literature review, with their proposed HFE methods on each respective PDP phase. The methods in bold are the ones that are also proposed by the IEC 62366 standard.

2.1 The Brazilian Scenario

In emerging countries, the MD sector has an above the average growth among other sectors of the economy, with a projected growth of 15 % per year over the next years. In 2009, the global MD market was US$28 billion. The growth projection for the year 2016 is US$487 billion. In Brazil, the MD market was R$19.7 billion in 2014 [22].

Table 1 PDP comparison regarding suggested usability tools and methods

PDP phases (Medina et al. [6])	Methodologies/tools suggested		
	Stanton et al. [14]	Shah et al. [15]	Almeida [16]
1. Clinical need definition and team formation	9, 10, 16, 17	1, 4, 5, 7, 9, 14	9, 10, 15, 26, 27
2. Feasibility, risk assessment and conceptualization	7, 25	1, 8, 9, 10, 12, 13, 14	9, 10, 15, 23
3. Detailed design, verification and validation	13, 17, 19, 20, 21	2, 3, 6, 8, 9, 10, 12, 13	2, 7, 13, 19, 22, 22, 24, 25
4. Production planning and qualification			
5 Market introduction and post-launch		2, 4, 5, 7, 9, 11	13, 18, 26, 27, 28

Tools/Methods: (1) Brainstorming sessions; (2) **cognitive walkthrough**; (3) discussion with users; (4) **ethnography**; (5) expert users meetings; (6) first human use; (7) focus groups; (8) in vitro tests; (9) **interviews**; (10) **observations**; (11) **surveys**; (12) think aloud method; (13) **usability tests**; (14) users/producers seminars; (15) user feedback; (16) cognitive work analysis; (17) **task analysis**; (18) **product demonstration**; (19) **prototype**; (20) **workload assessment**; (21) **heuristic evaluation**; (22) **expert evaluation**; (23) risk analysis; (24) design principles; (25) critical design analysis; (26) monitoring reports of use problems on similar devices—recalls; (27) call center questions/problems reports; (28) internal technical support/post sales information

The Brazil's trade deficit regarding MD has been steadily growing from the past years. Between 2007 and 2012, the deficit increased from 1.7 billion USD to 3.7 billion USD. One of the reasons can be attributed to the public, philanthropic, and charity-care hospitals. Together they are responsible for almost 65 % of Brazil demand. Because the Brazilian tax systems exclude those institutions from importing taxes, they tend to import products other than buy from Brazilian industries [23].

The economic data reveal that the competitiveness of Brazilian healthcare companies, in general, is unsatisfactory [24, 25]. Currently, the domestic demand is aimed on more sophisticated devices, which technology are dominated by large international companies, together with the tax system, drives the importation balance. On regarding the exportation, it is far from covering the imports [26].

In Brazil, there are more than 3670 registered companies, among manufacturers, importers and distributors [22]. The majority of the industries are medium and small enterprises with 76.6 %. 12.7 % are classified as medium to large and only 10.7 % are large companies [22]. Although, the large companies occupy about 42 % of the sector's workforce, capturing almost 70 % of sales, being predominating in segments with greater technological complexity [25].

The national manufactures, although in the majority, are predominantly small and medium-sized and are restricted to less technologically complex market segments (mature technologies), where competition tends to be based on the price [26].

The industrial sector and the government have sought to encourage the growth of the medical devices market with political action programs. The strategic axes

defined by the Brazilian Industry Development Agency (ABDI) are related to increase the innovative capacity of industries and strengthening and expansion of the Brazilian Industrial Base [27].

The Brazilian federal government formally adopted the concept of a Health Industrial Complex in the planning period 2008–2011, through the Brazilian Multi-Year Plan [28]. The Brazil government role as an articulator of the Health Industrial Complex was justified by the significant dependence of the country on the foreign market [29]. This can be seen as a correction of direction related to the opening policy started in the 90s, leading to increased imports and contraction of national production among other factors [30].

Among the strategies to stimulate the domestic production there are the *Partnerships for Productive Development*, with 98 existing partnerships, involving 69 partners, among manufacturers, suppliers, universities and research institutes. In the period 2011–2014 the volume of resources involved in those partnerships (both from the government and private investments) were in the order of R$8.3 billion [22].

2.2 Brazilian Legal Requirements

No product of interest to health, whether domestic or imported, can be industrialized, displayed for sale or delivered to the consumer in the Brazilian market before registered with the Ministry of Health [31]. The ANVISA (the National Health Surveillance Agency) is the agency responsible to regulate, supervise and control the products and services that involve a risk to public health, including, among other activities, the product registration. The registration of products at ANVISA is regulated by specific resolutions in accordance with the nature of each type of product [32].

The needs for compliance with standards are issued in normative documents by ANVISA. All standards must be first translated to Portuguese and published by the Brazilian Association of Normative Standards (ABNT).

The usability standard IEC 62366 [11], international version from 2007, have their Portuguese counterpart published in 2010. The usability standard IEC 60601-1-6 [33], version from 2010 was published by ABNT in 2011, and republished with corrections in 2013. The IEC 60601-1-6 is mandatory for Brazilian ANVISA registration since December 2015, being a relatively novelty in the Brazilian industry [34].

2.3 The Usability Engineering Standards Requirements

Proper documentation of usability evaluation and development activities focused on the user provides an important set of information for both internal documentation and to future developments, training and analysis opportunities for innovation in a product. In addition is a requirement for the registration process of medical

equipment in ANVISA since December 2015 following the norm IEC 60601-1-6 [33] which refers to IEC 62366 [11].

In general, the usability engineering activities are performed throughout the product development cycle. Thus, it is interesting to be an appropriate procedure for generating and storing the results of each step. ISO 13485 and ISO 14971, as well as AAMI HE74: 2001 can also provide complimentary information about this process.

The standard IEC 62366 [11] divides the usability engineering process in four major areas: project conceptualization, design input, output and design validation and design verification. After these steps, the project is ready to be submitted to the certification bodies and the post-market surveillance process begins.

The documentation process, from the point of view of the IEC 62366 standard, consists of two documents: the usability engineering file and the accompanying document.

According to the standard, all product development stages should be documented from the perspective of the product usability. All these documents, known as deliverables, must be part of usability engineering file.

The standard defines nine items that must be described within the usability file. These items are intended to cover the entire MDDP.

Items 1 to 3 (Application specification; Frequently used functions; Identification of hazards and dangerous situations related to usability) must be defined through user research or through the conceptual design of the product. They define the basic needs of the product and the possible risks and dangers with respect to usability and safety. This is an exploratory step.

Items 4 to 6 (Primary operation functions; Usability specification; Usability validation plan) are aimed at defining more specific guidelines for the development of the product itself. At this stage the tests are set to be performed and the usability of specifications that the product must meet these tests.

Item 7 (Design and implementation of the user interface) is performed throughout product development. The user interfaces are designed and implemented taking into account the results obtained in previous sections.

Finally, the items 8 to 9 (Usability verification; Usability validation) serve to assess whether the specifications were met. The verification can be performed during the development of the product. It may be useful to verify each interface change. The validation should be applied on the final version of the product, using methods that make use of end users in contact with the product interface, to ensure that the specified usability requirements have been met.

3 Proposed Framework

The three PDP frameworks seen so far, Stanton et al. [14], Shah, et al. [15], Almeida [16], although present tools to use, do not provide which tools are best or how to use them to comply with IEC 62366. Some tools appear in all three PDP's, reinforcing its usefulness, as interview (9), observation (10), focus groups (7) and

usability tests (13). The methods cognitive walkthrough (2), user feedback (15) heuristic evaluation (23) risk analysis (25) are cited by at least two PDP's models.

In order to help Brazilians manufactures to comply with IEC 62366, consequently to IEC60601-1-6, having in mind that most of them had never had contact with HFE, this study propose a framework with 4 phases and 6 methods, based on Silva guideline [8]. Asides being a simple guideline, all the three methods used by Silva to evaluate the MD usability are cited by the IEC 62366 standard [11], recommended by the FDA [35] and appear on at least two of the three PDP's frameworks from literature review. The guideline is also suitable to cover the phases 2 and 3 on the Medina PDP [6].

To cover the first phase, we selected the interview (9) and observation (10) to rise information about the users, the device and the environment. These methods are both recommended by the three models from literature and the IEC 62366 standard.

The last gap of information, required by the standard and is not covered by the methods cited so far, is regarding the abnormal use of the devices. The IEC 62366 standard has an explicit requirement for the developers to identify hazards and hazardous situations related to usability. For this specific purpose, the risk analysis tool was chosen.

Figure 2 shows the flow of activities from the proposed framework, considering the requirements for verification and validation of the user interfaces.

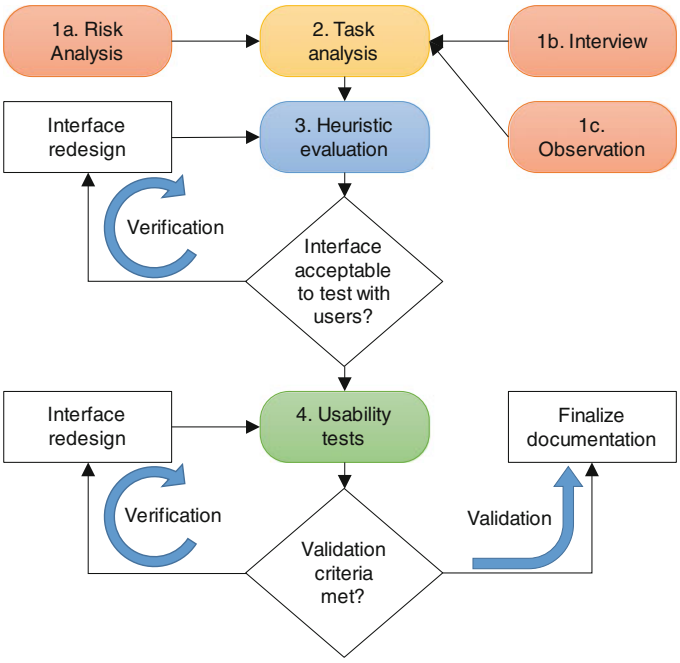

Fig. 2 HFE tools and usability process for the proposed framework

The main focus of the proposed framework is the usability test, as it can be used to validate the device respecting the standards requirements [11]. The usability test is also a required tool by the FDA to validate the device interface usability [35]. To correctly plan and execute the usability test, it is important to have knowledge regarding the tasks and associated hazards with each task. With this information, a test protocol can be designed to encompass all the critical tasks.

To make sure no critical task was left behind is important to have a complete list of all tasks (obtained from the task analysis) and evaluate each one to assert the critical ones (using the heuristic evaluation). Both task analysis and heuristic evaluation are recommended by the FDA to identify critical tasks [35].

The risk analysis, the interview and the observation tools are used to rise the required information to understand the device, the user and the environment, leading to a more comprehensive task analysis.

The first three activities (1a, 1b and 1c) can be performed in parallel. All information obtained by these methods will feed the task analysis. The activities 2

Table 2 Deliverables used as IEC 62366 documentations for the usability engineering process

MDDP phase [6]	IEC 62366 documentation item [11]	Method/tool	Deliverable to comply with IEC 62366 standard
1	5.1. Application specification	Observation and interview	Information about user, equipment and environment
1	5.2. Frequently used functions	Task analysis	Tasks list (listing most used functions)
2	5.3. Identification of hazards and hazardous situations related to usability	Risk analysis	Information about normal and abnormal use
1	5.4. Primary operating functions	Task analysis and observation	Identify the primary functions based on the task list and the observation
3	5.5. Usability specification	Task analysis and heuristic evaluation	Using the task list and the heuristic, define the acceptance levels to the validation tests
3	5.6. Usability validation plan		Document explaining the steps and methodologies used to the validation to the primary functions
3	5.7. User interface design and implementation		Document the evolution on the product interfaces along the development
3 and 4	5.8. Usability verification	Heuristic analysis, usability tests	Use errors and improvement opportunities
3 and 4	5.9. Usability validation	Usability tests	Use errors and risk management
5	Not in the standard	N.A.	N.A.

to 4 are organized sequentially, to maximize the use of the results obtained at each stage. The steps 3 and 4 can be performed more than once, depending on the project details and maturity.

The standard also requires a usability validation plan to be defined. As the validation tool in the framework is the usability test, the acceptance criteria can be stated as "no major risk violations or medium and low risk violation that they cannot be mitigated or accepted in risk management." Despite the current standard in Brazil leave the acceptance criteria open to the manufacturer, some certification agencies have defined guidelines to accept a validation result. FDA, for example, only accepts the presence of a usability problem/user error in a validation test if "further modification of the user interface would not be likely to reduce the use error rate" [35].

If, during the validation test, the product does not meet the criteria, the product failed the test. This requires the interface to be re-evaluated and reworked by the development team in order to avoid or reduce the errors. The result of a failed validation test can be used in the documentation as a verification test.

Table 2 shows where the results/deliverables from each framework tools can be used to document each item required by IEC 62366, and when is the suggested MDDP phase to apply each tool.

4 Conclusion

There are few product development processes for medical devices which have human factors needs embedded in the framework. The ones that mention HFE are somehow complex and hard to be used by small and inexperienced teams, which is the Brazilian scenario.

The legal requirements for the standards help to drive the manufactures to develop better products along the time. By adopting the usability standards in 2015 it is expected that Brazilian industries to change their conception on how to assess the usability of their products.

This paper presented a simple framework to guide manufactures on which HFE tools and methods to use on their product development to maximize their resources in the usability evaluation. The proposed methodology on using the outputs from one HFE method as input for the other ones helps to ensure that no information will be missed. The framework also provides information on how to document the usability process to comply to the IEC 62366 standard consequently with IEC60601-1-6.

It is important to test the model in a real case, however as it was based on literatures frameworks and in a guideline that was successful tested in a Brazilian environment. The proposed framework is also in "line" with the new FDA guide.

A practical guide in how to implement HFE into product development can benefit the Brazilian industry in order to be compliant with international standards in Usability Engineering. Our main goal with this, is to support the companies to

attend the local regulatory requirements by ANVISA and also to be competitive and able to export, as IEC 62366 is also mandatory to reach the European market.

The framework proposed here is not the only way to do human factors. It is focused on small development teams from Brazilian manufactures. Besides, the validation of this model might be also usable for other developing countries with similar industry characteristics.

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A Systematic Approach to Improve the Reprocessing of Surgical Instruments

Nina Scheinberg, Bill Zhang, Leah Raschid, Rama Mwenesi, Mark Grum, Moses Chan, Amy Cohn, Joseph DeRosier and James Bagian

Abstract Hospital systems currently face challenges associated with insufficient cleaning and maintenance of surgical instruments. These instrument reprocessing challenges jeopardize patient safety, cause significant damage to reputation, and contribute to additional costs. Our team collaborated with doctors, nurses, instrument reprocessing technicians, and supervisors in the neurosurgical service and the Central Sterile Processing Department at a university hospital. We focused on how instrument "cleanability" and the configuration of instrument sets impact the effectiveness and efficiency of surgical instrument reprocessing. We developed an Excel-based set-configuration tool to aid in reconfiguring instrument sets to reduce the impact of bioburden. To validate the tool, we separated bioburden-prone instruments from the neurosurgical service's most heavily used instrument set. We also developed a Cleanability Index to rate surgical instruments and sets based on their difficulty of cleaning.

Keywords Instrument reprocessing · Optimization · Process improvement · Surgical instruments

1 Introduction

1.1 Background

Surgical instrument reprocessing is the procedure of cleaning and disinfecting or sterilizing instruments after being used in a surgical procedure. The surgical instrument reprocessing cycle is complex and involves the effective coordination of multiple resources and staff within a health system. At the University of Michigan

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Health System (UMHS), the Central Sterile Processing Department (CSPD) is responsible for reprocessing and managing all instruments flowing to and from the Operating Rooms (ORs). Over 52,000 surgical cases are performed at UMHS annually [1]. Each case can require hundreds of instruments. Due to this high demand, UMHS staff process roughly 15,000 instruments per day.

1.2 Goal

Staff in both CSPD and the ORs have reported frequent problems related to the reprocessing and delivery of instrument sets. These problems include unavailable instruments and sets, dull or broken instruments, and insufficiently cleaned instruments. Instruments are considered to be insufficiently cleaned if they contain "bioburden" (human tissue from a previous surgical case) or "debris" (dirt, fuzz, etc.). In addition to compromising patient safety, these issues also adversely impact the institutional outcome measures shown in Fig. 1.

If one instrument is suspected to have bioburden or debris, its entire set is sent back to CSPD for reprocessing. Historical data has indicated that "bioburden events" are responsible for the vast majority of additional reprocessing. This correlation drove our team to focus on reducing the impact of bioburden on the outcome measures shown in Fig. 1. Our goal was *to have all items required for the proper care of the patient available at the time of surgery, properly cleaned and sterilized, and in working condition—while ensuring the efficient use of resources.*

To achieve this goal, our team collaborated with UMHS leadership and staff in CSPD and the ORs in the Neurosurgery Service to complete the following objectives:

1. Conduct process flow analyses to fully understand the reprocessing cycle.
2. Develop a "Cleanability Indexing" system to rate instruments and sets based on their level of difficulty to clean.
3. Create a tool to: (1) evaluate instrument set configurations with respect to their impact on the institutional outcome measures, and (2) recommend optimal instrument set configurations.
4. Separate one of the hardest-to-clean instruments from the instrument set most cited for bioburden events in an effort to reduce the number of instruments sent back for reprocessing.

Fig. 1 Institutional outcome measures

1.3 Challenges

Ensuring that instruments are available, functioning, and free from bioburden and debris can be complicated by the following factors:

1. High OR case volume: Because UMHS conducts over 100 cases per day, CSPD staff find it challenging to reprocess instruments within current constraints related to time, equipment, and procedures.
2. Time pressure to turn over ORs: UMHS's high number of daily surgical cases requires nurses to turn over the ORs swiftly. This can result in nurses to choosing to forgo point-of-use cleaning (i.e., pre-cleaning instruments in the ORs so that blood, bone, and tissue do not harden onto the instruments before they are decontaminated and sterilized) in order to meet immediate time pressures.
3. Instrument design complexity: Each instrument has a unique cleaning protocol dictated by the manufacturer's Instructions for Use (IFUs). All CSPD technicians are expected to adhere to the process as identified in the appropriate instrument-specific IFU, but this is complicated by the thousands of different instruments owned by UMHS. Additionally, many instruments contain small channels and grooves that are hard for CSPD technicians to access and effectively clean or determine if they have been effectively cleaned.

1.4 Literature Review

Before our team began work on our objectives, we conducted a literature review in an attempt to discover if aspects of the project had been pursued at other hospitals worldwide. We were unable to find research papers written about the same area of study.

2 Methods

2.1 Process Flow Analyses

The first method implemented had the goal of understanding the current flow of instruments in the UMHS reprocessing operation during current operating hours (morning shifts between 9 and 11 a.m. and afternoon shifts between 2 and 4 p.m.). Instruments were defined at tray/set levels for surgical use, so our team pursued process flow definition at the set level. Team members visited CSPD at different times to see the sequence of procedures at varying hours and shifts. We observed the instrument flow from the OR through CSPD excluding instrument use in the OR, as it was out of scope of this project.

Our team reviewed the instrument process beginning with OR decontamination and initial point-of-use spraying after surgery, through transportation to CSPD, through decontamination, washing, sorting, examination, sterilization, packing, storing and readying for use in subsequent surgical cases. After the initial observations our team conducted informal interviews with CSPD technicians to validate our understanding of the processes and permit us to add any missed steps throughout the instrument processing flow. Additionally, our team evaluated historical data analyses of CSPD for comparison. With a clear understanding of the CSPD reprocessing operations, we developed a visual current state process map (Appendix) and validated it with UMHS staff and leadership. Based on the collected current state data, we assisted the UMHS onsite industrial engineer in developing an ideal future state map.

Our team then focused on the CSPD decontamination process. It was observed that CSPD technicians did not always follow standard procedures and there was substantial inter- and intra-individual variation. According to policy, decontamination technicians were required to clean each surgical instrument set within 15 min which incentivized technicians to be time- versus procedural-compliance driven and could negatively impact the reprocessing quality. Our team identified two major areas to investigate further: the cleanability of instruments and the configuration of instrument sets.

2.2 Cleanability Index

After our team determined that different instrument sets required more or less time than what was allocated for cleaning, we focused our efforts on creating a "Cleanability Index" (CI). The CI is used to rate the difficulty of cleaning individual instruments based upon their design and instrument sets based upon an aggregation of the instrument CIs in the set. With help from UMHS staff, our team began by compiling a list of the 13 hardest-to-clean instruments in Neurosurgery. Staff then completed a survey created to rank the hardest-to-clean instruments' cleanability compared to the other instruments on the list. The results were analyzed using an analytical hierarchy process (AHP) which ranked the instruments in order from hardest to easiest to clean. This initial step allowed the team to assign a preliminary CI rating to each of these instruments. In order to make the CI more applicable to a wider range of instruments our team did an in-depth examination to identify what made instruments easy or hard to clean.

The next step involved creating a list of instrument design features that contributed to an instrument's cleanability. This resulted in the development of a list of 10 design features associated with cleanability. We then asked a senior technician in CSPD to identify which features each instrument possessed in Neurosurgery's most used set.

Based on the list of hardest-to-clean instruments generated by the AHP and the features that those instruments possessed, we assigned weights to each design

feature; if very hard-to-clean instruments possessed the same feature, that feature would be assigned a higher weight, and vice versa. This then allowed us to assign more thorough CI ratings to different instruments.

2.3 Instrument Set Reconfiguration

The process mapping and Cleanability Indexing helped our team to better understand how hard-to-clean instruments impacted the reprocessing system. From historical data, we found that the hardest-to-clean instruments consistently had a higher percentage of reported bioburden events than others. By separating hard-to-clean instruments from the "mother" set and creating "modified mother" and "daughter" sets, fewer instruments would need to be reprocessed when a bioburden event occurred due to one of the hard to clean instruments. As a proof of concept, the team created a tool that shows the effects of separating certain instruments from a desired set. The tool displays the configurations of the new sets and the expected bioburden rates for each mother-daughter set.

UMHS provided our team with a database containing all of the Neurosurgical sets used at the hospital. The database listed the instrument categories in each set, as well as the number of instruments in each category. Each instrument has a bioburden probability that contributes to the overall percentage that a particular set might be sent back for reprocessing.

Our team created an Excel configuration tool that allows users to select specific sets and see how reconfiguring the set (into two or more daughter sets) changes the probability of a set being returned to CSPD for reprocessing due to bioburden. When the user enters a set name (found in the database), the initial configuration of the set is shown along with the resulting probability of an instrument within the set containing bioburden. Users may alter the configuration in the tool to observe how the probability changes along with the total number of instruments in the original mother set and the new daughter set.

In addition to these features, the tool contains other data such as financial summaries and the storage space required for all sets (reconfigured or not). This data permits the cost of separation to be shown along with how separation can help avoid costs of future bioburden events. The tool also shows how the total number of instruments reprocessed due to bioburden decreases by separating out the hardest-to-clean instruments.

With this tool, the team was able to validate set-reconfiguration with Minor Neuro, Neurosurgery's most used instrument set. Implementing this set-reconfiguration process occurred in four key phases.

Phase 1 involved identifying the instrument set that would be best suited for reconfiguration. Relevant criteria included frequency of use, frequency of reported bioburden/debris incidents, and total number of instruments. Anecdotal evidence cited Minor Neuro as the most commonly recurring set with bioburden. The team analyzed 8 months of data collected between January 2015 and August 2015,

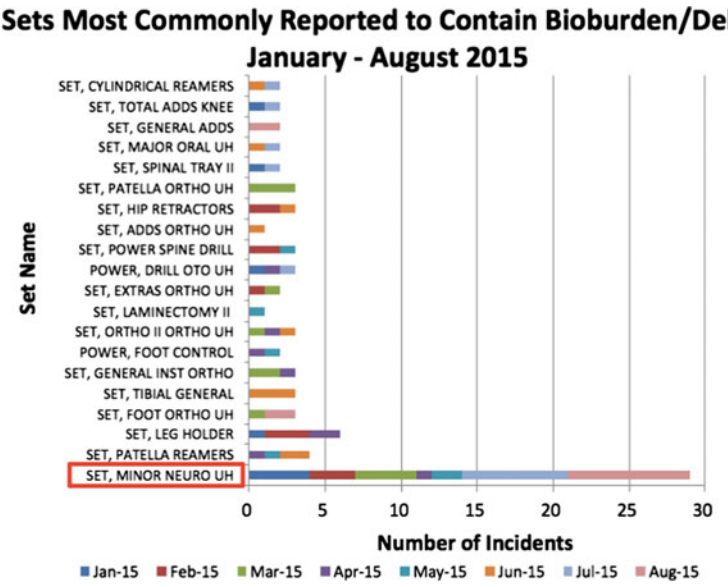

Fig. 2 Most common sets reported in the ORs with bioburden/debris

which validated the claims, as shown in Fig. 2. Minor Neuro was also the most commonly used set in the Neurosurgery database with an average monthly use of 128 times and an instrument count of 123 items.

Phase 2 involved identifying the instrument categories most commonly reported as having bioburden within the Minor Neuro set. In order of recurring frequency, bipolars, kerrisons, and suctions were the categories most commonly reported instruments. The team decided to not separate the bipolars due to the fact that a parallel improvement project was focused on addressing its bioburden issues. The team as a result selected kerrisons—the second most highly recurring instrument category—for separation from the Minor Neuro set.

Phase 3 was the most critical step in the process. The team engaged the CSPD and OR staff and leadership at all levels along with the Neurosurgeons over a 3-month period to first obtain buy-into the idea of piloting Minor Neuro's reconfiguration. The next task involved creating alignment in understanding with respect to the vision, goals, intended outcomes and workflow changes associated with the reconfiguration process as well as obtaining commitment from staff to successfully carry out the process.

Phase 4 entailed separating the kerrisons from Minor Neuro. CSPD staff performed this process during a 2-day weekend of low case volumes when the majority of the Minor Neuro sets were not in use. A second subset consisting exclusively of kerrisons was created and Minor Neuro was officially reconfigured on August 15, 2015. To increase the likelihood of implementation success, the team instituted weekly checks thereafter to ensure adherence to new workflows and address pilot concerns as they surfaced.

Additionally, the team collected feedback and concluded that the current kerrisons used were inconveniently designed for cleaning and sterilizing processes which was also the prediction of the CI. As a result, UMHS reviewed and piloted a new model of kerrisons in the OR before determining the instrument was worth the investment. These new kerrisons allowed CSPD technicians to access the center channel much more easily during cleaning.

3 Results

3.1 Process Flow Analyses

Our team delivered the current process flow map and identified the following findings:

- Most variability in the process occurred in decontamination.
- The 15-min per tray time allotted by policy for instrument set pre-washing was not sufficient for all instrument sets.
- There was no specific order of pulling carts of instruments for reprocessing once they reached CSPD and there was no specified limit to the time that instruments sat waiting before being prewashed in decontamination.
- To prevent blood and other bioburden from hardening, instruments were sprayed after use in the OR before reaching CSPD. This spray was initially blue, but UMHS temporarily switched to a clear spray for a short period of time. Using a clear spray introduced new problems resulting in the switch back to the blue spray.

After creating the current state process map, the team assisted in the development of an ideal future state map. This was led by the industrial engineer in CSPD and has been handed off internally for continuous improvement.

3.2 Cleanability Index

After assigning CI ratings to instruments used in Neurosurgery, we found that the majority of the instruments with the highest CI ratings positively correlated with the instruments that UMHS staff had reported to be the hardest to clean through the surveys. The instruments with the highest CI ratings were also the instruments that bioburden event data cited as the most problematic. While these preliminary findings were positive and significant, our team also noted that some instruments had high CI ratings but had not been flagged as hard-to-clean by UMHS staff. The order in which the instruments with the highest CI ratings were ranked also did not directly correlate with the order in which UMHS staff had ranked the

hardest-to-clean instruments. For these reasons, we believe that the CI rating system needs further development.

3.3 Instrument Set Reconfiguration

By separating only the kerrisons from the mother set and purchasing the new kerrisons of a different design, UMHS reaped the following benefits (calculated based on empirical data collected over a period of two months post separation):

- The expected probability of bioburden in the revised mother set decreased from 12.5 to 6.8 %.
- The number of instruments reprocessed due to bioburden decreased by 46 %.
- The total cost avoided per year (based on the set's usage each month) was $10,658.16.
- The cost avoided per year increased greatly when factoring in the OR disruption time.
  - Low case: 5 min per incident

    $27,490.56
  - High case: 30 min per incident

    $236,290.56

The results from the implementation are summarized in Table 1. Based on post-implementation data collected between August 15 and December 31, the team

Table 1 Financial and workload impact summary due to Minor Neuro kerrison separation

Metrics	Minor neuro pre-separation (mother set)	Minor neuro post-separation (modified mother set)	Kerrison subset (daughter set)
Average no. of sets used (per month)	128	128	128
Probability of rework due to bioburden	12.5 %	6.8 %	6.1 %
Average no. of sets sent back for reprocessing due to bioburden (per month)	16	Calculated: 8.70 Actual: 2.67	7.81 0
Average no. of instruments sent back for reprocessing due to bioburden (per month)	1968	Calculated: 1026 (*45.9 % decrease*) Actual: 315.06 (*84 % decrease*)	39.05 0
Average reprocessing cost (labor/equipment) due to bioburden (per month)	$1,066.08	Calculated: $579.68 Actual: $177.90	$341.92 $0
Total reprocessing cost avoided in CSPD (per year)	–	Calculated: $1,733.76 Actual: $10,658.16	
Total OR time costs avoided after separation (per year)	–	Calculated: $27,490.56 (*low case*) Calculated: $236,290.56 (*high case*)	

discovered that the benefits associated with set-reconfiguration were far higher in practice than predicted based on the Excel tool's calculations. The team observed more than double the expected benefits in regards to reductions in potential patient incidents, reprocessing workload and financial costs incurred as a result of mother set-related bioburden/debris events.

Overall, the team observed an 85 % decrease in the mother set reprocessing workload due to bioburden, a 45 % reduction in potential patient harm incidents from the mother set due to bioburden, and zero kerrison-related bioburden events as reported by the ORs. During the same time period, however, a total of three unrelated debris events were identified as well as one bioburden event attributed to suctions. This was expected, as the modified mother set still had a total calculated probability of rework due to bioburden of 6.8 % since only one of the hardest-to-clean instrument underwent separation but the observed occurrence was even lower at 2.1 %. The initial findings therefore support the team's hypotheses that our engineering approach to reconfigure sets by separating high- from low-risk instruments can yield increased efficiencies in production and quality. It is also important to note that the purchase and use of anecdotally easier-to-clean instruments was also a key contributing factor to the overwhelming success of the project.

4 Discussion

In theory and practice, our engineering approach to configuring sets by separating high- from low-risk instruments demonstrated a clear increase in efficiency, production, and quality. This was borne out by the improvement in the results with the modified Minor Neuro mother set as well as the Kerrison daughter set. Moreover, we believe that using an anecdotal, cleanability-based approach to instrument procurement contributed greatly to the results observed in implementation in the Kerrison daughter set. As it was not within the scope of our research, we did not objectively measure the efficiencies gained exclusively by using easier-to-clean instruments. We further suspect that the efficiencies observed during implementation were largely due to the increase in decontamination pre-cleaning time. For the mother set, both the reconfigured set of 118 instruments as well as the daughter set of 5 instruments would receive 15 min of decontamination pre-cleaning time. Prior to reconfiguration, all 123 instruments were given a total of 15 min of decontamination pre-cleaning time collectively.

In conclusion, our team successfully accomplished the project's objectives of improving the effectiveness and efficiency of the instrument reprocessing procedures. This success can be measured using the five outcome measures mentioned in the beginning of the paper: patient safety, quality, timeliness, financials, and staff satisfaction. The decrease in the number of bioburden events has increased both patient safety and quality since bioburden has the potential to lead to infections. Fewer bioburden events also means less time will be spent in the ORs searching for

replacement sets and instruments. Because OR time is costly, this saved time also translates into saved money aside from the improvement to patient care resulting from unnecessary delays during the surgical procedure itself. Additionally, fewer bioburden events mean less time and money spent in CSPD reprocessing extra instruments. Finally, since staff interviews indicated that fewer bioburden events and efficient production in both CSPD and the ORs contributed to higher morale, staff satisfaction has increased. Hospital reputation has the potential to improve as well if patients experience better results due to fewer intra-operative delays due to bioburden that can have to potential to impact safety from multiple perspectives.

4.1 Future Work

In the coming months, our team plans to focus on the following areas:

- *Enhancing and validating the Cleanability Index.* The team will collaborate with CSPD technicians to further investigate the specific instrument design features that cause instruments to be hard-to-clean, as well as use analytical hierarchy process (AHP) to provide a quantitative rating system for instrument features. These features' CI ratings could then be incorporated into an individual instrument's CI rating. By doing so, the index could be generalized to any other ORs within and beyond UMHS, serving as a potential universal standard of cleanability for surgical instruments.
- *Identifying and pilot testing the reconfiguration of additional instrument sets*. Our team plans to use the reconfiguration Excel Tool to identify and select a new instrument set in which to conduct reconfiguration. This practice would validate that the success in the Minor Neuro set was not accidental. Reconfiguration without purchasing of new instruments could also single out the sole impact of reconfiguration, excluding the potential additional variable of purchasing a new instrument.
- *Documenting and comparing CSPD workflow at other hospitals and clinics*. Our team also plans to understand the similarities and differences between the CSPD processes at UMHS and at other healthcare organizations. This would help us assess the usability of the Cleanability Index in other organizations and lay solid foundation for further expansion of the project beyond UMHS.

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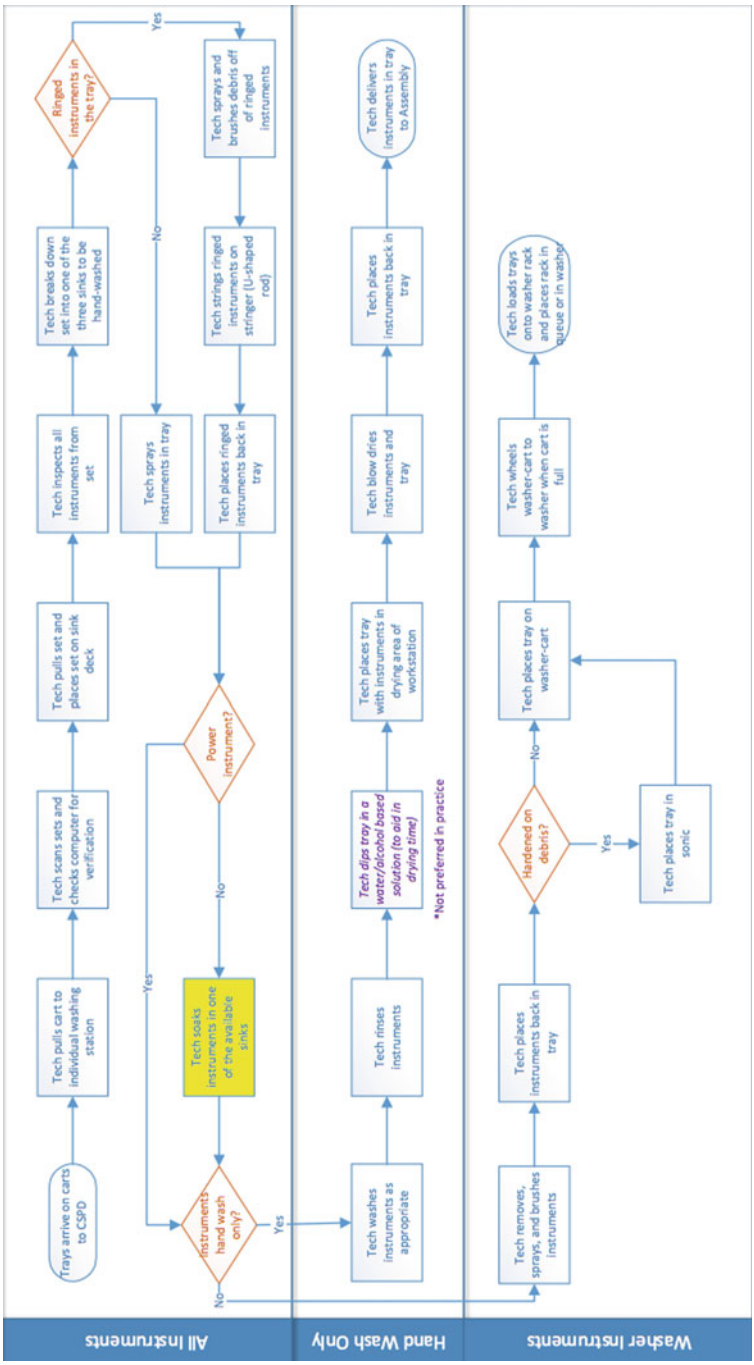
Appendix: CSPD Current State Process Map



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Building Safety into Medical Devices: The Non-injectable Arterial Connector Preventing Wrong Route Drug Administration

Maryanne Mariyaselvam, Arun Gupta and Peter Young

Abstract A never event is a serious and preventable error in healthcare. Wrong route drug administration into the arterial line can cause significant injury to the patients hand. Analysis of the incident data showed errors occurred during levels of heightened stress when medication was required to be given urgently, however during these circumstances healthcare workers did not seem to recognize the arterial line despite being coloured differently to standard venous lines. By using human factors design principles it was possible to develop a solution which prevents wrong route drug administration into the arterial line and does not interfere with normal clinical practice. We highlight that it was possible to eliminate a serious error in healthcare around the world.

Keywords Medical devices · Human factors systems engineering · Serious adverse events · Arterial systems · Wrong route drug administration

1 Introduction

In comparison to transport and energy, healthcare is a dangerous industry for users, with low productivity and efficiency and high error rates [1]. Research shows that 10 % of all hospital admissions result in a harmful adverse event and half of these

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could be avoided [2]. We know that this is an underestimate and that in healthcare, there is a culture of under-reporting errors and near misses. The Heinrich theory suggests that for every 1 adverse event, there have been 300 occasions where a near miss has occurred [3]. This can be highlighted by the Never Events Policy Framework, established to eliminate the occurrence of never events in the UK [4]. Significant measures have been taken to heighten awareness, to nationally standardise procedures and improve education and training of staff. All hospitals must report never events to the framework after conducting a root cause analysis of the incident locally and are required to have an action plan in place to prevent incidents from reoccurring [3, 4]. Despite this we repeatedly see the same errors reoccurring. James Reason's Swiss Cheese Model highlights how "defences, barriers and safeguards may be penetrated by an accident trajectory" [5]. In healthcare we know that most errors are averted by the healthcare worker, who performs the final check. If a distraction or mistake happens at this final stage then error is highly likely to occur. Therefore we rely on the healthcare worker to always be vigilant, behave correctly and appropriately at all times, despite clinical and emotional stress, fatigue or distraction. Essentially, we teach and train employees how to perform their jobs correctly and we *expect* them to do so without making errors. Therefore it is unsurprising that we repeatedly see the same errors reoccurring.

In high reliability industries, there is an understanding that human error cannot be prevented, therefore, the environment and working systems are built in order to account for and minimise this as much as possible [5]. This systems approach should be one that healthcare should learn from in order to minimise risk and prevent errors. The UK design council recognise that user error can be prevented by encouraging simple to use and intuitive designs in medical products, services and environments [6]. By engineering systems, as we find in high reliability organisations, it may be possible to "prevent people from doing the wrong thing and make it easy for them to do the right thing" and avert errors in healthcare [7].

It has taken several decades for the high reliability industries to improve their safety and develop systems in order for them to become highly efficient and productive with low error rates. However, this may not be as easily achievable in healthcare as a whole system. In these industries, although there is a highly stressful environment, the human operator is interacting with a machine, which can be turned off, or another professional with the same training and capability as themselves. In healthcare the clinician interacts with a layperson that is completely dependent and vulnerable to the decisions and capabilities of the clinician. These interactions are complicated by clinical stress, the patient may deteriorate and behave differently even minute by minute in some situations, emotional stress from the patient, their relatives and healthcare workers and tiredness for both the patient and the healthcare worker. Most importantly, in healthcare there is the factor of limited resources. In most industries money is invested into the system to in order to improve safety, efficiency and ultimately profit. This is simply not the case with most healthcare providers.

Therefore, one method of improvement is to look at isolated and specific errors and re-design systems in order to prevent these errors from happening. This method

re-designs the equipment that the healthcare worker interacts with and is the core definition of ergonomics. By doing this, it frees the clinician to concentrate their work on the patient's clinical variables that cannot be altered. This paper highlights how the use of human factors design principles were used to eliminate a serious error in healthcare around the world.

2 Never Events: Arterial Line Safety

Arterial lines are used in patients in operating theatres and intensive care units (ICU) in order to provide beat by beat blood pressure monitoring and to take numerous and repetitive blood samples [8]. There are numerous problems with the current arterial line system: use of wrong infusion fluid, accidental injection into the arterial line, bacterial contamination of the arterial line and blood spillage during blood sampling [8, 9]. Although accidental injection into the arterial line is reported to be an uncommon problem, when it does occur it causes damage to the blood vessels and surrounding tissue, leading to wide ranging effects from minimal paraesthesia to tissue necrosis and amputations, and in one instance death [8–11]. The National Patient Safety Agency (NPSA) issued a safety Alert in 2008 suggesting that arterial lines should be coloured red to highlight their presence and to prevent confusion with a venous line, to remind staff that medication should never be given via this line [8]. They also suggest that potential solutions should be better training in infection control, training in pre-procedure checks and management of samples [10]. However, this does not mitigate for human error.

3 Methods

Despite these recommendations, eight years on we still see the same errors with arterial lines occurring in clinical practice. In the busy ICU environment, with very sick patients there are numerous catheters and medication lines in the patient. With a clinically sick and deteriorating patient and when medication is rapidly required, it is easy to see how the arterial line can be mistaken for the venous line, through visual blindness or fixation error. In theatres both the arterial and venous lines and their normal access ports are hidden under sterile surgical drapes, where only the distal portion of the catheter, which is usually clear and attached to the fluid bag, is visible. In both of these cases the patient is anaesthetised and is dependent on the clinician to realise they have made the error. Or in most cases, the error is realised when the patient wakes up complaining of a painful hand unresponsive hand.

In the 2008 published alert the NPSA reported 76 incidents of problems with arterial line sampling with 21 % of these cases suffering moderate to severe harm [10]. In order to estimate the extent to which accidental administration of medication still occurs nationally we conducted an anonymous postal survey of all ICUs

and anaesthetic departments. An analysis of incident reports was conducted and determined theories as to why the error of accidental administration of medication into the arterial line occurs and we designed a simulation study in order to test this theory. Using human factors design engineering principles, we developed a medical device, in an attempt to design this error out of the system. Once a solution has been developed, the new device was implemented clinically and the results were evaluated in order to determine whether the device would prevent the error and be usable in clinical practice.

4 Results

In order to estimate the extent to which accidental administration of medication into arterial is still occurring after the publication of the NPSA guidelines, a national survey was sent to the clinical lead of both the Intensive Care Units and the Anaesthetic Departments of every acute Trust in the UK. They were asked whether they were aware of an incident of accidental administration of medication into the arterial line in the last 5 years. 1/3 of ICU clinical directors responded and 16/56 (28.5 %) reported that they had experienced mis-administration of medication into the arterial line. As only a single person's experience was surveyed in each unit we can assume that these figures of 28.5 %. These positive responses indicate a minimal national incidence of around 9 % and for a serious error these numbers are too high.

The arterial blood sampling process was observed in 11 UK ICUs. Despite standard guidelines, there was considerable variation in the process, where the mean umber of process steps was 19 but the range was between 15 and 28 process steps. This wide variation in clinical practice has the potential to lead to several errors when taking blood samples.

Arterial line incident reports over a 10 year period were analysed. These showed that the error occurred during times of heightened clinical stress, when medication needed to be given urgently. During these incidents, it appeared that the external stresses and the necessity for urgent action required to help the patient, the colour red did not trigger or alert the healthcare worker to the presence of the arterial line. During these incidents, healthcare workers gave the medication into the arterial line and did not necessarily realise that they had done so until the consequences to the patients were seen. This is of course inattentional blindness.

By understanding the theory of inattentional blindness, we applied this to arterial line errors and tested this in a simulation study using a sim man simulator in a critical care environment. 15 doctors were recruited to the study and asked to manage an intensive care 'patient'. The 'patient' had a central venous line, peripheral venous line and an arterial line, with a standard arterial connector. Participants were asked to perform routine tasks such as assessing and monitoring the 'patients' ventilation parameters. During the simulation the 'patient' was given a sudden bradycardia and participants were asked to urgently give atropine or

adrenaline to treat the symptoms. We found that 66 % (10/15) of participants injected directly into the arterial connector and did not realise they had done so.

Arterial blood gas samples are taken from the sampling port on the three way tap near the patient's hand. The majority of accidental arterial line wrong route drug administrations occur at the sampling port. The sampling port has a cap like covering, in order to prevent leakage of blood from the line, called an arterial connector. From analysis of the data reports, clinical evaluation and the observing the arterial sampling process across the region, a theory developed where a failsafe could be developed into the standard arterial connector and this could be the final error check in the sampling process. We designed a new arterial connector, the non-injectable arterial connector (NIC). This has a one way valve incorporated in it's internal mechanism. This allows the user to always take the blood sample and perform the normal daily tasks of the arterial line, but in the rare instance when a healthcare worker accidentally tries to make the error the one-way valve acts as the final fail safe, and physically prevents them from doing so. Because they are prevented from their action, the device also alerts the clinician to recognise the error they are trying to make alerting them to alerting them to modify their behaviour.

We then conducted usability tests on the device and introduced it into clinical practice in 11 hospitals in the UK. There was a high uptake in individual trusts, with the new arterial connector being used on 79 % of patients with an arterial line. The NIC was compared to the standard arterial connector and it was found that using the NIC simplified the process of arterial line sampling by requiring fewer numbers of process steps. There was also no difference seen in the ease of use of the new equipment and the time required to take a blood sample. Staff surveys (258 responses) showed that 98 % of healthcare workers believed it was important to have a device that prevented wrong route drug administration. 96.5 % of staff said the NIC allows increased identification of the arterial line and >80 % said that the NIC was easy to learn and use. 28 % of respondents said they have personally seen adverse events in their routine clinical practice when using standard arterial lines in the past and 93 % believe these would have been prevented had the NIC been in use.

5 Discussion

A never event is a serious and preventable incident when a patient experiences harm caused by a healthcare worker or system error [4]. By the very nature of the name, a 'never event' is a rare occurrence and may happen once in a single hospital over several years. This highlights that good practice is an everyday occurrence and that hospitals are generally safe. However, the never event is a catastrophic incident resulting in patient harm *and* emotional harm to the member of staff (2nd victim). It is mandated by NHS England that trusts must introduce measures to prevent never events from happening. However, the difficulty of this situation is that the error must be prevented and it must not affect or jeopardise the good practice that normally occurs in hospitals, as this will result in an overall increase in errors.

Accidental injection of medication into the arterial line is a rare error, however when it does happen there are significant consequences, the worst being necrosis of the hand requiring amputation [9, 11, 12]. Our analysis of the incident data shows that these errors are not due to incompetence or inexperience. The clinician will often have performed the procedure many times during their clinical practice, however, during that one particular procedure, there will have been human factors such as clinical distraction, fatigue or system errors, which influence the incident occurring at that particular time. In order to prevent these errors from occurring again, one method which many hospitals use is re-education and training. When hospitals highlight the awareness of an incident, introduce educational programmes or retraining, there is a shift of the Gaussian curve where staff are focused on prevention of that particular error and have a better understanding of the procedure. However, when the educational drives have finished, or a different one has been introduced focusing on another problem, there is a gradual regression back to former practice and previous habits, which may allow the error to occur again. Due to the nature of the working environment, the rare events and by understanding these events are due to human error, it is nearly impossible to prevent never events from re-occurring by educational methods alone, therefore alternative methods must be sought.

The NPSA alert recommended that staff need to be re-educated and trained appropriately and that arterial lines should be coloured red in order to highlight the presence of the arterial line [8]. Whilst this may work in some cases, it does not prevent the error from occurring in all cases and we still see reports of accidental injection into the arterial line. This was clearly seen with the results of the simulation study, where 66 % of doctors gave medication into the arterial line and did not realise they had done so. This is due to inattentional blindness. The simulation study highlights how easy it is to make simple errors, which can have significant consequences to patients. In the transport and energy industries, there is an understanding that human error cannot be prevented and therefore, the environment and working systems are built in order to account and minimise this as much as possible. By similarly engineering the medical equipment, it is possible to ensure that the healthcare worker always performs the procedure in the correct way, and thereby ensures that the error never occurs. With arterial lines, the error does not occur during the routine arterial sampling process, but at other times of heightened stress when medication must be given to the patient and in these instances the arterial line must be avoided at all costs. The healthcare worker is fixated on giving medication rapidly, to the extent that they do not recognise the red trigger, which should alert them to the arterial line. In designing the NIC, the device was designed to be a failsafe. The one way valve would only become apparent when the healthcare accidentally attempts to do the wrong thing.

This is important with these types of rare errors. In 99.9 % of cases arterial lines are used safely and without error. However, with this error the mistake does not occur with the routine clinical use of the arterial line, therefore making this procedure harder will interfere with normal practice and increase the number of errors. We therefore were required to think about how the connector would be used in

clinical practice during the development process. Our solution simplified the sampling process, made the workload easier for the clinician and provided a patient safety benefit. We feel the results of the staff survey.

By the use of human factors engineering principles it was possible to determine when and why mistakes with arterial lines occur. Through this a practical solution to the error was developed and was well adopted in clinical practice. We highlight that it was possible to eliminate a serious error in healthcare around the world.

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Mobile Technology Improves Therapy-Adherence Rates in Elderly Patients Undergoing Rehabilitation—A Crossover Design Study

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Abstract In this publication the results of an empirical study are analyzes regarding the research question if a mobile application on a tablet computer, to support the drug intake and vital sign parameter documentation, affects adherence of elderly patients. For the achievement in the management of patients with hypertension adherence of their medication is essential. Patients with no prior knowledge of tablet computers and a coronary heart disease were included. All Patients were instructed personally into the mobile application "Medication Plan", installed on an Apple iPad™. This study was performed in a crossover design with three sequences. The first sequence is the initial phase, followed by the interventional phase (28 days of using the app system) and at least the comparative phase (28 days of using a paper diary). The interventional and comparative phases were conducted alternately. Altogether, 24 patients (12 male; mean age 73.8 years) were registered. The subjectively assessed adherence (A 14 scale) was 50.0 before the study started (SD 3.44). After the enforcement of both interventions there was a significant increase, which was more pronounced after the intervention phase (54.0,

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SD 2.01) than the comparative phase (52.6, SD 2.49) (for all pairs $p < 0.001$). Furthermore, the medical conditions, or the number of drug intakes per day had no effect on the subjective adherence. For both blood pressure recordings ($p < 0.001$) and medication intake ($p = 0.033$) the obtained logging data showed a significantly stronger adherence for the medication-app than the paper diary system. The majority of participants (n = 22) denoted that they would like to use the medication-app in everyday life and do not need any further assistance. A mobile app for medication adherence strengthened objectively and subjectively metered adherence of elderly users folding rehabilitation.

Keywords Drug therapy · Self-management · Therapy adherence · Elderly patients · Mobile application · Tablet computer

1 Introduction

Management of hypertension is one of the key issues in secondary prevention of ischemic heart disease (IHD), which is among the main causes of death in the Western World [1]. Cardiac rehabilitation of patients with coronary heart disease embrace the risk assessment and management of comorbidities. Furthermore the lifestyle alters and psychosocial support has been shown to reduce mortality [2]. Nevertheless, adherence to self-management and medication is still a challenge, particularly for the management of hypertension and elderly patients with high comorbidity and reduced awareness of their medical condition [3]. The complexity of the daily life, shifting priorities and frequent polypharmacy conducive to patients' inability to deal adequately with their medical conditions. The important risk factors of IHD are known as diabetes, hypertension and dyslipidemia that up to 50 % of patients stop taking the medication during the first year of prescription [4]. Novel strategies are required to better address the needs of elderly and chronically ill patients [5]. To identify their needs, the mobile information technology may offer new system-solutions in future. With more than 1 billion users having access to mobile broadband internet and a rapidly growing mobile app market, stakeholders have high expectations that this technology may improve health care and create it in a new way [6]. Expectations range from overcoming structural barriers, via access in low-income countries to more effective, interactive treatment of chronic conditions. At the moment, previous work suggests that even when sophisticated technology is available, older users (e.g., age 50 and above) think that their initial experiences with medication applications are frustrating and insufficient [7]. To further investigate this issue the Institute of Industrial Engineering and Ergonomics of RWTH Aachen University instigated a study of the iNephro "Medication App", which had previously been developed by the Department of Nephrology and the Institute for Drug Safety, University Hospital Essen. With this study we focused elderly patients with a history of ischemic heart disease folding cardiac rehabilitation.

1.1 Objective

Pre-specified main endpoints of the statistical analysis were the effect on participants' affinity for technology, reported medication compliance/orderliness of self-reliant vital parameter measurements as well as objective adherence which was assessed by the logged interaction protocols.

2 Materials and Methods

2.1 Ethics

The Ethics Committees of RWTH Aachen University as well as the Ethics Committee of the Medical Faculty of Essen University were consulted and ethics approval issued (EK 340/14; respectively 14-5842-BO). To take part in this study all participants needed to provide a written consent. They received a patient information before participating the study. Furthermore, all participants got sufficient time to read and understand the information about objectives, methodology, insurance, data protection etc. The investigator explained the document to the participant and answered their questions. Following participants had to sign a declaration of consent, which declares that they understood everything and take part in the study voluntarily. Afterwards the investigator signed both documents additionally. One copy of each document was given to the patient and the other one was archived by the investigator.

2.2 Participants

The Institute of Industrial Engineering and Ergonomics of RWTH Aachen University adjusted 24 participants via local cardiac-rehab sports groups (phase III rehabilitation). All participants were afflicted with hypertension and coronary heart disease and had experienced myocardial infarction requiring inpatient six-month hospital stay before this study. On average 2.2 (SD 0.9) the following additional chronic conditions were reported: hypertension (n = 14), dyslipidemia (n = 9) and diabetes (n = 9), liver (n = 2) and lung disease (n = 2). All of the 24 participants have been instructed by their physician to take their drugs between twice and six times a day, on average 3.8 drugs (SD 1.4). The consulting physician of the participant requested them to undertake blood pressure readings between once and four times a day (mean 2.0; SD 0.9). All of them are retired and lived autonomously at their homes so none of them needed assistance in activities of daily life. Furthermore, none of the participants had prior experiences with a smartphone or tablet but 14 of them owned a computer and 17 used the internet regularly. We only

accepted participants with a minimum visual acuity of 0.75 using their vision aid, if it was adaptive. Within the group of participants, the sex and age were balanced and used as a control variable. All patients participated voluntarily and their participation had no context with medical treatment. There was no financial compensation given for the participation.

2.3 Apparatus and Inductor Session to User

This usability trial of elderly cardiac patients used the app "Medication Plan" (version 1.3) on a first generation Apple iPad™ (iOS version 5.1.1) in 2014 [8, 9]. Specifications supported regular drug-intake of patients with chronic conditions on polypharmacy (Fig. 1). The home screen of the test iPad was individually modified that only the app "Medication Plan" was available in the dock and all further standard applications were placed in a folder on the second menu page. To ensure that the participants do not delete the app "Medication Plan" itself, we disabled the possibilities to delete applications in the device's restrictions settings. Furthermore, we put a green sticker on the iPad's home button to help the user locating it more easily. The feedback of the users of pre-tests had shown that this facilitated usage (the first generation iPad did not offer the smart cover functionality which turns on the display when you open the cover) acts as an easy visible cue for the orientation on the iPad when the participants wanted to turn it on. For introducing the system we arranged an interactive learning-by-doing tutorial session in which the participants were introduced to the touchscreen usage and the iNephro application. We wanted to enable the user an autonomous exploration of the device by facilitated discoverability. After the physician issued the prescription and individual medication it was entered into the Medication Plan system. We also explained the general concepts of tapping and swiping since none of the participants used a tablet computer or smartphone before. The test subjects were familiarized with the functions of the application (i.e., confirming medication intake and recording blood pressure values) and how to recover if a wrong input has been made. Furthermore, the application "Medication Plan" changed its layout accordingly by rotating the iPad, if the participants prefer the portrait or landscape mode. The personal tutorial session was concluded by a brief test consisting of small series of tasks which should strengthen the knowledge of the participants. Users were asked to turn on the device, to confirm their medication intake, enter blood pressure records and modify the data that was entered into the application "Medication Plan". In addition, the participants received a two-page manual which consists a one page FAQ-like "error treatment" and illustrate how to use the application. The volume of the acoustic pill reminder was set as desired by the users in the test groups but the participants were instructed how to adjust it later on by themselves. The users also received a paper-based notepad to write down any problems or particularly positive

Fig. 1 Creating a medication plan on the smartphone [14]

aspects (e.g., which might have been difficult at first) they encountered when utilizing the system while the study. However, the intervention was not used in the context of a medical treatment and no feedback was given by a doctor on recorded vital signs.

2.4 Study Design

The study was conducted in a crossover design with three sequences: initial phase without assistive systems, interventional phase (28 days of using the app system) and a comparative phase (28 days of using a paper diary). The Interventional and comparative phase were experienced by the users alternately. Furthermore, half of the users were randomly assigned to each group and switched after 28 days (Fig. 2). The environment for this study was the individual participants' home. According to the study design the users were visited at home by the same investigator for three times: initially (when introducing the system) and after using each system. The participants read and filled in the questionnaires on technical affinity

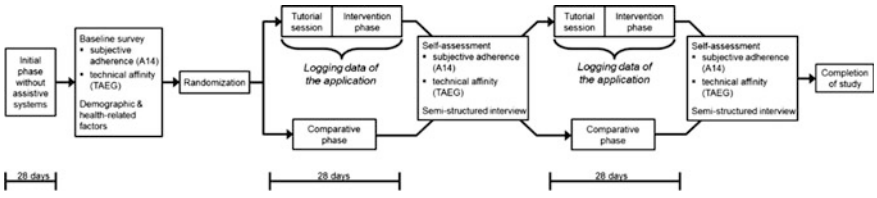

Fig. 2 Different phases of the study and obtained data

and the subjective adherence themselves to minimize the influence of the examiner. If the participant had a query, the examiner gave support and answered all questions. The semi-structured interviews were audio-recorded to enable later analysis, if participant agreed before. Each of the data collection sessions took between 30 min and 2 h, depending on the participants and on the upcoming period (e.g., introduction to use the system or handing out the diary). During the study, all materials and information were given in German language, which is the native language of the participants. After the participants completed the initial questionnaires, the examiner listed medications currently prescribed on a prepared form, based on the patient's self-report. The following data were required: name of the medication, number of intakes per day, and corresponding doses. Prior to the system phase, the examiner entered the participant's specific and individually medication and doses into the app "Medication Plan" on the iPad. Throughout the comparative phase, the participants used a paper diary as a traditional method to record their medication intake and blood pressure values. Logged medication intakes and vital sign parameter recordings were evaluated according to the automatically registered data of the app after interventional phase respectively the diary as a relative indicator for adherence was analyzed after the comparative phase.

2.5 Questionnaires

Initially, the participants completed a questionnaire, which contained items on their demographics and general medication-related questions anonymously. To classify the participants, we categorized them accordingly as novices, intermediates or experts and used an adapted version of the computer literacy scale (CLS) to estimate the existing of technical knowledge and experience [10]. The A 14 questionnaire determined subjective adherence, which contains 14 items on subjective adherence weighted according to a 5 point Likert-scale ranging from "never" to "very often" [11]. Values below 50 are regarded as non-adherent, values between 50 and 56 as adherent (sums ranging between 0 and 56). Finally, for measuring the affinity for technology we used the TA-EG questionnaire [12] consisting of 19 statements on different aspects of technology that are rated on a five point Likert scale from "Do not agree at all" to "Completely agree" designed to assess person's positive attitude, excitement, and trust toward technology. The scores for negative formulated items were poled so that a higher score results a lower rating on the negative aspects of technology. This leads to a consistent representation in which higher scores represent a higher affinity for technology. To get a broader insight into the use of the system, we conducted semi-structured interviews after the participants completed the questionnaires. The semi-structured interviews were designed around central questions including how participants incorporated the system in their daily lives and what they liked or disliked about it [13]. All questions were adapted to harmonize norm based upon ISO 9241.

2.6 Objective Indicators for Technology Adherence

Furthermore, we analyzed all confirmation rates of medication intake, the number of blood pressure records in the system and the data of the paper diaries. We execute a target-performance comparison for comparing the outcome. The target was defined as the number of medications each participant had to take every day multiplied by the days they actually used the system or the diary. An absolute performance was defined as the actual number of confirmations. If one participant had to take more than one unit (i.e., more than one pill) of a single medication at the same point in time/day it was considered as one medication intake ("all or-none") since the application cannot register whether participants only took a subset of a particular medication. To finally confirming medication for the rate of adherence is the ratio of performance and target multiplied by 100 for percentage scale.

2.7 Data Collection and Analysis

Data was double-entered and analyzed using SPSS statistics software version SPSS 21.0 (IBM, U.S.A.). A multi-factorial analysis of variance (ANOVA) with repetitions for the different factor levels of the response variables with a significance level of 0.05 was conducted. Significant findings were additionally analyzed by a post-hoc analysis and the Bonferroni correction to exclude an alpha-error cumulation by paired comparison of mean values. Septicity was assessed by Mauchly's test. In violation of the Mauchly's test, the corrected value according to Greenhouse-Geisser was used.

3 Results

3.1 Subjective Adherence

The mean subjectively assessed adherence before the study without supporting system was 50.02 (SD 3.44), after the interventional phase (medication-app) 53.96 (SD 2.01) and after the comparative phase (paper diary) 52.60 (SD 2.49). Furthermore, the inferential analysis of the three measurement points proofs, if there is a significant effect of the respective type of intervention ($F = 31.662$; $df = 1.613$; $p < 0.001$; Fig. 3) with a medium effect size of $\omega^2 = 0.07$ [20]. Post hoc pairwise analysis with Bonferroni correction showed significant differences between both interventions ($p = 0.02$) and in comparison to the initial phase (both $p < 0.001$). The effect on adherence was more pronounced after medication-app intervention than after the paper diary. The individual medical conditions and therapy were represented by the quantity of chronical diseases ($F = 2.494$; $df = 3$;

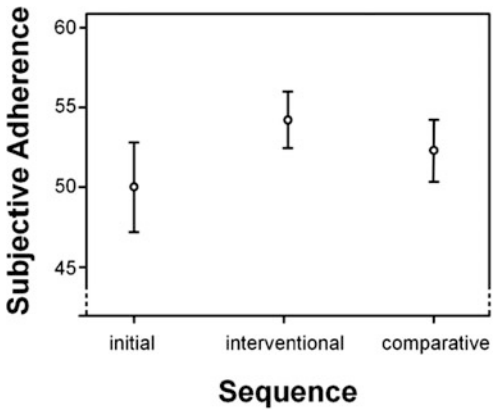

Fig. 3 Subjective adherence of the participants after initial, interventional and comparative phase

$p = 0.106$), number of drug intakes per day (F = 0.994; df = 4; $p = 0.627$) as well a number of vital parameter readings (F = 1.583; df = 3; $p = 0.515$) no effect could be identified.

3.2 Objective Adherence

The analysis of the logging data of the application and the documented medication intake of the paper system with regard to blood pressure recordings (F = 27.404; df = 1; $p < 0.001$) showed a significantly stronger adherence for the medication-app system than the paper diary system with a medium effect size of $\omega^2 = 0.09$ (Fig. 4). Intaking the medication per day (F = 0.072; df = 4; $p = 0.980$) and the number of chronic diseases (F = 2.521; df = 3; $p = 0.244$) as a well as

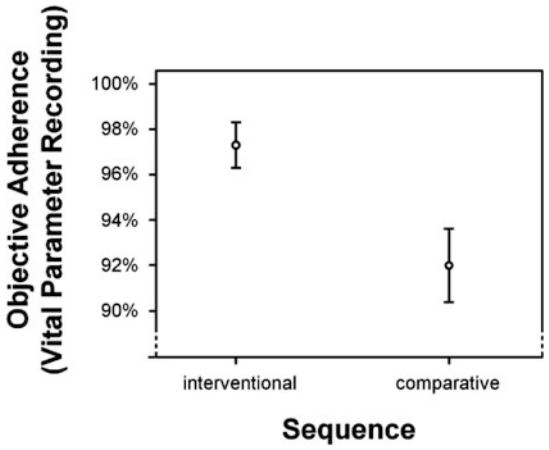

Fig. 4 Analysis of blood pressure documentation

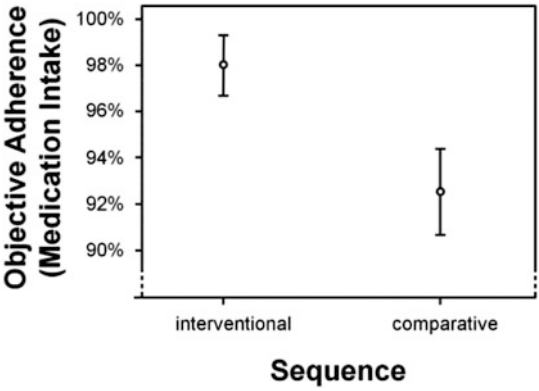

Fig. 5 Analysis of medication intake

required blood pressure readings (F = 0.641; df = 3; $p = 0.700$) did not affect the "recording" adherence for blood pressure monitoring.

The documentation of medication intake showed significantly stronger adherence (F = 361.349; df = 1; $p = 0.033$) while using the medication-app (small effect size $\omega^2 = 0.05$), in relative to the paper system (Fig. 5). Similar to the influence on the blood pressure recording, the documentation of medication intake was not affected by the number of chronic diseases (F = 1.882; df = 2; $p = 0.458$), medication intake/day (F = 11.748; df = 4; $p = 0.215$) and the number of required blood pressure readings (F = 3.138; df = 3; $p = 0.388$).

3.3 Technical Affinity

Technical affinity differentiate significantly after each intervention (F = 13.538; df = 2; $p = 0.003$). The correlation had a medium effect size of $\omega^2 = 0.07$. Further, paired testing showed significant differences between all values (naive vs. tablet-experienced: $p < 0.001$; naive vs. paper diary-experienced: $p = 0.043$, tablet-experienced vs. paper diary-experienced: $p = 0.002$). As expected, the 28 day intervention phase with assistance through the tablet computer had the strongest impact of technical affinity.

Computer literacy of the participants, which was assessed by means of the computer literacy scale (CLS) [16] were positively associated with technical affinity (F = 4.504; df = 2; $p = 0.028$) with a small effect size of $\omega^2 = 0.03$. While the difference between expert and novice is significant ($p = 0.021$), no significant difference could be detected between novice and intermediate ($p = 0.262$) and intermediate and expert ($p = 0.784$).

3.4 Impact of Comorbidities on Usage

The user, which suffer from hypertension were significantly more adherent (small effect size $\omega^2 = 0.05$) for the functionality of vital sign documentation than the other ones ($F = 480.720$; $df = 1$; $p = 0.036$) ($\omega^2 = 0.05$), while there was no significant effect on confirmation of medication intake compared to the other participants without this condition ($F = 35.98$; $df = 1$; $p = 0.131$). Other conditions like diabetes and dyslipidemia did not affect the technical adherence.

3.5 Interviews on User Experience

In structured interviews the vast majority of participants (n = 22) denoted, that they would like to use the medication-app in everyday life, without needing any further assistance. A Few of the participants (n = 2) felt that the system of the medication app would overly control them, while 20 reported that they did not feel that way. Most participants (n = 21) stated that they think that the system was useful for them and a large proportion (n = 18) said they would propose the system to other people. All of the test persons said that the size of the user interface elements was appropriate and that they liked the touch-screen interface and appreciated its precise use. Furthermore, three of the participants noted that "for me, the displayed information could be half of its current size" while almost half of test subjects (n = 11) were comfortable with the font size: "…also suitable for elderly, the numbers are nice and big". All participants liked to use the native iOS picker that displays numerals which are used to enter the blood pressure values. Most of the participants (n = 19) preferred this method over using a keyboard or an on-screen keyboard because it was faster especially since the last entered values were pre-selected. Two mentioned that this method was "fun" and "nice". One of the participants had a red-green color deficiency but had no problems telling apart the different colors of the status of the medication intake (i.e., red, green, and blue). N = 14 users said it was "fun using the system". Another participant denoted "The application and its structure are super". Only minor problems were reported, e.g. two participants forgot how to confirm all of the medication of one single moment of intake and another participant said he struggled twice with how to confirm his medication that he had to take late in the evening but did not confirm before the next day since the app always auto-switches to the current day. Four participants accidentally deleted one of their blood pressure records. All users spent between 1 and 6 min per day using the Medication Plan system app. Only three of them required the manual provided for additional help. Most of the participants (n = 19) preferred using the tablet computer in portrait mode, three of them had no preference. More than a half (n = 13) used the diagram function of the blood pressure values, four used it from time to time and six did not use the diagram function at all. Test persons who used the diagram function summed up that "It is useful to spot

peaks", "It is easy to see whether it is a random outlier or a trend", "It is much clearer than looking at the numbers". Three said they did not use the function at all because they were not able to interpret them: "I took a look but I don't know what to do with it. Without my doctor, I'm not able to explain this graph". One person said that he would like to see the exact moment he confirmed his medication intake.

4 Discussion

The study at hand is the first one to describe a medication-app versus paper-diary intervention to support therapy adherence in a crossover design amongst cardiac patients. Forgetfulness is stated quite often as a reason for unintentional non-adherence, which this study demonstrates. In addition, this study suggests—as other technology intervention studies—that it maybe is a benefit to enhance therapy adherence in future. Thus far in most cases text-messaging has been used to help e.g. aid tobacco cessation, improve physical activity and stimulate weight management efforts and improve diabetic control among countless other applications [14]. Studies with various clinical contexts and integrated text-messaging services report a revised medication adherence [15]. In this context it is interesting to mention that our participants had no experience with mobile devices before this study. However, this is conspicuous since the situation in the generation segment 60+ in neighboring countries is essentially different. For example in Switzerland, more than half of the population with the age between 55 and 69-years uses mobile communication technology [16]. Germany stays behind Spain, Italy, Canada, the US, or the United Kingdom in general usage of smartphones, even with disregarding age [17]. Previous studies confirmed that the lack of acceptance within the target group causes the below average utilization of such applications [18]. On the other hand, we demonstrated that after a relatively short introduction the participants could handle a mobile device quite certain and did not need further assistance. Our results give additional awareness into what has been termed the "digital divide" [19], an expression coined by developers, which implies, that in comparison with the younger generation the elderly generation is less likely to make extensive use of digital technology [20, 21]. It is important to mention that all patients lived autonomously at their home and none was in need of further assistance for activities of daily life, which suggests that they were not severely cognitively affected. All patients were responsible for their own self-management and needed no help by other ones. One critical point of using technology with elderly people is that maybe older adults are unable or have problems to use technology if they have cognitive disturbances. Our research results are contrary to this kind of criticism because the appropriate population for technology are those patients who can manage their illnesses on their own. One may expect that the driver for acceptance is the technology to offer a "relative advantage" over the status quo (Diffusion of Innovation

Model; [22]) and less demographic characteristics of the user [23]. Together with our research results that the technical intervention improves subjective drug adherence, one may reasoned that that the use of applications like "Medication Plan" may improve drug-therapy and -safety.

4.1 Limitations

In this study, the medication intake simply had to be confirmed via the users' iPad. Although a patient's report (confirmation) does not necessarily mean that the patient took the medication essentially. It was also possible, that conversely a participant forgot to report an intake. However, the shown method is very similar to pill counting which gives an objective and quantifiable insight into the level of adherence. Furthermore, assessing adherence for blood pressure recording is slightly different because it could happen that participants may take more records each day than actually arranged. For instance, a participant would still comply an adherence rate of 100 %, if he had to take one record each day and actually took two records on one and none the next day. To eliminate this factor, the adherence was calculated for every single day, capped at the rate of 100 % and then averaged. An additional restriction is the duration of the study, which was carried out within 56 days per user. Other mobile phone researches report that weights users place on user experience and enjoyment of use decrease within a period of five months. However, the weight referring to usability increases. In addition, the objective adherence was acutely high and it was conspicuous that the smart device intervention improved adherence over the already high adherence on the paper diary. Adherence was probably higher with using both applications (the diary and the tablet), caused of the measurement reactivity. However, that either of these conditions is really an intervention. In the following phase of research, medication adherence should be controlled by using electronic monitoring methods such as monitored pill bottles (e.g., MEMS cap), so that the correspondence of objectively monitored medication adherence with self-reported medication taking behavior using the app could be verified. Obviously, these suggestions are for the future and beyond the scope of this study at hand.

4.2 Interpretation

Adherence still illustrates a multi-dimensional problem and cannot be solved solely by Apple's promise "there is an app for that" as it introduced its App Store in 2008. With this study, we demonstrated that a mobile application for medication adherence increased objectively and subjectively measured adherence. However, it is compared with a baseline and a paper diary intervention in elderly users undergoing phase III cardiac rehabilitation. Patients, whose average age was over 70, indicated

an empathy to continue the using of the app. Furthermore, the app was amended with a face-to-face initial training stage and did not require any further technical support. The clinical implication is, that mobile technology, combined with an offline support, can be an effective tool for supporting adherence to medication with elderly populations. These users, which are not technology-savvy, can be conquered by a training phase, which promise that the tools can be spread and utilized over time in cardiac rehabilitation and patient care in general, if sufficient technological support is provided for patients.

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Development of the Elderly Healthcare Monitoring System with IoT

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Abstract Stroke is a brain attack (or infarction of a portion of the brain) caused by the sudden disturbance of blood supply to that area. In recent years, even though the number of stroke-related deaths has been decreasing in Korea, the incidence of stroke is increasing, and the incidence increase with age. The chances of surviving from an acute and sudden infarction are much higher if the elderly people get emergency medical assistance within a few hours of occurrence. Elderly health monitoring and emergency alert system are mentioned as one of the main

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application areas of pervasive computing and biomedical applications. Moreover, a proactive elderly health monitoring system involves active capture of brain and body movement signals, signal analysis, communication, detection and warning processes. The primary objective of this research will be concerned itself with ambient assisted living issues for the successful detection and generation of alarms in cases of stroke onset, which will allow the timely delivery of medical assistance, to mitigate the long-term effects of these attacks.

Keywords Aging · Elderly healthcare monitoring system · Internet of things · Stroke · Cerebral infarction

1 Introduction

Stroke is a brain attack (or infarction of a portion of the brain) caused by the sudden disturbance of blood supply to that area [1]. In recent years, even though the number of stroke-related deaths has been decreasing in Korea, the incidence of stroke is increasing, and the incidence increase with age [2]. Stroke is still the leading cause of death in Korea [3]. Stroke is an important health burden in Korea as well as worldwide. The stroke population as well as global population is aging [4]. On average, every 5 min stroke attacks someone in Korea [1]. A patient suffering from the onset of a stroke needs a trained care assistant close by to recognize the symptoms; in many stroke situations, an isolated individual would be unable to request help alone. The chances of surviving from an acute and sudden infarction (i.e., stroke) are much higher if the elderly people get emergency medical assistance within a few hours of occurrence. Wireless health monitoring is the most interesting research application field for wearable electronics. Smart healthcare monitoring using IoT (Internet of Things) is the integration of smart computing and remote health monitoring. It can be considered as the major application field of remote computing technologies for rapid communication between patients and healthcare professionals. Elderly healthcare monitoring and emergency alert system are mentioned as one of the main application areas of pervasive computing and biomedical applications. The primary objective of this research will be concerned itself with ambient assisted living issues for the successful detection and generation of alarms in cases of stroke onset, which will allow the timely delivery of medical assistance, to mitigate the long-term effects of these attacks. This paper is organized to give some of the background information related to the development of the elderly healthcare monitoring system with IoT.

2 Background

2.1 Aging in Korea

Korea is one of the most rapidly aging countries in the world, people over 65 years old will account for 38.2 % of Korea's population in 2050. Aging results from increasing longevity, and most importantly, declining fertility [5]. The life expectancy of males is expected to rise from 77.2 years in 2010 to 83.4 years in 2040. The life expectancy of females is expected to increase from 84.1 years in 2010 to 88.2 years in 2040. Unless Korea responds adequately to the decline in the working-age population, it is certain that the country will witness a slowdown in its economic growth [6]. As stated by the Korea's National health insurance company, the elderly are expected to consume 65.4 % of total health care expenses in 2030, which is huge comparing with the current state (37.9 % as of 2015). In Korea, the elderly dependency ratio is projected to increase. By 2060, the elderly dependency ratio is expected to exceed 80 % (about 20 % as of 2015), i.e., the number of "elderly dependents" will increase [7]. The elderly Koreans are more likely to live alone and the proportion of single person households is expected to increase further. As of 2010, the proportion of single person household was 34.2 % and it is expected to increase to 38 % by 2035 (Fig. 1).

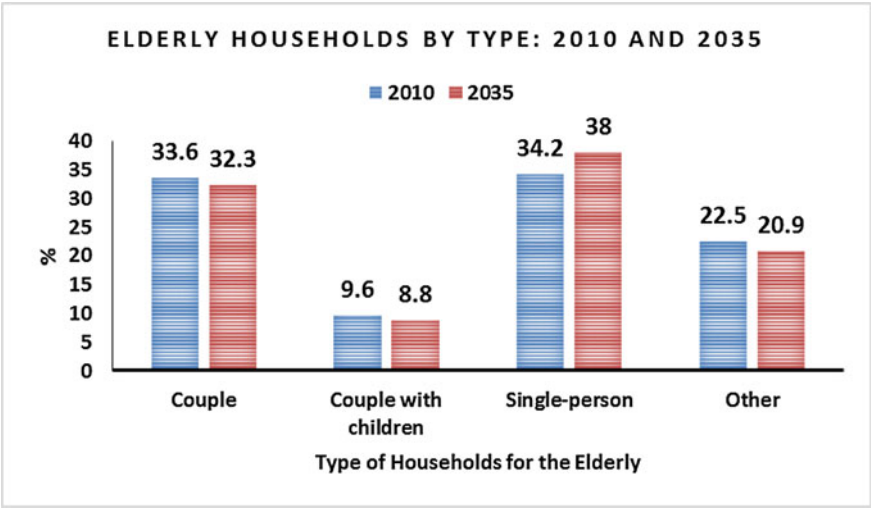

Fig. 1 Types of households for elderly aged 65 and over

2.2 Elderly Smart Healthcare Monitoring System

In this 21st century, technology has made human lives very easy and advanced. With the increasing aging population day by day, demand is increasing for smart healthcare systems to encounter the various healthcare related incidents because the aging population is much more prone to living alone than before and they are more likely to have an accidental death [8]. The conventional and old health monitoring system comprises of individual human health parameter sensors to measure one single health parameter while each was connected to a data collection device to make a database for healthcare record, which is time-consuming and not suitable for tracking down the emergency. Recent internet based technology developments have allowed the successful integration of several sensors equipped with one wearable healthcare system which can be wearable in the human body, or can be transported with the elderly patient to any remote place where emergency health care can be required. The newer internet based wearable healthcare monitoring systems have been developed for emergency and elderly health care, thus making the smart health monitoring very simple, portable and faster communication based [9–12]. Programmable emergency alarms are also integrated into the healthcare monitoring systems, which indicate emergencies to notify healthcare personnel for help.

2.3 IoT-Based Elderly Smart Healthcare Monitoring System

IoT-based smart healthcare systems depend on the vital definition of the IoT as a network of wearable smart devices, which connect with each other to measure the parameters, interpret the results and make the emergency alert to notify the medical personnel. IoT devices can be utilized for operating on a remote basis for smart health monitoring and emergency notification systems. For the elderly, smart healthcare monitoring systems are objectively designed to get the immediate measurements required to track down several health parameters in an urgent situation and in a cost effective way. In the smart elderly healthcare monitoring systems, several parameters like systolic and diastolic blood pressure, body temperature, pulse rate, heart rate, important muscle activity, blood sugar level testing, blood oxygen content(SPO_2), human brain activity, motion tracking etc. are all very important to track down the healthcare status [13–15]. Specialized sensors for health monitoring can also be equipped with a wearable device within living spaces/rooms/homes of elderly to monitor the health and emergency of senior citizens. Sensor mobile gateway integrated with healthcare sensor can ideally be presented on a small, wearable and portable device, suitable for daily and continuous use, such as a smartphone or PDA (personal digital assistant) [16–19]. Therefore, IoT-based systems are radically reducing the costs and improving health by increasing the availability and quality of care [20–23].

2.4 Application Areas for IoT-Based Elderly Smart Healthcare Monitoring System

A wide variety of application for IoT-based elderly smart healthcare monitoring system is possible. For example, smart car, smart home, smart bed, etc., In the Smart car, there have been numerous researches undertaken. Researchers at Nottingham Trent University [24] are working on new kind of car seats that could measure vital signs such as ECG of the driver to prevent accidents caused by drivers falling asleep. The sensor system can be used to detect heart signals, which indicate a driver is beginning to lose alertness and trigger a warning to pull over. In another study [25], the smart seat belt (Harken device) have been developed to sense heart rate. The Harken device is an innovative solution because it measures both variables on a scenario affected by vibrations and user movements, using intelligent materials embedded in the seat cover and the seat belt. The sensor system can be used to detect heart signals, which indicate a driver is beginning to lose alertness and trigger a warning to pull over. Most recently [26], Ford's European Research and Innovation Centre in Aachen, Germany is working on a car seat that can detect heart attacks. The device uses six embedded sensors to monitor heart activity. The system will then notify the necessary authorities in an emergency. Faurecia's concept Active Wellness seat has built-in biometric sensors to analyze a driver's heart rhythms and breathing patterns.

3 Conclusion

In this study, we presented some of the background information related to the development of the elderly healthcare monitoring system with IoT. As stated, the primary objective of this research will be concerned itself with the development of ambient assisted elderly healthcare monitoring system with IoT. The developing system can successfully detect and generate alarms in case of stroke onset, which will allow the timely delivery of medical assistance, to mitigate the long-term effects of these attacks. With the use of IoT, wearable healthcare devices collect and share information effectively in a database system with patient and medical personnel to make it feasible to make a faster communication and decision about the emergency situation much more accurately. IoT offers bigger promise in the field of healthcare and rehabilitation, where its smart remote technologies are already going to be applied to improve access to care, increase the immediateness of care and most importantly accuracy of the care.

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Development of an Intermittent Pneumatic Compression System to Manage Soft Tissue Mechanical Properties

Chi-Wen Lung, Tse-Yu Cheng, Yi-Jhen Li, Ben-Yi Liau and Yih-Kuen Jan

Abstract The pneumatic compression system has demonstrated the potential to manage hypertrophic scar tissues using localized intermittent compressive forces. The underlying mechanism associated with these repeated, intermittent compressive forces is the remodeling capacity of collagen fibers of fibrous tissues in response to mechanical forces. Although intermittent compressive forces are clinically proven effective on managing hypertrophic scar, the optimal configurations of pressures and timing of intermittent compressive forces are largely unknown. In this study, we have developed a motor-driven ultrasound indentation system to apply programmable compressive forces and simultaneously assess soft tissue mechanical properties and responses. We further tested this system in various conditions with Institutional Review Board-approved protocols in human participants. The compressive force applied by the system was 40 mmHg on the skin of the forearm for

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1 h with a frequency of 0.1 Hz. Soft tissue mechanical properties were assessed at three conditions, including (a) the forearm resting on the table with the wrist at a neutral position, (b) the forearm resting on the table with the wrist at 90° of extension or the maximal extension of the subject, and (c) forearm resting on the table with the hand holding a 1 kg weight. The effective Young's modulus was calculated to characterize mechanical properties of forearm soft tissues. Before the 1 h intermittent compression treatment, effective Young's modulus of conditions a, b, and c was 18.0, 11.3, and 16.8 kPa, respectively. After the treatment, the effective Young's modulus of conditions a, b, and c was reduced by 13, 7, and 51 %, respectively. The results support our general hypothesis that intermittent compression therapy may modulate soft tissue properties (e.g. hypertrophic scar). Future work should investigate the long-term effect of intermittent compression therapy on modulating soft tissue properties in patients with hypertrophic scars.

Keywords Intermittent pneumatic compression system · Massage therapy · Scar · Soft tissue interface

1 Introduction

Hypertrophic scar is one of the most significant problems in patients after skin injury [1]. Treatment of hypertrophic scar results in an enormous financial burden to the healthcare systems in the United States and is estimated at least $4 billion per year [2]. Hypertrophic scar appears either red or pink in color, pruritic, and raised [3]. The mechanical pressures caused by the hypertrophic scar limit the supply of blood, including oxygen and nutrients to the scar tissues [4]. It has been shown that compressive forces my alter the degree of collagen synthesis and degradation [5, 6].

The intermittent compressive force therapy may improve wound healing by 45.7 % [7, 8]. However, the optimal configurations of pressures and timing of intermittent compressive forces requires further investigation [9–11]. The purpose of this study was to explore the influences of various compressive forces on soft tissue mechanical properties and responses after massage therapy by the intermittent pneumatic compression system. The details of this indentation system and pilot results were described as follows.

2 Methods

In this study, we developed a motor-driven ultrasound indentation system to apply programmable compressive forces and simultaneously assess the force-deformation responses of the soft tissues at the forearm of the research participants. Three subjects were recruited into this study (N = 3; mean ± SD: age, 32.7 ± 18.5 years; height, 171.0 ± 10.6 cm; weight, 72.0 ± 21.4 kg; body mass

index, 24.3 ± 4.5 kg/m^2). We further tested this system in various conditions using an Institutional Review Board-approved protocol.

2.1 Compression System

The intermittent pneumatic compression system mainly consists of pneumatic devices (Takasima Eye-Care M-2203, Taiwan Family Enterprise CO., LTD. Taipei, Taiwan). The frequency of the intermittent compressive forces was chosen at 0.1 Hz in one indenter head with the diameter of 3 cm. The sequentially inflated and deflated pressures were regulated from 0 to 40 mmHg [12]. The compression system was in series applied to the soft tissue of the forearm 10 min for simulating the common massage protocols [13].

2.2 Soft Tissue Property Measurement

The indentation tests were conducted before and after intermittent compression therapy. Three forearm postures corresponding to different states of muscular contraction. The subject was asked to sit with the elbow rested at 180° flexion on a supporting table. Three conditions of forearm, including (a) the forearm resting on the table with the wrist at a neutral position, (b) the forearm resting on the table with the wrist at 90° of extension or the maximal extension of the subject, and (c) forearm resting on the table with the hand holding a 1 kg weight.

After a preload force of less than 0.5 N was applied on the skin over the dorsal forearm perpendicularly, a load of 5.0 N or less if the indentation had reached 20 % of the total thickness from the real-time ultrasound images was applied on the same location [14, 15]. The indentation velocity was set to be about 1 mm/s and the maximum indentation was about 20 % of the initial bulk soft tissue thickness, as evaluated by ultrasound signals with a minimum loading of 0.1 N [16]. A cyclic loading of 45 s was applied on the skin of the forearm with approximately 2–5 s per loading cycle (Fig. 1). About 200–400 data points obtained from the ultrasound signals were used to extract the effective Young's modulus of the forearm (Fig. 2).

2.3 Motor-Driven Ultrasound Indentation System

The motor-driven ultrasound indentation system mainly consists of four parts: ultrasound system, load cell, stepper motor, and standoff holder. Details of the indentation system have been described in our previous publications [17]. In brief, a 7.5 MHz ultrasound transducer (32-Channel BSUS20-32C, Broadsound Corporation, Hsinchu, Taiwan) with a 49-N load cell (Model UKA-E-005, Li-Chen Measure CO., Ltd., Kaohsiung, Taiwan) in series was applied to indent the soft

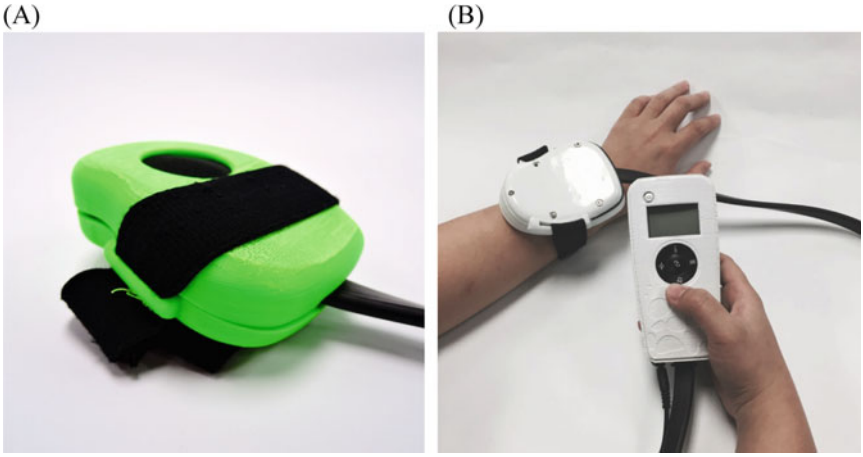

Fig. 1 The intermittent pneumatic compression system. **a** Pneumatic device; **b** an example of applying intermittent compression therapy in a subject

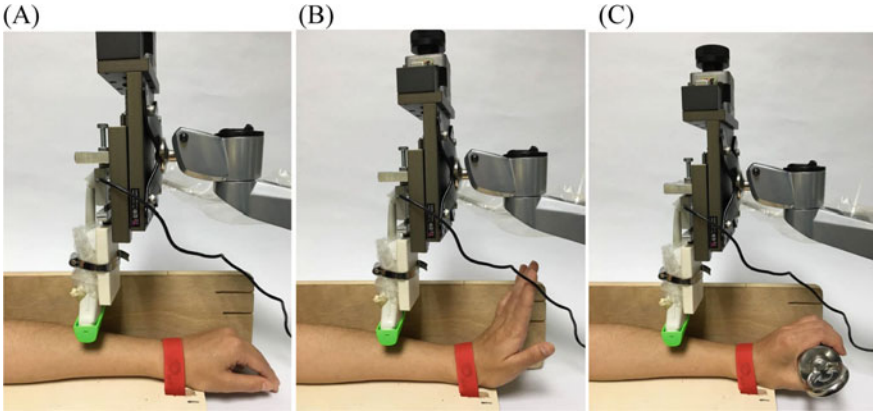

Fig. 2 Three conditions of forearm, including **a** the forearm resting on the table with the wrist at a neutral position, **b** the forearm resting on the table with the wrist at 90° of extension or the maximal extension of the subject, and **c** forearm resting on the table with the hand holding a 1 kg weight

tissue and the ultrasonic signal was collected to extract the initial thickness and force-deformation responses of the tissue. The sampling rate of the images frame and force data were recorded at 22.5 and 100 Hz DAQ data acquisition device (USB-6218, National Instrument, Austin, TX, USA). In this indentation system, a stepper motor (Model TL-SL1010-X, Tanlian Electro Optics CO., Ltd., Taoyuan, Taiwan) with a total travel of 50 mm and a step travel of 0.000625 mm which is driven by a 1600 microstepper per revolution (Model TL-1T, Tanlian Electro Optics CO., Ltd., Taoyuan, Taiwan) was adopted to accomplish an automatic cyclic

indentation instead of a manual operation. A standoff pad was mounted on the ultrasound transducer head with accommodative standoff holder that can be used for reduced transducers probe surface into 4.5 mm radius for soft tissue indenter size [18]. The standoff holder comprised of a standoff pad (coupling medium, cylinder with 4.5 mm radius and 20 mm thickness, Aquaflex ultrasound gel pad, Parker Laboratory, Orange, NJ) also can provide an optimal acoustic characteristics.

The indenter was motor-driven or pneumatically [16] onto the skin surface to apply programmable compressive forces and assess soft tissue mechanical properties and responses. The test itself very much resembles that of palpation of the plantar soft tissues [19, 20]. The first ultrasound echo is associated with the standoff pad and skin interface while the second one represents the tissue-bone interface. The thickness of the soft tissue is presented by the distance between the first and second echoes [21] (Fig. 3).

2.4 Data Analysis

To quantify elastic properties of soft tissues, we used the effective Young's modulus (*E)*. It is a traditional material constant [22, 23]. To extract effective Young's modulus *E*, the equation is defined as below.

$$E = \frac{(1 - v^2)}{2a \cdot k(v, a/h)} \cdot \frac{P}{w} \tag{1}$$

v, Poisson's ratio; *a*, the indenter radius; *k*, a scaling factor dependent on the Poisson's ratio (0.45) [23], indenter radius (4.5 mm), and tissue thickness [22]; *h*, the soft tissue thickness; *P*, the force of pressure loading (indentation); *w*, the depth of indentation.

Paired samples t tests were used to compare the effective Young's modulus between before and after intermittent pneumatic compression under each forearm postures (wrist neutral position, wrist extension, and hand holding). The statistical tests were performed using SPSS 22 (IBM, Somers, NY) at the significance level of 0.05.

3 Results and Discussion

The effective Young's modulus was calculated to characterize of mechanical property of forearm soft tissues. Before the 1 h intermittent compression treatment, effective Young's modulus of conditions a, b, and c was 18.0, 11.3, and 16.8 kPa, respectively. After the treatment, the effective Young's modulus of wrist neutral position, wrist extension, and hand holding was reduced by 34, 11, and 38 %, respectively. However, there were no significant pairwise differences in before and after intermittent pneumatic compression.

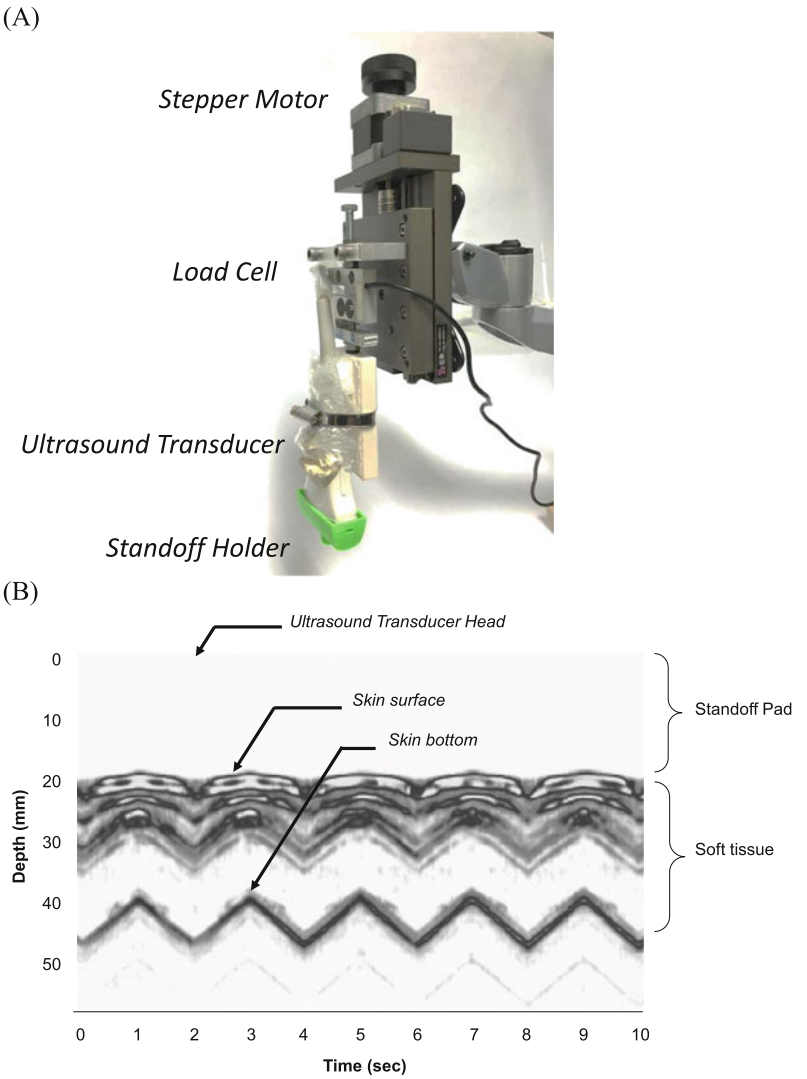

Fig. 3 Motor-driven ultrasound indentation system. **a** The motor-driven ultrasound indentation system. **b** It shows the ultrasound echo trains. After the standoff pad, the first echo is associated with the ultrasound standoff-skin interface while the second one represents the tissue-bone interface. The thickness of the soft tissue is present by the distance between the first and second echoes

Compare to the mechanical properties of the forearm in the wrist extension position, the forearm with the wrist in the neutral position and with the hand holding a weight increased the effective Young's modulus [24].

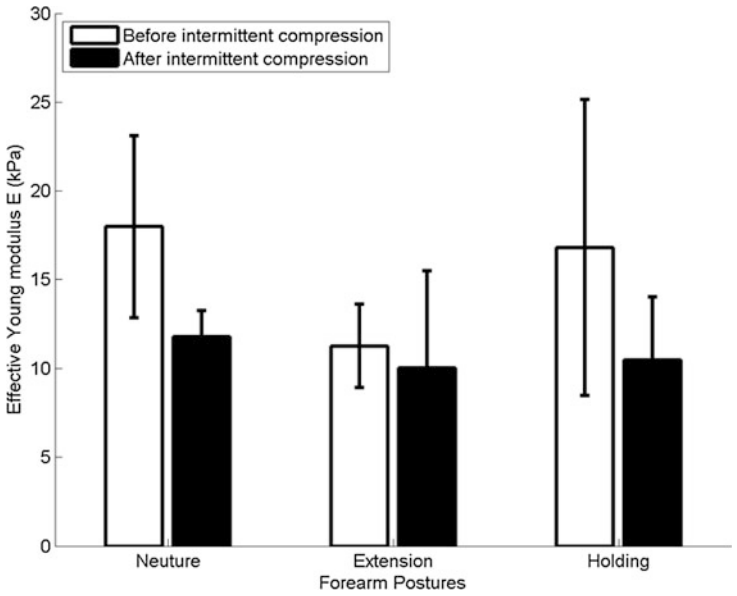

Fig. 4 Comparison of effective Young's modulus under the three forearm postures (wrist neutral position, wrist extension, and hand holding) responded to before and after intermittent compression treatment

After the intermittent compression therapy, effective Young's modulus of the soft tissue decreased by 11–38 %. This finding indicates that the intermittent compression therapy (e.g. compression massage therapy) may soften the soft tissues. This study had limitations. First, the intermittent compression therapy was applied only on the skin of the forearm. Future work should study other locations of hypertrophic scar. Second, only 3 subjects were recruited into this study. Future work should test the efficacy of intermittent compression therapy in a larger sample size. Third, the future work should investigate the long-term effect of intermittent compression therapy on modulating soft tissue property in patients with hypertrophic scars (Fig. 4).

4 Conclusion

The results support our general hypothesis that intermittent compression therapy, massage therapy, may modulate soft tissue property.

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Part VI
Healthcare Testing

Ergonomic Performance Measurement and Evaluation for Worksystems in Healthcare

Pradip Kumar Ray and Esha Saha

Abstract The principles of ergonomics can be applied to the study and design for the components of any worksystem involving human(s) and machine(s) embedded in environment. As a first step towards exploring the enormous potential and concept of ergonomics at workplaces, many organizations, including healthcare systems, are required to take steps to institutionalize the process of implementing a framework to determine the level of ergonomic performance at their different workplaces. Relevance ergonomics-related factors of performance should be identified and assessed on a regular basis to improve the performance, productivity and reliability of any unit of analysis, and application of the concept of 'remedial' ergonomics in many areas, operations and factors of production or service may lead to substantial improvement in overall system performance. This paper highlights the details of an ergonomic performance measurement system developed for a hospital system in India.

Keywords Ergonomic variables · Ergonomic performance · Worksystems healthcare systems

1 Introduction

The principles of ergonomics can be applied to the study and design for the components of any worksystem involving human(s) and machine(s) embedded in environment, and as such application of these principles is not limited to a particular technology or to the scale of the system. In essence, application of these principles provides a standardized approach to analysis of any system with emphasis on

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consideration of interaction between human(s), machine(s) and environment. As a first step towards exploring the enormous potential and concept of ergonomics at workplaces, many organizations, including healthcare systems, are required to take steps to institutionalize the process of implementing as a whole, and have also felt the need to develop a framework to determine the level of ergonomic performance at their different workplaces. The factors of performance and/or operations where deficiency and nonconformance occur should be identified and assessed on a regular basis to improve the performance, productivity and reliability of any unit of analysis, and application of the concept of 'remedial' ergonomics in many areas, operations and factors of production or service may lead to substantial improvement in overall system performance.

Keeping in view that identification and assessment of effective variables contributing toward overall performance of a human-machine system in healthcare is a primary requirement, the paper highlights the details of an ergonomic performance measurement system developed for a hospital system in India. In specific terms, the objectives of such a performance measurement system are manifold: to identify and characterize the ergonomic variables for a given worksystem in healthcare with regard to work efficiency, operator safety and working condition, to design a comprehensive ergonomic performance measurement system for quantitative evaluation of the ergonomic status (in terms of design requirements and performance labeling) of a given worksystem and unit of analysis, and to apply the performance measurement model to evaluate the degree of ergonomic maturity of a given worksystem or unit of analysis. The methodology leading to the design and development of ergonomic performance measurement systems has a number of steps, viz., identification of ergonomic factors, as well as design and performance factors, development of interaction matrix, design of assessment tool, and testing and validation of the assessment tool in varied situations and worksystems.

The comprehensive performance measurement tool as developed is tested for its verification, validation and applicability in a number of worksystems, such as, outpatient department, inpatient department, emergency department and other related systems of a hospital as specified and identified by the management of the organization. Appropriate modifications of the performance measurement systems are made based on actual observations, review of opinions of the concerned personnel, and performance evaluation. With the help of the measurement systems as developed, the prevailing conditions in a given worksystem are assessed against a number of factors, in respect of key principal parameters, viz., work efficiency, operator safety and working condition. The factors considered are: pace or speed of work under the control of the operator, adequacy of fatigue allowances for jobs, occurrence of human errors, frequency of lifting of weights, movement of human body, assessment of visual environment in workplaces, engineering anthropometry, work postures, assessment of thermal environment in workplaces, operators' complaint regarding physical environment, tasks resulting in excessive material waste, repetitive motions, use of hand tools, information overload and assessment of auditory environment.

The performance of any hospital worksystem is measured with a normalized total rating that may be graded on a five-point scale. Against each of these scale ratings,

such as excellent, very good, good, poor or very poor rating, the corresponding action steps are identified and expected with the implementation of such action steps within a specified time frame. This performance evaluation system is thus considered an effective scientific tool for measuring quality of working life of healthcare personnel, and it may also be used as a benchmark to grade ergonomics maturity of different worksystems in any organization, manufacturing and service. The details of the application of the comprehensive ergonomic performance systems, as per the select criteria, parameters, and methodology, in a hospital in India are provided in this paper.

2 Objectives

Keeping in view that identification and assessment of the effective variables contributing toward the overall performance of a human-machine system is the primary requirement, an Ergonomic Performance Measurement System is proposed to be designed and developed for an organization. Hence, the objectives of the study are set as follows:

(i) To identify and characterize the ergonomic variables for a given worksystem in healthcare with regard to work efficiency, operator safety and working condition,
(ii) To design a comprehensive ergonomic performance measurement system for quantitative evaluation of the ergonomic status (in terms of design requirements and performance labeling) of a given worksystem and unit of analysis, and
(iii) To apply the performance measurement model to evaluate the degree of ergonomic maturity of a given worksystem of healthcare system.

3 Ergonomics Performance Measurement System: Characteristic Features

This section is designed to understand and quantitatively assess the importance of base parameters for a worksystem. In order to help define, assess, and quantify a parameter in the most logical and objective way, each ergonomic factor with its scale value is required to be defined for an objective assessment of base parameters. It is opined that the conditions as described in the guidelines are an exhaustive representation of different working conditions and systems at the present level of technology at the worksystem considered. It is recommended that the analyst studies the prevailing conditions against the following 15 factors (F1–F15) considered with regard to key principal parameters; viz. work efficiency, operator safety, and working condition, and matches with those given in the guidelines below as suggested in [1].

3.1 F1. Pace or Speed of Work Under the Control of the Operator

(i) The operator has to work with utmost care, attention, high pace, and cannot distract attention; failure results in waste/reworking; continuous flow.
(ii) The operator can work in a relaxed mood; failure may not necessarily result in wastes/reworking; intermittent flow.
(iii) The operator has to work separately in the jobs assigned at a place, and can easily manipulate the pace of work; process pace is not a significant factor for operator pace of working.

3.2 F2. Adequacy of Fatigue Allowances for Jobs

(i) The work results in tiredness very soon; recovery time from fatigue is more; engaged in dangerous and/or heavy work; may result physical and mental stress or both.
(ii) The work results in tiredness when work duration is substantial; recovery time is fast; not engaged in dangerous or heavy work; may result physical and mental stress occasionally.
(iii) The operator feels at ease in coping up with the workload; enjoys the jobs; no evidence to suggest that the worker is mentally or physically stressed or overworked.

3.3 F3. Workers Away from Their Workplace During Work

(i) The operator feels extremely uncomfortable while working; cannot work continuously at the stipulated workplace, and leaves the workplace with virtually no control on his or her movements by the management; actual working time less than or equal to 50 % of the total available working time consistently.
(ii) The operator leaves the workplace at an infrequent interval although the condition at the workplace and the job characteristics may not necessarily compel the operator to do so; the operator is engaged in work, most of the time.
(iii) The operator does not like leaving the workplace at all during the working time.

3.4 F4. Occurrence of "Human" Errors

(i) Human errors may occur due to improper equipment design or performance; may result in catastrophic economic loss, and endanger human life of the self and other persons directly or indirectly affected; elaborate and detailed study as well as alternate technology needs to be employed.
(ii) Human errors may occur with no significant economic loss and no chance of major equipment failure or musculoskeletal injury; the operator may not feel safe in some situations.
(iii) Human errors may occur with no significant economic loss or body injury or accidents; the operator becomes aware about the implication of errors, and is in a position or trained to overcome the problem on his/her own initiative.

3.5 F5. Frequency of Lifting of Weights

(i) The operator has to manually lift a weight at a high frequency at a regular pace as the present level/type of workplace requires; "alternatives are not available".
(ii) The operator has to manually lift a weight at a low frequency at a regular pace as the level/type of technology requires; "better alternatives are not available".
(iii) The operator may have to manually lift weight at an predetermined interval; no physical stress; "alternatives may be available".

3.6 F6. Force Required to Push or Pull Objects

(i) The working condition and the method of doing work make pushing or pulling objects very difficult; the operator has to exert a lot of physical effort either individually or in a group; a permanent feature of the existing working method and condition at the workplace.
(ii) The working condition and working method make pushing or pulling objects somewhat difficult; the operator has to exert physical effort individually; an important feature of the working condition and the method at the workplace.
(iii) The working condition and method of working are such that pushing or pulling objects is not at all difficult for the operator; the type of technology employed makes the job very easy to undertake; indicative of existence of convenient and safe working methods and norms.

3.7 F7. Movements of Human Body

(i) During manual material handling, body movements are primarily bending, or twisting; producing excessive compressive stress on body joints with a high risk of spinal injury.
(ii) During manual material handling, frequency of bending and/or twisting movements is less and under control; there is less risk of musculoskeletal injury.
(iii) The design of the work method is such that no such body movements occur in most cases; chance of musculoskeletal injury is most unlikely.

3.8 F8. Assessment of Visual Environment in the Workplace

(i) The amount of illumination as measured for the job does not conform to the standards: 50 % or more off the standard.
(ii) The amount of illumination as measured for the job does not conform to the standards: within 50 % off the standard.
(iii) The amount of illumination as measured for the job is conforms to the standards.

3.9 F9. Engineering Anthropometry

(i) Mismatch between work system and operators concerned at extreme level with frequent reporting of complaints;
(ii) Mismatch between a few work systems and operators concerned with no apparent reporting of complaints;
(iii) No mismatch whatsoever between the work system and the operators concerned.

3.10 F10. Work Posture

(i) Existing work postures in majority of the cases are unacceptable with serious negative consequences in the long run.
(ii) Existing work postures do create imbalance and discomfort in some situations or jobs in the workplace.
(iii) Working postures do not affect adversely productivity and quality, and are not at all considered a problem.

3.11 F11. Assessment of Thermal Environment in the Workplace

(i) It is concluded that the actual thermal environment of the work system under consideration conforms to the standards with regard to radiant temperature, humidity, and airflow within an acceptable limit.
(ii) It is concluded that the actual thermal environment of the work system under consideration does not exactly conform to the standards with regard to radiant temperature, humidity, and airflow at the workplace on the basis of the deviation from the standards.
(iii) It is firmly concluded that the existing thermal environment of the work system under consideration is judged comfortable for the majority of the persons engaged; a sustained acceptable productive effort in the existing environment is guaranteed.

3.12 F12. Workers' Complaints About Physical Environment in Their Workplaces

(i) In terms of severity of potential hazards in the physical environment, there are high task demands and high risk of musculoskeletal injury; worker complaints are supported by facts; permanent total disability/long term health problems may exist or will occur.
(ii) In terms of severity of potential hazards at the workplace, task requirements exceed the mental and physical capabilities of some workers; complaints of these workers are supported by facts; permanent partial disability is likely.
(iii) Task requirements are difficult for some workers, but within their capabilities; minor injury likely but major injury is very unlikely; there are hardly any complaints reported.

3.13 F13. Tasks Resulting in Excessive Material Wastes

(i) The material wastes generated at the workplace severely restrict the productive effort of the workers concerned; it is also a critical problem in relation to the working environment for almost all jobs.
(ii) The material wastes generated at the workplace restrict the productive effort of the workers concerned in some jobs only; it may not adversely affect the quality of the working condition.
(iii) The material wastes generated at the workplace are not considered a problem; there is no reporting of any adverse effect on the working condition.

3.14 F14. Repetitive Motions/Frequent Use of Hand Tools/Both Hands and Feet Operating/Same Posture/Information Overload/Insufficient Time to Sense and Respond to Signals/Physical Fitness/Knowledge of Training

(i) It is observed that the productivity of the person(s) concerned is severely affected by one or more of the factors such as repetitive motions, frequent use of hand tools or levers, physical fitness, level of training, fatigue (whole body or local), overexertion, slip/trip and musculoskeletal injury considered as critical problem areas at the workplace for almost all the jobs.
(ii) It is observed that the productivity of the person(s) concerned is restricted by one or more of the factors only for a few jobs, and the problem areas, as mentioned are not at the critical level.
(iii) It is observed that the workplace consideration is not affected, more or less, by such factors as mentioned. The worker(s) concerned is/are mentally and physically fit, and exert(s) productive efforts for the jobs assigned.

3.15 F15. Assessment of Auditory Environment

(i) It is concluded that the existing auditory environment of the workplace under consideration does not conform to the standards established for maximum intensity of sound and total allowable exposure time on the basis of deviation from the standards; there is a strong feeling that permanent hearing loss may occur unless preventive/corrective measures are taken immediately or in near future.
(ii) It is concluded that the existing auditory environment of the workplace under consideration does not conform fully to the prescribed standards.
(iii) It is concluded that the existing auditory environment of the workplace under consideration conforms to the standards established for maximum intensity of sound, and corresponding total allowable exposure time; slight deviation from the standards may occur only sometimes without any adverse effect to the workers engaged/concerned with no complaints whatsoever from the workers.

4 Methodology for Measuring Ergonomic Performance

The important steps of the methodology leading to the design and development of the Ergonomics Performance Management Systems assessment tool are as follows:

4.1 Identification of Ergonomic Factors

A general framework involving all relevant factors and sub-factors related to human characteristics, physical workspace, physical environment, and organizational factors is required to be developed.

4.2 Identification of Design and Performance Factors

A list of factors related to three specific aspects, viz. operator safety, work efficiency, and working condition including functional requirements, if any, is prepared and standardized at this stage.

4.3 Development of Interaction Matrix

At this stage, the interactions (strong or weak) matrix between the ergonomic and design or performance factors to be ascertained for a given unit of analysis is prepared in order to limit the number of factors with which a given work system may be assessed to a reasonable level. The guidelines for the selection of appropriate number of factors are established. The rules for determining the relative weights (reflecting importance or criticality of a factor in the presence of other factors, or on its own) are to be specified at this stage.

4.4 Design of the Assessment Tool

On completion of the above three steps, (i) to (iii), a comprehensive framework for (1) determining the ergonomic performance of a worksystem, (2) identification of deficient area(s) in relation to ergonomic factor(s), and (3) setting the priority of improvement actions suggested, is established at this stage.

4.5 Testing and Validation of Assessment Tool in Varied Situations and Worksystems

The proposed tool is to be tested for its verification, validation, and applicability in a number of representative situations as specified and identified by the management of the organization.

5 Applications in Healthcare

Healthcare industry as a working environment comprises a unique set of characteristics, opportunities and challenges for applying ergonomics. The Ergonomics Performance Management Systems for worksystems in healthcare is especially developed for the hospital settings in the operating rooms, surgical wards, radiology, etc. The purpose and value of using ergonomics to study the divergent medical environments is evident from the literature surveyed. The various methods applicable for the study of human factors and ergonomics in the healthcare setting are explained in detail in the review paper [2]. The human factors and ergonomics area is an expanding field in the healthcare domain and has contributed significantly to the understanding of relationship between ergonomically designed medical devices and work performance, ergonomically designed worksystem and performance, postural stress due to inefficient working conditions of the surgeons during surgery, uncomfort of medical staff in lifting the boxes of medical items from floor to shelf, etc. The hospital worksystem is explained by a simulation model in [3].

As each of the 15 factors considered is generic in nature, they are to be defined in terms of characteristic features and situations prevailing in a healthcare system. The specific ergonomic factors for a given worksystem in healthcare with regard to work efficiency, operator safety and working conditions are highlighted in Table 1.

Table 1 Ergonomic performance-related factors for a worksystem in healthcare

Factor no.	Ergonomic performance-related factors	Description	References
F1	Pace or speed of work under the control of the operator	Medical personnel work with utmost care, attention, high pace, and cannot distract attention	
F2	Adequacy of fatigue allowances for jobs	Postural stress of surgeons during surgery	Bartnicka [4]
F3	Workers away from their workplace during work	Medical personnel feels uncomfortable in the working conditions	
F4	Occurrence of “human” errors	Safety challenges in the use of medical equipment during the training of nurse anaesthetists	Santos et al. [5]
F5	Frequency of lifting of weights	Lifting of boxes of Intravenous fluids from floor to cupboard	Hignett [6]
F6	Force required to push or pull objects	Pushing and pulling on the slope of the switch of surgical scalpels	Wu et al. [7]
F7	Movements of human body	Patient handling tasks	Nelson et al. [8]

(continued)

Table 1 (continued)

Factor no.	Ergonomic performance-related factors	Description	References
F8	Assessment of visual environment in the workplace	Relative balance between monitor light and background reading room lighting is important in determining the degree of radiologist fatigue, efficiency and accuracy	Goyal et al. [9]
F9	Engineering Anthropometry	Stationary position of the patient without the possibility to change it to another during surgery; inadequate height of the surgical table; different anthropometric features of medical staff	Bartnicka [4]
F10	Work Posture	Working posture of surgeons in operating room	Serratos-Perez et al. [10]
F11	Assessment of thermal environment in the workplace	Temperature controls in the working environment of radiology department	Goyal et al. [9]
F12	Workers complain about physical environment in their workplaces	Musculoskeletal injury among the hospital workers	Janowitz et al. [11]
F13	Tasks resulting in excessive material wastes	Medical wastes generated in the hospitals is disposed by the workers	
F14	Repetitive motions/frequent use of hand tools/both hands and feet operating/same posture/information overload/insufficient time to sense and respond to signals/physical fitness/knowledge of training	Repetitive movements of the surgeons during operations	Serratos-Perez et al. [10]
F15	Assessment of Auditory Environment	Noise in the working environment of radiology department	Goyal et al. [9]

6 Determination of Ergonomic Performance for a Worksystem in Healthcare

A number of integrated steps in sequence are to be followed for measuring ergonomic performance for a worksystem in healthcare. The specific steps are as follows:

- Step-1: Select the principal parameter(s) relevant for the worksystem in healthcare.

Table 2 Assessment concept of scale rating

Levels	Ergonomic intervention	Rating
Level I	No ergonomic intervention	6
Level II	Lower level of ergonomic intervention	9–12
Level III	Higher level of ergonomic intervention	15–18

- Step-2: Select the base parameter(s) influencing the identified principal parameter(s) in Step-1.
- Step-3: Assess the situation against each base parameter considered and assign its scale rating (SR) as shown in Table 2.
- Step-4: Repeat Step-3 for all other base parameters selected.
- Step-5: Compute the sum of scale ratings (SRs) obtained in Step-3 and Step-4.
- Step-6: Assess the intensiveness of safety programmes adopted, and assign an appropriate rating for safety awareness (CO–SA) in a scale of (0–10).
- Step-7: Compute the total ratings obtained in Step-5 and Step-6.
- Step-8: Compute the normalized total rating (NTR) in a scale of (0–100) by using the following formula:

$$[\mathrm{NTR}] = \frac{\left[\sum_{i=1}^{n} \mathrm{SR_i} + m\right]}{\mathrm{n} \times 18 + 10} \times 100 \tag{1}$$

The performance of the emergency department of a hospital in India has been assessed with the methodology as developed. While assessing the performance, all the 15 factors are considered. The ratings against each of these factors are given in Table 3.

With the ratings as assigned, the Normalized Total Rating of the emergency section is given by:

$$[\mathrm{NTR}] = \frac{\left[\sum_{i=1}^{n} \mathrm{SR_i} + m\right]}{n \times 18 + 10} \times 100 \tag{2}$$

where, *SR* is the scale rating, *i* is a factor and *n* is the total number of factors, and *m* is the safety awareness (CO–SA) rating (0–10).

Let safety awareness (CO–SA) rating (0–10) = m = 8.

$$\text{Hence, Grand TS} = \left[\sum_{i=1}^{n} \mathrm{SR_i} + m\right] = 160 + 8 = 168$$

Maximum Scale Rating = n × 18 = 15 × 18 = 270.

Normalized Total Rating (NTR) in 0–100 scale is given by:

$$[\mathrm{NTR}] = \frac{\left[\sum_{i=1}^{n} \mathrm{SR_i} + m\right]}{n \times 18 + 10} \times 100 = \frac{168}{270 + 10} \times 100 = 60 \tag{3}$$

Table 3 Ratings assigned to ergonomic performance-related factors

Factor no.	Ergonomic performance-related factors	Data collected from emergency department of a hospital	Rating assigned
F1	Pace or speed of work under the control of the operator	Medical personnel work with utmost care, attention, high pace, and cannot distract attention	15
F2	Adequacy of fatigue allowances for jobs	Fatigue allowances for medical personnel	10
F3	Workers away from their workplace during work	Medical personnel feels uncomfortable in the working conditions	6
F4	Occurrence of "human" errors	Safety challenges in the use of medical equipment, etc.	11
F5	Frequency of lifting of weights	Lifting of boxes of items required in emergency department	9
F6	Force required to push or pull objects	Force required to push and pull certain medical instruments	6
F7	Movements of human body	Patient handling tasks	10
F8	Assessment of visual environment in the workplace	Lighting in emergency department	6
F9	Engineering anthropometry	Stationary position of the patient; inadequate height of the bed; different anthropometric features of medical personnel	16
F10	Work posture	Working posture of personnel	11
F11	Assessment of thermal environment in the workplace	Temperature controls in the working environment of emergency department	17
F12	Workers complain about physical environment in their workplaces	Musculoskeletal injury among the medical personnel	9
F13	Tasks resulting in excessive material wastes	Medical wastes generated and disposed by the workers	9
F14	Repetitive motions/frequent use of hand tools/both hands and feet operating/same posture/information overload/insufficient time to sense and respond to signals/physical fitness/knowledge of training	Repetitive movements of medical personnel in emergency department	15
F15	Assessment of auditory environment	Noise in the working environment of emergency department	10
	Total score		160

According to the ergonomic performance grading, range of NTR values within (85–100) indicates 'excellent' performance; (70–84) 'very good'; (50–69) 'good'; (45–49) 'poor' and less than 45 considered 'very poor'. Using the performance measurement system as developed the ergonomic performance of the emergency

department is found to have a value of 60 grading indicating a 'good' grade. These assessment indicates that the working condition in the emergency department is acceptable; however, there is enough opportunity and scope for improvement in its ergonomic performance and a time bound remedial ergonomic interventions are required wherein work organization-related factors like work norms, shift schedules, occupational hazards, job allocation norms, as well as job design aspects need to be under control.

7 Conclusion

It is essential that a total integrated approach needs to be in place for ergonomics performance measurement and evaluation of any worksystem. The application to the emergency department of the hospital of the proposed ergonomics performance system refers to the level of maturity as achieved by the organization in ergonomic design of the worksystems. The methodology can be applied to any other healthcare worksystems for comparison and improvement purpose.

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Development of a New Psychometric Scale (PYTHEIA) to Assess the Satisfaction of Users with Any Assistive Technology

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Abstract This paper presents the early findings of a new psychometric scale called PYTHEIA. It was developed in Greek according to the most well known guidelines recommendations in order to assess the satisfaction of users with any assistive technology device (e.g. robotic, rehabilitation device, etc.). Field test studies were conducted with 147 subjects (inpatients and outpatients of a rehabilitation hospital) who were administered the original questionnaire. The scale is applicable in patients with different diseases, ages, and disabilities using various assistive devices. According to the inclusion criteria selected, all of them scored above 17 in the Mini Mental State Examination (MMSE). Intraclass correlation coefficient (ICC = 0.992), Pearson's correlation (r = 0.984) and Cronbach's α (α = 0.793) indicated sufficient reliability measures. Test-retest outcome showed great stability. The paired samples t-test between initial assessment and reassessment indicated no statistically significant differences (p value = 0.059). Various types of validity were also investigated. According to the results, PYTHEIA is a stable, valid and reliable instrument. Thus, it can be used to measure the satisfaction of patients with any assistive device. PYTHEIA uniqueness is that it can be used to assess not only the general satisfaction of the users with any assistive device, but also to evaluate independently any individual characteristic and functionality that the device may have. To this end, it can be used for evaluating also new and experimental developments (e.g. robotic assistive devices, etc.) in lab environment and can help

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researchers assess their products in terms of efficiency, comfort, quality, performance, ergonomics and usefulness as perceived by the end users.

Keywords Assistive technology · Rehabilitation · Scale · Psychometric · Satisfaction · Assessment · Validation · Reliability · Questionnaire

1 Introduction

Information and Communication Technologies (ICTs), robotic technology and nanotechnology have evolved rapidly, and promise unique opportunities and technological achievements that can help people in their daily lives [1, 2]. End user satisfaction is being measured in almost any domain in order to improve the provided services and products. Patient satisfaction is also a major issue in healthcare [3–5]. Focusing on the use of assistive technology devices (e.g. wheelchairs, scooters, robot aid devices, etc.) it is of extreme importance to measure the level of satisfaction. The matching between the selected assistive technology and the user is a major concern. To this end, the abandonment of selected assistive devices has been reported in numerous studies [6–9]. Abandonment may be due to assignment of inappropriate devices or failure to meet the user needs and expectations and is directly related to device characteristics. The end user perspective is important during all phases of a product cycle (i.e. design, pilot testing, improvement, final product). It is critical therefore the use of a valid and reliable scale for the subjective assessment of the used assistive technology.

There is a limited body of literature on the evaluation of assistive technology. Most outcome measures are associated with quality of life or functioning. Assistive devices vary in type, functionalities implemented, etc. However, despite these differences, the reasons for evaluating assistive products are similar to those for other consumer products. During the development phase of any assistive device there is a great need to collect accurate data on several issues, e.g.: (i) do they have the claimed functionalities? (ii) do they perform satisfactorily? (iii) do they serve the needs of the targeted end users? etc. [10]. Another major issue when trying to evaluate assistive technology devices is the wide range of functionalities they may have that could be totally different from each other, as well as the type (e.g. robot assistive devices, artificial limbs, simple wheelchair, etc.) and complexity (e.g. cane, scooter, etc.) of the assistive technology used. Ergonomic features, safety issues, social acceptance are only some of the characteristics that have to been taken seriously into account during the evaluation phase.

The authors propose that the following twelve aspects could be tested using an appropriate scale/questionnaire in order to elicit users' perspective and satisfaction [11]:

1. Utility (How a product can be used to reach a certain goal or to perform a certain task. Utility increases as the number of tasks increases).

2. Performance Expectancy (The degree to which an individual believes that using the system will help him/her to attain gains in performance).
3. Effort Expectancy (To which extent the user perceives a system will be easy to use).
4. Attitude toward Using Technology (All positive or negative feelings and attitudes about solving working tasks supported by the assistive device).
5. Self-Efficacy (A person's perception of his/her ability to reach a goal).
6. Attachment (An affection-tie that one person forms between himself/herself and another person or object).
7. Reciprocity (The positive or negative response of individuals towards the actions of others).
8. Embodiment (The relationship between a system and its environment. It may have impact on social expectations).
9. Emotion (It is an essential part in social interaction and thus it has to be considered during the assessment and design of assistive technology products).
10. Feeling of Security (Investigate how safe the users experience the assistive device).
11. Co-Experience (It describes experiences with objects regarding how individuals develop their personal experience based on social interaction with others).
12. Societal Impact (It describes all effects the introduction of assistive technology consequences for the social life of a specific community—taking into account cultural differences—in terms of quality of life, working conditions and employment, and education).

The above aspects have to be taken into account when evaluating an assistive device. In many cases however, researchers tend to use custom-made questionnaires in order to investigate some of the aforementioned fields. This drives in non-validated scales/questionnaires and makes it difficult to compare the results from different researchers [12].

Nowadays, there are few evaluated scales for the assessment of assistive technology. The Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) provides a standardized satisfaction assessment tool designed for assistive technologies [13–16]. Jardon et al. report QUEST 2.0 as a tool applicable for the functional assessment of assistive technology [17]. QUEST is an outcome measure designed to evaluate patients' satisfaction with their assistive technology device. The second version (QUEST 2.0) consists of 12 items. The 8 items assess the user's degree of satisfaction with device properties and the remaining 4 items are related to assistive technology services [18]. Items are rated on a 5-point Likert scale indicating the level of satisfaction with the aspect of the device or service. The user is also asked to identify the satisfaction variables most important to him/her. QUEST 2.0 was developed in Canadian English and French and then translated into other languages [19–22]. QUEST 2.0 covers only some subjective aspects (i.e. ease of use, feeling of security, perceived effectiveness).

Another valid scale is the Assistive Technology Device Predisposition Assessment (ATD PA) [23]. However, only the ATD PA-Device Form (a 12-item

questionnaire) examines user's subjective satisfaction when using assistive technology. The Device Form is actually the last part of the 66-itemed ATD PA, a questionnaire based at the Matching Person and Technology (MPT) Model. The 12 items are rated on a 5-point Likert-scale. ATD PA-Device Form gives limited information, mostly on learnability, performance expectancy, effort expectancy, attitude toward using technology, perceived effectiveness and self-efficacy [24].

The Psychosocial Impact of Assistive Devices Scale (PIADS) is another already valid psychometric instrument [25]. It emphasizes in the psychosocial impact of assistive devices, without targeting on evaluating the actual experience of interacting with an assistive device, but rather on the impact that this interaction has in quality of life. Other questionnaires such as the USE-IT scale [26] are not well valuated or not widely used from researchers in the bibliography.

Concluding, we can support that there is no single valid and reliable scale that can be used independently to evaluate assistive technology prototypes. Moreover, none of the aforementioned scales can be adopted in order to measure the independent functionalities of an assistive device.

The current paper presents the development of a new psychometric scale called PYTHEIA. PYTHEIA intends to be used for the subjective assessment and the measurement of end user satisfaction with any assistive device while being able to measure independently the different functionalities that may be implemented in the device.

2 Methodology

For the evaluation of PYTHEIA we recruited 147 subjects. The required approval was obtained by the Bioethics and Deontology Committee of the Technological Educational Institute of Athens. The subjects were either inpatients or outpatients of a Greek rehabilitation hospital. The study lasted for seven months. The subjects involved were of both sexes, aged from 16 to 93 years old. They were using different assistive devices (e.g. scooter, walkers, manual wheelchair, electric wheelchair, rollator, etc.) for at least one month. To participate in the study, all of them should have scored equal to or greater than 17 in the Mini Mental Stale Examination (MMSE) [27]. Several data were recorded during the study (i.e. demographic data, MMSE and Functional Independence Measure scores, assistive device used, frequency of use, pathology, etc.). Experienced physiatrists, occupational therapists and physical therapists participated in the study. The participants were informed about the scope and the plan of the study and signed an informed consent. Then, they filled in the questionnaire with the presence of an experienced physical therapist. The questionnaire was administered in two time intervals (the second time was one week later from the first one). The sample size was sufficient for the purpose of our study [28].

The PYTHEIA scale has 20 items in total and is divided in two main sections. The first section, comprising 15 items, evaluates the used assistive technology as a

whole, while the second section (items 16–20) is used to evaluate any individual functionality of the assistive technology (e.g. navigation, gesture response, oral commands, etc.). Thus, items 16–20 have to be used every time a new functionality is tested. PYTHEIA is using a 6-point Likert scale [0-N/A, 1-Not at all satisfied, 2-Slightly satisfied, 3-Moderately satisfied, 4-Very satisfied, 5-Extremely satisfied] for items 1–9. Another 6-point Likert scale [0-N/A, 1-Not at all (0 % of the time), 2-Sometimes (around 25 % of the time), 3-Half the time, neutral (about 50 % of the time), 4-Often (around 75 % of the time), 5-All the time (100 % of the time)] is used for items 10–15. The second section of the PYTHEIA scale (items 16–20) is using the first Likert scale.

2.1 Statistical Analysis

The Statistical Package for the Social Sciences (IBM SPSS version 19) was used for analyzing the collected data. The assumption of normal distribution of the collected data was tested using the Kolmogorov–Smirnov test. PYTHEIA scale was evaluated for its validity and reliability. Regarding the reliability of PYTHEIA, we tested its internal consistency, test-retest reliability and repeatability. Internal consistency evaluates how well different questions (items) that test the latent structure of the instrument should give consistent results. The internal consistency was assessed with Cronbach's alpha coefficient using the data obtained from the initial assessment. A threshold value of 0.70 was chosen, which indicates sufficient reliability for research purposes. The Cronbach's α "if item deleted" was used as an additional evaluation test. The test-retest reliability of PYTHEIA was evaluated using the intra-class correlation coefficient (ICC) with 95 % confidence interval (CI). This indicates the degree to which the subjects maintained their opinion in the repeated measurements of the scale. The ICC, which is the most suitable statistical test for the assessment of reliability, ranges from 0 to 1, with 1 indicating perfect reliability. The Cronbach's α and ICC correlations were characterized as follows: 0.00–0.25 = little, if any, correlation; 0.26–0.49 = low; 0.50–0.69 = moderate; 0.70–0.89 = high; and 0.90–1.00 = excellent [29]. The repeatability is defined as the stability of participants' responses over time, that is, the ability of the instrument to give consistent results whenever it is used. The repeatability is determined by calculating Pearson's product moment correlation coefficient (Pearson's r) between the initial and re-assessment total scores of questionnaire. The Pearson correlation coefficient values were specified as follows: 0.00–0.19 = very weak correlation; 0.20–0.39 = weak correlation; 0.40–0.69 = moderate correlation; 0.70–0.89 = strong correlation; and 0.90–1.00 = very strong correlation. Moreover, item analysis and Exploratory Factor Analysis (EFA) with Varimax rotation was carried out to investigate the factor structure of PYTHEIA. The validity of PYTHEIA validity was measured by assessing the scale's/subscales' construct validity. The construct validity refers to the degree to which an instrument measures the construct under investigation. The item-total correlations within each

PYTHEIA subscale were compared in order to test whether all items of each subscale were related to the same construct. Acceptable construct validity should be indicated by high or excellent (0.70–1.00) item inter-correlations for all item pairings. The discriminant validity tests whether concepts or measurements that are supposed to be unrelated are, in fact, unrelated. In our study, we performed discriminant validity test between the different subscales of PYTHEIA.

3 Results

The mean age of the patients was 62.45 years (SD 19.29). 55.7 % (64/115) of them were women. The mean scores of the MMSE and FIM tests were 25.41 (SD 4.01) and 104.74 (SD 65.06) respectively. The participants spent about 7.5 min to complete the questionnaire and, according to the inclusion criteria, they were users of an assistive technology for at least one month. They were using a variety of assistive technology devices, such as: walker, cane, rollator, scooter, wheelchair, orthosis, hearing assistive technology, etc.

Table 1 EFA of PYTHEIA

Item #	Factor 1 "independent functionalities"	Factor 2 "fit to use"	Factor 3 "ease of use"
1		0.729	
2		0.673	
3			0.641
4			0.679
5			0.540
6		0.714	
7		0.696	
8		0.691	
9		0.429	
10		0.655	
11		0.626	
12		0.527	
13		0.583	
14			0.692
15			0.524
IF1	0.948		
IF2	0.979		
IF3	0.983		
IF4	0.978		
IF5	0.983		

3.1 Exploratory Factor Analysis

According to the results from the exploratory factor analysis (EFA) with Varimax rotation performed (Table 1), the PYTHEIA instrument presents a three-factor model. The resulting three factors satisfy the rule that meaningful factors should be associated with eigenvalues greater than 1.0. Criteria used to select factors included eigenvalue >1 and factor loading >0.30. The "Independent Functionalities" factor explaining 26.743 % of the variance, and the "Fit to use" and "Ease of Use" factors explaining the 20.492 and 11.188 % respectively. Factor loadings are the correlation coefficients between the items and the factor, ranged from 0.948 to 0.983 for the first factor, from 0.429 to 0.729 for the second and from 0.445 to 0.692 for the third one (Table 1).

3.2 Reliability

The overall Cronbach's α of PYTHEIA was found 0.793, indicating sufficient consistency (see Table 2). The ICC was excellent (ICC = 0.992, $p = 0.000$), indicating that the PYTHEIA total scores were highly consistent between initial

Table 2 Item analysis

Item #	Mean (SD)	Cronbach's α if item deleted
Item 1	4.56(0.793)	0.798
Item 2	4.33(1.220)	0.791
Item 3	3.52(2.130)	0.786
Item 4	4.57(1.057)	0.800
Item 5	4.65(0.832)	0.800
Item 6	4.68(0.749)	0.788
Item 7	4.76(0.696)	0.795
Item 8	4.90(0.345)	0.794
Item 9	4.72(0.690)	0.796
Item 10	4.49(1.027)	0.794
Item 11	4.65(0.917)	0.787
Item 12	4.16(1.330)	0.792
Item 13	4.33(1.203)	0.790
Item 14	2.34(2.335)	0.808
Item 15	3.38(1.618)	0.792
IF1	1.58(2.250)	0.748
IF2	1.75(2.367)	0.748
IF3	1.73(2.343)	0.747
IF4	1.72(2.347)	0.748
IF5	1.77(2.382)	0.747

assessment and reassessment. The paired-samples t-test between the two administrations indicated no statistically significant systematic bias ($p = 0.059$). The Pearson's r correlation coefficient indicated stability of participants' responses over time (Pearson's r = 0.984, $p = 0.000$).

3.3 Validity

Examination of item convergent validity showed that all item intercorrelations for all item pairings were strong or excellent. Pearson's r ranged from 0.946 to 0.996 for the first subscale "Independent Functionalities", from 0.465 to 0.724 for the second "Fit to Use", and from 0.354 to 0.732 for the third subscale "Ease of Use". This provide evidence that all subscales' items are related to the same construct (Table 3).

The correlation between the three subscales indicate that discriminant validity exists between the subscale measuring "Individual Functionalities" and the

Table 3 Convergent validity (item-total score correlations)

Factors	Pearson's *r*
Factor1 subscale item ("Individual Functionalities")	
IF1	0.946
IF2	0.991
IF3	0.993
IF4	0.991
IF5	0.996
Factor2 subscale item ("Fit to Use")	
Item 1	0.724
Item 2	0.695
Item 6	0.681
Item 7	0.633
Item 8	0.614
Item 9	0.465
Item 10	0.719
Item 11	0.600
Item 13	0.655
Factor3 subscale item ("Ease of Use")	
Item 3	0.354
Item 4	0.518
Item 5	0.485
Item 12	0.628
Item 14	0.732
Item 15	0.612

subscales measuring "Fit to use" (=−0.052) and "Ease of Use" (=−0.223) respectively, and also between the subscale measuring "Fit to use" and the subscale measuring "Ease of Use" (=0.383). The three subscales measure theoretically different constructs.

4 Discussion

The scope of the research was to examine the reliability and validity of the PYTHEIA scale. PYTHEIA is a new scale that intends to be used for the assessment of assistive technology devices. One of the advantages of the current research is the heterogeneity of the studied population. They were patients with different characteristics (i.e. diseases, age, etc.) and disabilities and they were using a wide range of assistive technologies.

According to the results presented, PYTHEIA is a valid scale that can be used for the assessment of satisfaction with assistive technology. The Exploratory Factor Analysis conducted revealed a three factors schema. The first factor "Independent Functionalities" had excellent factor loading and is related to the individual characteristics of the examined device. This can be considered as an added value of the PYTHEIA scale, since "Independent Functionalities" can be used as many times as needed in order to measure each characteristic independent from the overall assessment of the device. The second factor "Fit to Use" assesses the adaptability of the device, and the third factor "Ease of Use" examines the user-friendliness of the device as well as the need for support while using it. However, we need to further investigate the factor structure of PYTHEIA using confirmatory factor analysis.

The results of statistical analysis indicated that the scale is a valid and reliable tool. Cronbach's α and ICC values were found excellent, indicating that the responses of our sample were internally consistent and stable across time. Moreover, items' Pearson's coefficient investigation confirms the three subscales structure. Specifically, it confirms the utmost relevance of the subscale's items, while satisfying simultaneously the requirement of discrimination of the produced subscales.

5 Conclusion

Concluding, we can support that PYTHEIA can be applied effectively to assess a wide range of assistive technology devices. We have already started the examination of PYTHEIA comparing it to other already existed and valid scales and in the short future we will present the comparison results. A unique characteristic of PYTHEIA is the fact that it can be used for the measurement of satisfaction of the end users with assistive technologies, while being able to evaluate any individual features/functionalities implemented. This is not present in any other scale, at least to the knowledge of the authors.

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A Study on the Methodology to Analyse and Prevent Medical Errors Due to Non-observance

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Abstract It is necessary to tackle medical errors in order to provide safe healthcare. Medical errors are defined as departures from standards and can be divided into 2 categories: the first occurs even though workers follow standards, and the second occurs because they act contrary to standards and is called non-observance. Although some studies, as typified by error proofs, have been performed on the former, there are few studies on the latter. Therefore, errors due to non-observance chronically occur in hospitals. In this paper, we define non-observance as intentional departure from standards and discuss a mechanism generating non-observance. Furthermore, we propose a method to analyse non-observance and to prevent it by improving work methods and education.

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Keywords Non-observance · Medical errors · Process improvement · Error prevention

1 Introduction

It is necessary to deal with medical errors in order to provide safe healthcare. Although they've been trying to address the issue in hospitals, it still remains one of the most important issues. Medical errors are defined as departures from standards. They can be divided into two types; one happens even though workers are going along standards, and the other happens because they are acting contrary to them.

Although some studies as typified by Error Proofs have been done on the former, there are few studies on the latter. Therefore, errors due to violation chronically happen in hospitals. In this study, we define violations as intentional departures from standards and then a mechanism generating violations are discussed. Furthermore, we propose a methodology to analyze violations and prevent them by improving work method.

2 Previous Studies

Reason [1] has defined violations as deliberate deviations from practices deemed necessary to maintain the safe operation of a potentially hazardous system. Besides, two categories have been proposed; one is routine violation and the other is exceptional violation. The former is a habitual violation and the latter is seen in relatively indifferent environment and unexpected.

And Hollnagel [2] pointed that human tend to take efficiency, not completeness, on completeness-efficiency trade-off situation.

However, these studies aren't fragmentary enough to explain violations. Hence, effective methodologies to prevent violations haven't been proposed.

3 Method to Analyze Violations

3.1 Consideration of Violation Mechanism

In order to analyze violations, it's necessary to reveal violation mechanism and then set a frame of analysis. We therefore investigated 44 violations that were caused in hospital A from the April of 2007 to the July of 2007 and interviewed the staff to consider violation mechanism. Then, we set a frame of analysis. The followings are consideration processes with two of the violation cases.

3.2 Case Study Analysis

Case 1.
Summary. When the worker prepared medications, she failed to prepare some medications that were set out of the cart. She was supposed to refer prescriptions for information of medications to dispense and confirm them. However, she referred the medications in the cart for information, and hence she didn't notice some medications that weren't in the cart. Those medications weren't dispensed as a result.

Analysis Result. According to the standard operating procedure, a worker refers prescriptions for information of medications to dispense and confirm them. Despite it, the worker referred the medications in the cart for the information and tried finding them in the prescriptions, which was a violation. Because she referred only the medications prepared in the cart, she failed to prepare the other medications that were out of the cart when she took such a violation.

As a result of the hearing investigations about the reasons why she violated the standard procedure, the opinion was obtained that it was much easier and more efficient to obtain information from medications in a cart than to find information on prescriptions. Even though they knew the standard procedure, they operated in the different way to refer medications in a cart for information because it was much easier than the standard procedure.

Consequently, we obtained the conclusion that the human natural tendency to refer easier one and the condition that was that there was a big difference in easiness to obtain information between the sources were the causes of the violation.

Case 2.
Summary. When the nurse tried to dispense the post-meal medications, the patient hadn't finished eating. Then, she decided to do it later and put those medications in her breast pocket. However, she finally forgot to dispense and lost them somehow in the pocket.

Analysis Result. According to the standard operating procedure, a worker shouldn't put medications in her breast pocket but in a cart when she dispensed them later. Because there is a possibility that workers lose medications if they put and keep them in their breast pockets. Despite it, the worker put them in her breast pocket.

As a result of the hearing investigations about the reasons why she violated the standard procedure, two reasons were obtained.

One is that the operation tends to be suspended because it's necessary that patients have finished easting before it.

And the other is that the standard operation procedure has a heavy workload in time. In the procedure, workers have to return to staff station from patient room and put medications in a cart when patients haven't finished easting yet. And they also have to take them in the cart when they try to dispense them to patients again.

However, such an operation has a heavy workload in time that they think it's more efficient to take medications in their breast pocket, not to return them in a cart and do so.

Consequently, we obtained the conclusion that the human natural tendency to operate in more efficient way and the condition that operations tend to be suspended and have a heavy workload in time were the causes of the violation.

Violation Mechanism. As a result of these case study analyses, there are workers' intentions to operate in a more efficient way in violations. Those are seen as every worker's common tendencies, and we believe those are human behavior characteristics. Besides, those are to decrease workload and then appear in specific operation conditions.

Consequently, the violation mechanism that specific operation conditions (defined as behavior-induced factors) evoke human behavior characteristics (defined as behavior characteristics) and they violate the operations standards was found.

3.3 Viewpoints of Analysis

We set viewpoints of analysis for violations based on the violation mechanism that was obtained in Sect. 3.2. According to the mechanism, violations are behaviors based on the human behavior characteristics that specific operation conditions evoke and against standards. Therefore, it's necessary to figure out workers' intentions and what operation conditions evoked behavioral characteristics.

As for workers' intentions, we should figure out if they know the standard operations to determine if their behavior is a violation. And then, we determine those as violations if they know the standard operations and figure out workers' intentions. Consequently, we set "workers' intentions" as one of viewpoints of analysis.

As for operation conditions, we reveal behavior factors from the viewpoint of workers' intentions. To achieve it, it's necessary to capture operations in appropriate units. Wherein, a work-element [3] that is useful to analyze operations was adopted. A work-element is defined as the segmentation of an operation, in which "a person focuses on a certain object and identifies/changes the condition of the object". Consideration of the results in Sect. 3.2 with work-elements, behavior-induced factors can be divided into 2 categories; the first is found in each work-element and the second is found is found relationship between work-elements. For instance, in case 1, the operation condition whereby there was a big difference in easiness to obtain information between the sources appeared in each work-element. And, in case 2, the condition that procedures tend to be suspended appeared in relationship between work-elements. Consequently, we set "each work-element" and "relationship between work-elements" as viewpoints of analysis.

It is possible to reveal behavioral characteristics and behavior-induced factors by analysis based on the above viewpoints.

4 Results of Analysis

We analyzed totally 123 violation cases that are the cases in Sect. 3.1.1 plus 79 additional violation cases from hospital A between June 2007 and May 2008 on the viewpoints in Sect. 3.2, and obtained the results obtained the behavioral characteristics and the behavior-induced factors. These are the results of the analysis of 123 violation cases that occurred in hospital A between 14 months, and consequently it should be considered that we obtained cyclopaedically major causes of violations even though there is a little possibility of other behavioral characteristics or behavior-induced factors that haven't occurred in this period.

4.1 Behavioral Characteristics

The behavioral characteristics as the results of the analysis are shown Table 1.

As Table 1, 7 behavioral characteristics on operation process and 1 on error detection process were obtained.

There are "Selective recognition" and "Partial recognition" on information acquisition process. Selective recognition is a characteristic to recognize objects that are easier to recognize. For instance, when workers take and prepare medications from carts and other storage areas, they check if all medications on prescriptions are prepared based on information on prescriptions. As selective recognition, however, they tend to refer medications instead of prescriptions because medications are much easier information sources to recognize and obtain information. And consequently, some medications out of carts are not prepared and then not dosed. Partial recognition is a characteristic to recognize partially objects. For instance, when workers dose or inject medications, they confirm patient names, medication names and etc. on prescriptions about. As partial recognition, however, they tend to recognize and confirm partial information on prescriptions. And consequently, wrong medications are dosed or injected, or medications are dosed or injected to a wrong patient.

There is "Predictive judgment" on information judgment process. Predictive judgment is a characteristic to predict results and skip judgments. For instance, when workers change an infusion for new one, they confirm medication names, power of infusions and etc. on prescriptions. As Predictive judgment, however, they tend to think that power of a new infusion ordered is the same as the previous one and skip referring prescriptions. And consequently, medications are infused on wrong power.

There are "Streamlining", "Prioritizing", "Omitting", and "Helping" on action process. Streamlining is a characteristic to operate in a different way that is thought more efficient. For instance, when workers dose medications for internal use, they

Table 1 Behavioral characteristics

Large classification	Small classification	Behavioral characteristics		Number of cases	Percentage (%)
		Label	Explanation		
Operation	Information acquisition	Selective recognition	To recognize objects that are easier to recognize	25	20.3
		Partial recognition	To recognize partially objects	30	24.4
	Information judgment	Predictive judgment	To predict results and skip judgments	13	10.6
	Action	Streamlining	To operate in a different way that is thought more efficient	26	21.1
		Prioritizing	To operate for only objects that are prioritized higher	13	10.6
		Omitting	To omit operation in order to save efforts	6	4.9
		Helping	To help others despite not in charge	2	1.6
Error detection	Error detection	Twisting	To interpret something wrong to one's own advantage	8	6.5
Total				123	100.0

hand medications to patients for sure. As streamlining, however, they put medications on patient table or other places in such a case as they cannot hand medications to patients for some reasons. And consequently, medications that put on patient tables or other places are lost somehow. Prioritizing is a characteristic to operate for only objects that are prioritized higher. For instance, workers confirm to all patients if they take medications after handing them. As prioritizing, however, they tend to confirm to only patients who are prioritized higher by themselves. And

consequently, they cannot notice that some patients haven't taken medications. Omitting is a characteristic to omit operation in order to save efforts. For instance, after they set an injection pump, they confirm whether it works normally. As omitting, however, they tend to think that it is going to work without confirmation and skip it. And consequently, they cannot notice troubles in such a case as injection pumps are not set properly. Helping is a characteristic to help others despite not in charge. For instance, workers dose medications to patients who they take charge of. As helping, however, they tend to help others in such a way that they dose medications to patients who they don't take charge of. And consequently, charge of dosing which patients become obscure and then some patients are not dosed medications with.

There is "Twisting" on error detection process. Twisting is a characteristic to interpret something wrong to one's own advantage. For instance, if they find that a patient doesn't wear a name band, they stop an operation and point out. As twisting, however, they tend to interpret that such a situation that a patient doesn't wear a name band would happen and not to point out it.

4.2 Behaviour-Induced Factors

The behavior-induced factors as the results of the analysis are shown Table 2.

As Table 2, the results of the analysis are as follows: there are mainly 2 types of behavioral-induced factors. One is about workload and the other is about properties of operations. Moreover, workload is grouped into temporal, physical and cognitive workload and properties of operations are grouped into direction, repetitive, scarcity, redundancy and tendency to be suspended.

Temporal workloads involve such situations that there are too many patients to be observed during drip infusion, too many operations to be done at the same time, or workers have to wait until previous operations have been done. Physical workloads involve such situations that a pile of prescriptions is too heavy to bring to a patient bedside, or there is not space enough to put prescriptions on and verify information about medications and patients. Cognitive workloads involve such situations that there are many points to be checked on preparing medications, or it is difficult to find necessary information on prescriptions.

Directions of operations involve such a situation that there is a big difference in easiness to obtain information between information sources. Scarcities of operations involve such a situation that an operation to check whether a patient dose medications and stamp prescriptions repeats. Redundancies of operations involve such a situation that an operation to check whether previous operation has been done is not always necessary and there is often no problem even if it is skipped. Tendency to be suspended involves such a situation that it depends on patients' conditions or previous operations' conditions to start dosing medications.

Table 2 Behaviour-induced factors

Behaviour-induced factors			Number of cases	Percentage (%)	Related behavioral characteristics
1st classification	2nd classification	3rd classification			
Workload is too heavy	Temporal workload is too heavy	Objects are too many	13	11.9	Streamlining, prioritizing, omitting, helping
		There're too much other operations in parallel in beginning of operation	3	2.8	
		Time to begin operation is fluctuate	2	1.8	
	Physical workload is too heavy	Load of tools is too heavy	2	1.8	
		Environment for operations is not enough	3	2.8	
	Cognitive workload is too heavy	Quantity of information is too large	26	23.9	Partial recognition
		It's too difficult to recognize information	4	3.7	
Operation has a property	Operation has direction	There is a big difference in easiness to obtain information between the sources	25	22.9	Selective recognition
	Operation is repetitive	Same operations are repetitive	3	2.8	Streamlining
	Operation has scarcity	Operation appears little times	10	9.2	Predictive judgment
	Operation has redundancy	Purpose of operation is to confirm if previous operation is done	13	11.9	Prioritizing, omitting
	Operation tends to be suspended	Condition required to start operation is so irregular that it tends to be suspended	5	4.6	Streamlining
Total			109	100.0	

5 Discussion

5.1 Significance of the Study

It has been generally thought that departures from standard due to violation happen because workers mistake carelessly and hence violation mechanisms or causes haven't been considered enough.

In this study, we analyzed the violation cases in hospital A and revealed the violation mechanism whereby behaviour-induced factors of operation conditions evoke behavioral characteristics that, in turn, violate standard operations. Consequently, it explains well how workers violate standard operations. Furthermore, it is possible to evaluate probability of violation occurrence of operations and prevent violations based on the violation mechanism, the behavioral characteristics, and the behaviour-induced factors.

5.2 Approach to Actions Against Violations

One of general approaches to actions against violations is to educate and motivate workers. It can be explained that the purpose of this approach is to restrain the behaviour characteristics. However, they are nature that human have unconsciously and it's difficult to restrain them. Hence, in order to prevent violations, it is one of the most efficient approaches to improve operations easier for workers to follow.

There are 2 types of the approach to improve operations; one is to prevent violations and the other is to accept violations. The former approach is to improve operations to eliminate the behaviour induced factors. For instance, in Case 1 above, it is quite possible to prevent violations by eliminating "temporal workload". The latter approach is to prevent errors by improving operations as premises for violations. For instance, in Case 2 above, it is though as one of actions based on this approach to prevent errors by adding lack of information in the medication carts as premises for "selective recognition". By this action, even if a worker refers medications in a cart instead of prescriptions, an error that some medication out of the cart is not prepared does not occur.

We are developing these approaches and proposing an action-planning method to violations in the future.

6 Conclusion

In this paper, we considered the violation mechanism based on the analysis of the cases in hospital A. Furthermore, we revealed the behavioral characteristics and the behaviour-induced factors.

Further tasks involve proposing an action-planning method to violations and considering a method to evaluate probability of violation occurrence of operations.

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Part VII
Human Factors and Ergonomics in Environmental Design

Ergonomic Design of Bathrooms for People with Cerebral Palsy in the Philippines

Quirby Alberto, Brian Atanacio, Cyrill Cucueco, Ana Mercado and Benette Custodio

Abstract Around 2–3 out of 1000 births in the Philippines are born with Cerebral Palsy that affects the brain leading to complications of one's motor skills. Partnered with Philippine Cerebral Palsy Incorporated (PCPI), which has a current bathroom layout that failed to meet the standards set by the Philippines, the study proposes an ergonomic bathroom design for Cerebral Palsy patients. Anthropometric and biomechanical data of the patients were integrated to the derivation of the specific measurements of different parts of the bathroom. In addition, qualitative inputs for the design were also gathered. Combining both qualitative and quantitative measures, a bathroom design that conforms to Philippine standards was created. This application of ergonomics in Cerebral Palsy facilities is a step closer in allowing Filipino patients suffering from this condition to attain independence in activities that are part of a person's daily routine.

Keywords Philippines · Cerebral palsy · Ergonomic · Anthropometric · Biomechanical · Qualitative measures

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1 Introduction

1.1 Background of the Study

Cerebral Palsy is a developmental disability that affects muscle coordination, body movement, and motor skills. "Cerebral" refers to the brain, while "Palsy" refers to the disorder of movement and posture. The severity of the disability is dependent on which parts of the brain are damaged. It mainly affects the learning capabilities and development of children who grow up with this disability. It is the most common disorder in the world. In the Philippines, statistics shows that approximately 1–2 % of the population suffer from this condition.

1.2 Problem Statement

The bathroom is known to be an area of difficulty for people with disabilities including those suffering from Cerebral Palsy. In the Philippine Cerebral Palsy Incorporated (PCPI), the current bathrooms do not comply with the standards set in Batas Pambansa (BP) 344–1984 Accessibility Law, specifically the minimum cubicle area of 33 ft^2, the minimum wheelchair space of 25 ft^2, and the minimum door width of 3 ft. As such, it is crucial to have bathrooms that comply with the standards set for the disabled in the Philippines to ensure their safety and comfort, and allow independence in personal activities.

1.3 Objectives

The study aims able to design an ergonomic bathroom that conforms to the existing Philippine standards and norms of the general population, integrating anthropometric and biomechanical measurements of the disabled to ensure that it will be fit for all users.

1.4 Scope and Limitations

The study focused solely on the bathroom's physical environment, the associated risks, and its impact on the behavior of Cerebral Palsy patients in the Philippines. Patients with varying types of Cerebral Palsy, as well as the staff and therapists in the PCPI facility, were the subjects of the study. The bathrooms designed are applicable for both the male and female bathrooms.

2 Review of Related Literature

2.1 Cerebral Palsy Background and Definition

Cerebral Palsy describes a group of permanent disorders that affect the development of movement and posture as a result of non-progressive disturbances in the fetal brain. Infants who suffer from Cerebral Palsy take a long time to reach developmental milestones such as learning to roll over, sit, crawl or walk. Apart from the motor disorders associated with Cerebral Palsy, disturbances of sensation, perception, cognition, communication and behavior are also present. Furthermore, individuals diagnosed with Cerebral Palsy are also susceptible to epilepsy and secondary musculoskeletal problems [1, 2].

2.2 Risks and Hazards in the Bathroom

Bathrooms are essential to every human being to perform activities of daily living—toileting, washing and showering [3]. Nonetheless, no room at home poses more threats to safety than the bathroom. The Centers for Disease Control and Prevention estimates that every year, around 235,000 people are brought to the hospital due to nonfatal bathroom injuries. Most injuries (81 %) are caused by falls as people get in and out of the shower and toilet [4].

"An item is considered potentially hazardous if it could lead to accidents, due to at least one of the following scenarios: (1) exaggerated body positioning or loss of balance, (2) slipping or tripping, or (3) weight bearing on a material unlikely to withstand the load [5]." The hazards in a bathroom environment may include restricted space, obstructions caused by fixtures, as well as slippery floors and surfaces. To reduce risks, the layout and the fixtures must be tailored to fit the needs of the users. In addition, the bathroom must satisfy all requirements and standards set by the government [3].

2.3 Anthropometry

Anthropometry is the measure of physical features of humans, including body size and shape. In the context of the bathroom, anthropometry can be used to determine the size of door openings, the height of counters and so forth [6].

To achieve a universal design, body dimensions representative of the population are necessary. However, in acquiring body dimensions, several measurements may not be accurate due to physical weakness and disability to perform certain postures. If specific anthropometric measurements are impossible to obtain due to movement

and function difficulties, segment lengths can be expressed as percentages of total body height [7].

In general, bathroom facilities must be designed to accommodate 95 % of the population. The 5th percentile is used in determining the reachability and limitation for the bathroom facilities, while the 95th percentile is used to ensure adequate clearance to avoid unwanted contact [8].

2.4 Biomechanics

Biomechanics is the measure of body movement and strength, including requirements for operating forces, reach ranges, and energy expended [6].

One relevant biomechanical consideration is grip strength that can be measured using a dynamometer. Grip is applied to produce normal forces that compress the grip object in the hand. In many cases, grip is applied to produce torque that prevents objects from rotating in the hand. Moreover, grip is applied to produce thrust forces that prevent objects from sliding out of the hand [9].

3 Methodology

3.1 Qualitative Measure of Loughborough University

The qualitative measure of Loughborough University was used to assess the level of difficulty of performing a task in the bathroom. Significant tasks in the bathroom, such as washing hands, taking a bath, urinating, and defecating, were evaluated using a scoring system from 0 to 4. Afterwards, questions regarding the use of diapers and the changing table were asked. Lastly, participants were asked regarding what they wish to be able to do more easily given a different bathroom configuration [10].

3.2 Sample Size Determination

The equation used to determine the number of samples required for the anthropometric and biomechanical measurements is:

$$n = \left(\frac{t_{\alpha/2,n-1} s}{k\bar{x}} \right)^2. \tag{1}$$

$\bar{x}$, s and k represent the sample mean, sample standard deviation and acceptable fraction respectively [11].

3.3 Anthropometric Measurements

The essential anthropometric measurements include the following:

1. Stature
2. Standing Elbow Height
3. Standing Shoulder Height
4. Sitting Popliteal Height
5. Sitting Shoulder Height
6. Sitting Elbow Height

Using the corresponding percentages of total body height, the standing elbow height, standing shoulder height, sitting popliteal height, sitting shoulder height and sitting elbow height were estimated.

3.4 Biomechanical Measurements

The necessary biomechanical measurements include:

1. Middle Fingertip Length
2. Thumb Tip Length
3. Inside Grip Breadth (Diameter of a circle that can be made by touching the thumb tip with the middle fingertip)

4 Analysis of Data

4.1 Survey Results

46 patients from Philippine Cerebral Palsy Incorporated were surveyed, out of which 30 were male and 16 were female. It was an interview-type survey conducted face-to-face, and the questions concerning the respondents were asked through the help of their caregivers, who have observed or accompanied them in using the bathroom.

Results show that 59 % of the respondents used diapers, thus, a safe and ergonomic bathroom must be designed to encourage Cerebral Palsy patients to make use of bathrooms instead of solely relying on diapers. In addition, 72 % of the

respondents used wheelchairs or needed assistance, appropriate space requirements must be set to accommodate them specifically. Furthermore, given that bulk of the respondents scored a 0 (not done) or a 1 (considerable help), designing of bathroom facilities must consider that patients will receive aid from their caregivers. When asked if there was anything that would make them perform the tasks they do inside the bathroom easier, the respondents answered:

- Knobs that are easy to operate
- Grab bars
- Non-slip floors
- Bath chairs
- Height of fixtures
- Bidet attached to toilet bowl
- Toilet bowl diameter
- Open spaces
- Wheelchair-friendly
- Walls with padding

4.2 Sample Size and Acceptable Fraction

In computing for the required sample size, both the level of significance α and the acceptable fraction k are set at 0.05.

The actual number of samples gathered exceeded the computed value for all measurements, and, the actual acceptable fraction all are below the 0.05 that was set, thereby making all data valid.

4.3 Recommended Dimensions

The sample mean $\bar{x}$ and the sample standard deviation s were used to compute for the 5th and 95th percentiles of the anthropometric measurements to be used as basis for dimensions and placement of bathroom fixtures. For the grab bars, the mean middle fingertip length, the mean thumb tip length and the mean inside grip breadth were used to compute for the optimal diameters of the top and bottom grab bars.

Furthermore, the dimensions based from the anthropometric measurements were compared with the current layout, as well as existing standards and space requirements so as to finalize the recommended measurements that will be used for the proposed bathroom design (Table 1).

In general, the anthropometric and biomechanical measurements were used for the proposed bathroom design given that the measurements are within range or there is no specific mention in the standards.

Table 1 Proposed dimensions for the new bathroom design

Door	Current	Standard		Anthropometric	Proposed
		Enabling environments	BP 344		
Space between doorframe (in)	36	36	32	–	36
Door knob height (in)	–	–	33–42	35	35
Door height (in)	84	–	–	70 (min)	84

Switch	Current		Standard	Anthropometric	Proposed
	Male	Female	BP 344		
Switch height (in)	37	35	48–52	45	45

Lavatory	Current	Standard	Anthropometric	Proposed
		BP 344		
Hand basin height (in)	28	32 (max)	31	31
Water faucet height (in)	–	–	33	33

Grab bar	Current		Standard	Anthropometric	Biomechanical	Proposed
	Male	Female	BP 344			
Top horizontal handrail height (in)	38	37.8	28–36	34	–	34
Bottom horizontal handrail height (in)	30.5	30.8	–	23	–	23
Top horizontal handrail diameter (in)	2	2	1–2	–	1.5	1.5
Bottom horizontal handrail diameter (in)	1	1	–	–	1	1
Vertical handrail maximum height (in)	–	–	–	59	–	59
Vertical handrail minimum height (in)	–	–	–	34	–	34

Toilet stall	Current		Standard				Proposed
	Male	Female	Assisted	Lateral transfer (90°)	Lateral transfer (45°)	BP 344	
Width (in)	38	38.5	63	52	56	67 (min)	67
Length (in)	81.5	70	79	52	56	71 (min)	79
Area (in^2)	3097	2695	4977	2704	3136	4757	5293

(continued)

Table 1 (continued)

Changing table	Current	Standard Accessible and usable building and facilities	Anthropometric	Proposed
Changing table Changing table height (in)	Current 24	Standard Accessible and usable building and facilities 28–34	Anthropometric 27	Proposed 27
Changing table width (in)	26.5	–	–	26.5
Changing table length (in)	60.5	–	70	70

Toilet	Current	Standard BP 344	Anthropometric	Proposed
Toilet seat height (in)	14	18 (max)	16	16
Toilet flush placement (in)	26	–	33	33

Shower	Anthropometric	Proposed
Shower head height (in)	74	74
Shower knob height (in)	35	35

5 Results and Discussion

The proposed bathroom design for Philippine Cerebral Palsy Incorporated's new facility can be seen in Fig. 1.

A single bathroom of this design requires a floor space of 195 ft^2; ergo, having a separate men's and women's bathroom will yield a total area of 390 ft^2. The design includes 1 toilet cubicle, 1 changing table, 1 shower area and 2 sinks. The following are the necessary changes proposed with regard to PCPI's current bathroom—swinging doors are opened outwards to allow easy exit. In addition, a turning space of 25 ft^2 is also allocated per door inside the bathroom. The proposed toilet cubicle is more spacious to account for the area needed by wheelchair users and their caregivers during assisted and lateral transfers to toilet seat. To accommodate patients who are limited to using diapers, a fixed changing table surrounded by curtains for privacy is installed. The new PCPI facility will also begin providing water therapy to its patients, thereby requiring a shower area in the proposed bathroom design. Based on the interviews, most patients sit down while their respective caregivers give them a bath. A handheld shower type is suggested in order for the caregiver to rinse his patient more effectively. Grab bars are placed within the patient's reach for the toilet cubicle and shower area to support them in performing the tasks with less difficulty. The 2 sinks are placed on bathroom countertops, with grab bars in front, to accommodate more users and an area for their belongings.

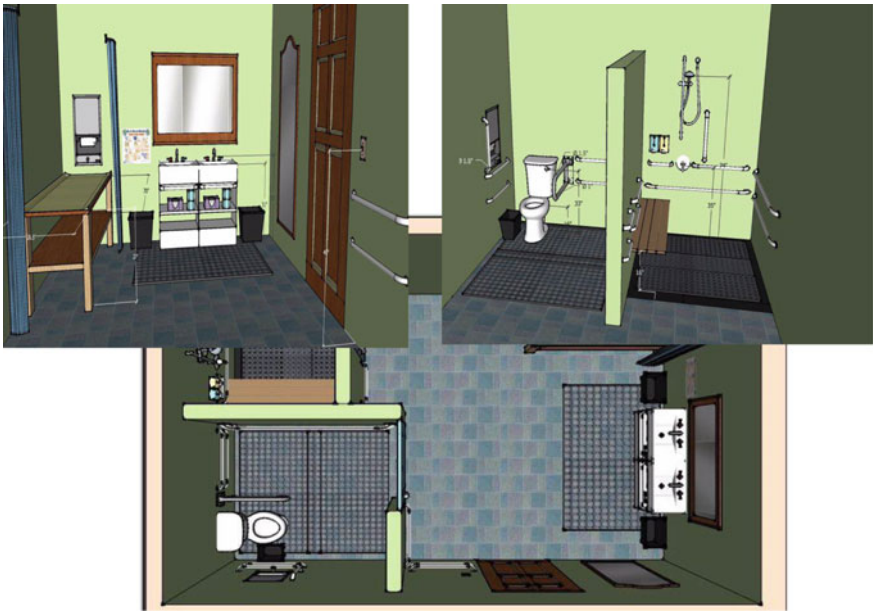

Fig. 1 Proposed 3-dimensional bathroom design

Apart from the aforementioned fixtures, the accessories included in the proposed design are trashcans, a mirror, and non-slip rubber mats placed inside the toilet cubicle, shower area, and under the sink to prevent the possibility of falls due to slippery floors and surfaces. It is recommended that the knobs and taps located inside the bathroom must be labeled properly to reduce accidents concerning the temperature of the water. Other mechanisms found in the bathroom, such as soap dispensers, must be within reach ranges and must be able to operate using a closed fist to accommodate patients that are incapable of opening their hands. No other toxic or infectious substances besides the shampoo and soap should be stored inside the bathroom to avoid the possibility of misuse of these substances. The toilet should include a children's toilet seat and an installed bidet inside the toilet bowl to lessen the movement of the patient or his caregiver when washing after defecating. Signs will also be installed to ensure that the users are knowledgeable in fulfilling the different activities effectively.

6 Conclusion and Recommendations

Altogether, the researchers believe that the proposed design can be applied to different Cerebral Palsy facilities in the Philippines. Through the application of ergonomics, Filipino Cerebral Palsy patients are capacitated to independently conduct bathroom activities that are crucial to everyday living.

Areas for future studies can focus on the addition of padded walls, effective color schemes, appropriate illumination and temperature levels, proper noise and vibration levels, and the placement of other bathroom accessories.

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The Place of Health Design for Health Promotion: The Pediatrics Design Process Focus in Humanization at Santa Casa's Hospital Montes Claros—Brazil

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Abstract Child who remains long periods in hospital are the one that suffers most from the influence of hospitals, but is the largest contributors to the humanization of studies. This work has its origin in the project process of Santa Casa de Montes Claros—Brazil hospital analysis focus in the concepts of humanization. It analyses the relationship between the health pediatric environment and the importance of the proposals of the humanization programs dedicated to the admitted child. One APO (post-occupation analysis) was adopted with cognitive approach, in order to diagnose, describe and analyze the built environment, perception and environmental cognition from the point of view of users. As there is a lack of studies in Brazil about that, from the information obtained from this paper, you can to propose suggestions for structural improvements to the hospital that contributes to the effective healing process of patients.

Keywords Humanization · Health design · Healing environment · Pediatric

1 Introduction

As we know the child who remains long periods in hospital or often returning to the hospital is the one that suffers most from the influence of hospitals, but is the largest contributor to the humanization of studies, their perception of spaces and medical interference on your body. Knowing that the attendance based on humanization concepts collaborates with the patient's autonomy, improves the psychological relations of them with the physical space and turns the admission experience into a less traumatic one, this work has its origin in the project process of Santa Casa de Montes Claros-MG hospital analysis focus in the concepts of humanization. It looks for relating the emerging paradigms of modern architecture to health with pediatric units of hospital environment from the investigation and perception of the users

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(patients, companions and workers). It analyses the relationship between the health pediatric environment and the importance of the proposals of the humanization programs dedicated to the admitted child. Involves the perception of spaces from the perspective of the users, showing the appreciation of humanization in pediatric environment as a procedure able to contribute to the therapeutic process, providing physical well-being, mental and spiritual, helping reduce the length of stay in hospital and reducing the consumption of drugs.

However, to understand the hospital space as it is current understood, it is necessary to understanding its transformation; the evolutionary process in which the health institution had been through. Until mid-17th century, the hospital was a kind of tool of mixed exclusion, assistance and spiritual transformation, in which the medical role did not appear. The hospital also had a social responsibility, it essentially was a poor people assistance institution, and also of segregation and exclusion. Poor people had the need for assistance, and as ill, a disease carrier and possibly contagious, they were dangerous. For these reasons, the hospital should be there both to gather them, and to protect the others from the danger they represented.

Until the 18th century, the main character in the hospital was not the ill person who needed to be cured, but the poor one who was dying. It was correctly said then that the hospital was a place to die, and people who worked at the hospital area were not destined to cure the patient, but to get their own salvation. The patient was someone who should be assisted materially and spiritually, someone to whom the final cares should be given, as the final sacrament. This was the essential function of the hospital [1].

However, by the end of the 18th century, there are records of the first hospital projects based on scientific therapeutic concepts. At this time, the importance of organizing the therapeutic space appears, with the division of patients by pathologies and/or symptoms, as rigorous asepsis practices [2]. Then, by the end of the 18th century, around 1780, the disease was then acknowledged as a pathologic factor and the hospital has become a tool destined to cure. But the great revolutionary change on the hospital institution was the phenomenon called “Hospital Medicalization”, described as the union of medical and hospital series and, which occurred when the hospitals acquired a therapeutic role with the patients, through functional and administrative command of the medical class. It is on the two processes adjustment—medical intervention displacement and hospital space discipline—the medical hospital is to be found [1].

On the 19th century, the main theme of the hospital architecture was concerning the salubrity of the buildings and the environmental comfort. In England, the nurse Florence Nightingale changed the concept of nursing, by creating the Nightingale infirmary. To her, the main flaws at the hospitals were the lack of ventilation and inappropriate illumination, as well as the overcrowding, which would be solved at the infirmary. Her concept has contributed a lot to the hospital humanization, transforming them in a diseased-aimed institution [3].

It might be said that the first transformation factor of the health space was not looked for a positive action of the hospital toward the diseased or the sickness, but the annulment of the negative effects of the hospital, a concern that has oriented the humanization and can be found at the hospitals until today. Since 19th century the hospital has been transformed from an exclusion space into a treatment and healing space, with this process being conducted by the physician [4]. Despite all the developments, according to Ceccim and Carvalho [5], the children who remains long periods admitted or the ones who regularly return to the hospital are the children who suffer the most with the hospital environment influence.

2 Humanization

2.1 The Humanization Process

In the 1970s the concept of humanization has been discussed in a national symposium named Humanizing Health Care [6]. The movement defended the need to put the patient on the focuses of the treatment and healing processes, and give him power.

The movement was disseminated and strengthened, and in 1978 was created in California, USA, by Angelica Thierot, the *Planetree*, a non-profit organization, which has as goal work for the humanization of the establishments of health assistance, promoting care focused on patient. Herself, a dissatisfied patient with the non-humanized treatment received during an admission to a hospital in San Francisco [7].

There are many scientific research at *Planetree* that prove the application of its concepts brings series of benefits to the patients and other users of health buildings: faster recovery, lesser cost with medicine, requisition of support from nursing reduction, moral elevation on health professional, besides higher productivity and reduction of admission cost. Also, ten elements are highlighted as a must-be used on patient-centered care. (1) Humanization—attention centered on the person. (2) Interaction between patient, family and health multi-professional staff. (3) Need of emotional support to family and friends. The value of human contact. (4) Access to information—knowledge of the records with explanation and conscientization about the diagnoses, prognostic, therapy, prevention and rehabilitation. (5) Insertion of alternative and complementary therapies. (6) Comprehension of all senses of the human being—synesthesia. (7) Importance of good nutrition and well nourishment. (8) The role of spirituality on each one's life, with no religious prejudice, but as a comprehension of existence and its proposal. (9) Insertion of art and beauty, including the planned spaces with special architecture analyzing color, light, shape and function, among others. (10) Integration with healthy communities.

In Brazil, the movement has arrived through an area of Mental Health, with the Psychiatric Reform. The movement sensitized public instances and the Federal Government, with the support of the Health Ministry [8].

In 2000, after the importance of Humanization in the quality of attendance to public hospitals users was identified, it was created the Technical Committee of Metal Health professionals. They elaborated a Pilot Project for the National Program of Hospital Assistance Humanization (PNHAH), implemented in ten hospital across many regions of the country, situated in different sociocultural realities and with different sizes, profiles of services and management templates [9].

The program was developed based on the daily experience of public attendance on health services and on the results of services assessment surveys, which demonstrated the quality of the attention to the user is one of the more critical matters on health care system, more than the absence of a physician.

To comprehend the demands and wills of the patient, it is necessary understand the concepts of Humanization in health architecture of PNHAH, which defines humanizing as: accept this necessity of rescue and the articulation of subjective aspects, inseparable from physical and biological aspects [9].

To Ulrich (2008) [10], it is necessary neutralize the patient's tension and the habitual coldness of a health environment, creating a therapeutic environment, or Healing Environment, in which the physical structure participates and contributes on the healing process, with the objective of creating spaces for caring the patient and reducing external sources that may cause stress, which would provide peace, hope, motivation, joyful, reflection and comfort. The physical space interferes positive and negatively on the recovery of the patients, through aspects that might help or hamper the activity, by exposing the patient to infection.

However, Eriksson [11] affirms that architecture must work in order to: minimize the high level of noise from technology; allow the integration with nature through windows that permit natural illumination and visibility to external; promote privacy through the individualization of spaces; specify materials according to the user of space, differentiated for working spaces and living spaces; predict areas for the family to participate by giving social support to the patients; promote "positive distractions", as water fountains, windows facing green areas; promote a layout that allow the familiarity, visibility to external and autonomy to the patient. It points out as advantages of the humanized projects: patient and family stress reduction; pain and infections reduction and improvement on the sleeping quality of the patients; benefits for the workers; and, cost reduction.

Bitencourt *apud* Nord (2006) [12] shows as the result of the research about "The environment and the perceptive sensorial factors" that comfort is capable of producing relevant results for the humanization of health assistance, for instance: promoting stress reduction of health professionals and improvement of assistant efficiency, improving patient's security, reducing patient's stress and amplifies the possibility of clinical success and promoting a wide improvement on the quality of assistance given.

2.2 Pediatric Wing Requirements

It is flagrant the necessity of adapting the health spaces to the necessities of users and their specifications, which foments substantially the work of the architect, but it also implies on further efforts. For it is known that architecture has as priority create and develop proper spaces to 'many activities of human beings, looking for functionality and comfort [13].

If elaborating architectonic projects for health environment is already complex, even more are the pediatric ones. For Dougherty and Simpson [14] however it has been made a substantial progress on developing quality measures and implementing improvement strategies for the children health care, this one is still behind while compared to the adults conditions. To make significant progress will demand not only the attention supported by those concerned about the child health improvement and health care, but also activities to build a wide support basis in health care and deciders of the key public. The authors recommend that at least 4 fixed-activities: (1) to build public support to assess the quality and improvement on children health care; (2) to create information technology infrastructure that can make obtaining and using data easier; (3) to improve reliability, validity and feasibility of existent measures; and (4) to create a basis of evidences to the quality improvement measures development.

Considering that the hospital project must consider the necessities and preferences of patients, Ribeiro [15] demonstrates in his studies about humanization of assistances to the admitted child that strategies, which evolve exchanging relations between the health professionals, admitted child and family, should be used. They may be through ludic activities, music, children stories readings. It is also cited the use of the architecture itself as a way to promote well-being to the child and family, also facilitating the development of the work process of health professionals. Reassuring this idea, Brito [16] shows that play therapy has a therapeutic value and it needs to be incorporated in the process of pediatric nursing, for, despite not being effective on Brazilian institutions, the results are pointed by the motivation/gratification, lack of effort, initiative and impotence categories.

The health professionals know that a family has needs, being inseparable part of the assistance. Souza [17] testifies that it is also possible to verify that despite the existence of a strong trend of valuing the technical and mechanical aspects of the assistance represented by direct care, the nursing staff realizes a series of indirect cares that aim an integral and human approach. It is affirmed that is necessary a nursing staff which assists the admitted child to execute dynamically its attention to the providing of the family needs, being apart from a technical template, valuing in this way its job, becoming more visible and humanitarian.

Barrera et al [18] insists that the best pediatrician to the child is the mother, and sometimes she is excluded on the hospitalization. It is highlighted that benefits have been noticed with the mother presence on the quality of medical attention, keeping the affective relation and the nutritional estate, reducing the infection, reducing medicine and, hence, with a lesser cost on the admission. It is also informed that

even some difficulties in keeping them close appear, these would be smaller and solvable, for they may reduce the nuisance of familiar compassion, maternal angst and anxiety. The importance of having psychological support to the family with long hospitalizations is also highlighted.

Silva et al [19] testifies that on general pediatrics field and on first line attendance, the new ways of understanding the process health-disease and the development on the knowledge about involved factors on disturb genesis are not on an isolated way. The everyday hospital may seize the potential role as therapeutic resource, which allows the child to express his/her emotions, it helps to understand the proceedings that are done and might make the child closer and cooperative to the health staff. It highlights that the results show that the therapeutic toy has been used in Brazil through different ways, from the waiting room of a child clinic to the assistance of children with cancer. It informs that a child enjoys unexpected situations to play and, in all cases, there has been improvement on the patient's conduct concerning the proceedings, a higher comprehension of the family toward the disease and its treatment. It emphasizes that the main difficulties pointed out are little related to the little time available for the therapeutic toy technique application on the daily professional routine.

Ângelo et al [20] concludes that the admitted child attendance refers to a variety of questions of educational-recreative character to be explored, which should be offered to children, not only because of it is in the law (11.104/2005), but for knowing the importance of the hospital humanization and of the relation of playing on the child's routine. It emphasizes that exist an intense interaction between the children and the professional in charge, which strengthen the link with the institution.

Esteves et al [21] reflects the concept of "humanization", concerning the potentialities of some existent programs, the ones that gather art, recreation, leisure and humor as privileged ways of communication and expression. Among them, it highlights the intervention of hospital clowns, as a way to promote the free expression of the child, his/her autonomy, creativity, exploration and knowledge of the world and consequent psychosocial development, treasuring the importance of psychosocial aspects of pediatric admission and looking for the child "under" the sick body, looking for promoting comfortable and extenuatory environments from the negative experiences lived by the child (and family) during the admission.

Therefore, the physical environment can help the relation between patients, companion, nursing staff and medical staff to be issued, the architecture must create spaces dedicated to pediatric treatment. According to Judkins [22], the changes on the physical environment in which pediatric emergencies are treated increase the level of satisfaction of the users, and the staff gets more confident by dealing with patients in a pediatric dedicated area.

To Bergan [23], his work aimed to investigate the aspects of architecture and the environment built on the humanization process of the pediatric hospital and its influence on the recuperation of admitted child. It affirms that at the core of the representation appears the element "attendance", while "reform", "medicine", "organization" and "care" appear on the peripheral system. And concludes by

informing that the humanization for these subjects appear to be strongly attached to the right of health and access to services. However, aspects that model the quality of attendance, and that have been listed as humanization, are not neglected. The comprehension, planning and quality of the health building projects with rationalization, adequation and humanization of the spaces have become fundamentally important.

3 Context

3.1 The Santa Casa Hospitals in Brazil

It is known that the concern with assistance and health institutions is not recent; in 1480 he Portuguese Crown judged itself on the duty of assisting groups of people, even crowds that followed the old Roman ways, where hostels were installed and among them clumsy hospitals in order to attend the ones who were sick or exhausted. Hence, appeared the Irmandades da Misericórdia, Irmandade de Nossa Senhoras, Mãe de Deus, Virgem Maria da Misericórdia, nowadays known as Santa Casa de Misericórdia, with the goal of helping the sick and the most in need of the European cities, scourged by famine, pestilence and war [24]. The hospital came up as a way to control the progress of sicknesses, and also to contribute to the basic sanitation politics [25].

3.2 The Santa Casa de Montes Claros-MG Hospital—Brazil

According to the Revista Tempo magazine [26], due to the clear need of hospital cares in the city and the existence of a licensed physician, it was established that the first institutional building that should comprise the structure of the new city would be a hospital. In 1871, fourteen years after the emancipation, it was opened in Montes Claros the "Hospital da Caridade", after named as "Santa Casa de Caridade".

In agreement with Santos and Silva [27], Santa Casa de Montes Claros was founded with the goal of gathering the most needed and to improve the health of the city, after all the diseased treatment was conducted, until then, in houses or private clinics.

In the beginning the physical structure was rather simple, however, a new head office was adapted in 1908 and in 1947 the main headquarter was built, which bred the hospital complex that exists there until today.

3.3 *Pediatrics in Santa Casa de Montes Claros-MG Hospital—Brazil*

The Pediatrics in Santa Casa de Montes Claros hospital is a reference to high and medium complexity, as certified by the CNES (Health Establishment National Register/Cadastro Nacional de Estabelecimento de Saúde) register, and it has 47 pediatric beds and an average occupation of 80.62 % (Fig. 1).

On the professional day to day of a health space architect and on the living of the health environment it is known that the pediatrics unit is surrounded by some singularities on the hospital context; the child loses the references for being away from home and from all that is common to his/her daily routines. Moreover, the hospital environment causes fear and restrictions. Considering that a child needs more attention and care, and that whichever destabilization in his age group interferes in quality of life and in the development, taking care of an admitted child demands an interaction in the nursing team and the admitted child's family. This offers various benefits to the recovery of the child, but on the other hand, it might present a source of conflicts that may alter the assistance into a complex exercise, especially due to the possible cultural shock [28].

Since the family is emotionally shaken due to the disease of the child, taking care of the family is also a responsibility and a moral commitment of the nursing and it is necessary to exist a caring environment that favors the relationship between nursing and family so as to build a practice that helps facing the difficulties, especially in cases of sickness. The hospital might be understood, by the child and the family, as a strange environment; which breeds physical and emotional suffering. This fact makes them exhausted and uncomfortable to take care of the child

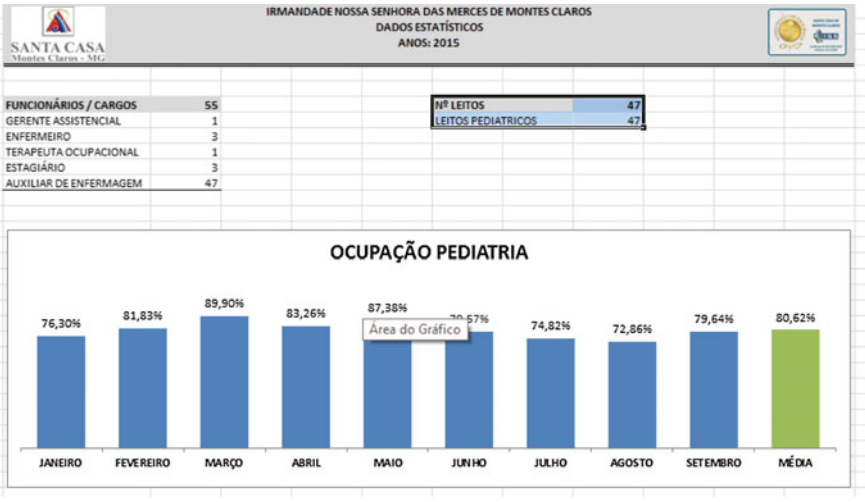

Fig. 1 Pediatrics profile. *Source* Santa Casa Controller, 2015

and, generally, being neglected in its needs, the family has a traumatized experience at the hospital, and so does the child [29].

The assistance professionals refer that the inexistence of a physical structure and proper accommodations imply in a lack of care, not contemplating the necessities of the family in the pediatric unit. To them, the lack of proper accommodations is a potential factor of the hospitalization suffering [30].

In the attempt of changing the admission experience into a less hostile one, some movements as the *Planetree* philosophy, which have as concept: receive the family and friends of the patients; treasure the human beings and not the technology; make possible to the patients the participation on their treatment; be flexible concerning the personalization of the care of each patient; encourage the provider of the care to be receptive to the patients; instigate the connection between nature and beauty. These movements have turned the sickness experience into a growing factor to the patient, it might be a reassessment period, dimensioning priorities and redefining potentialities. They point out that the health environment project should provide the stress reduction and sensory stimuli; as a way to include on the environment program: support and comfort areas; educational environment that promotes personal growth; environments that allow family participation; and sacred places [31].

4 Materials and Methods

4.1 Study Lineation

This study is composed of a quantitative, exploratory and analytic study.

4.2 Research Place

The scenario for developing this study will be the biggest hospital in north Minas Gerais, Irmandade Nossa Senhora das Mercês Santa Casa de Montes Claros, Minas Gerais, Brazil. General Hospital Class I, awarded ONA level II of excellence, part of Emergency and Urgency (level III), with 385 registered beds in CNES, with 80 % of these destined to attendance through Public Health System. Nowadays it realizes more the 100 thousand proceedings per month and it is registered as a Childen's Friend Hospital. The hospital is a reference in health assistance for more than 110 counties. It has been there for 144 years and it has more than 2.100 collaborators, composed of more than 400 physicians and other professionals, who compose the clinical, assistant and administrative body of the Institution. There are more than 682 employees among nursing technicians and assistants, divided in 48 sectors that include: maternity, medical clinic, pediatrics, surgical block, intensive care unit, among others.

4.3 Participants

This study will count on the universe of nursing technicians and assistants active in Santa Casa de Montes Claros, MG-Brazil. Currently in the pediatric ward has 55 funcionáros between technicians and nursing assistants and 05 physicians to meet 47 pediatric beds.

Inclusion Criteria. The inclusion criteria are: the individual has to be patients, companions, physicians and workers a nursing technician or assistant at Pediatric area Santa Casa de Montes Claros; to be found on the reference sector until a second attempt; to accept the participation on the research under agreement via signing an informing document.
Exclusion Criteria. The exclusion criteria are: individuals who do not work directly in the pediatric area of the hospital or refuse to participate.

4.4 Data Collection

Prior contacting physicians, coordinators, managers and supervisors from the sectors with an objective of propagating the research and scheduling the most proper day and hour for data collection. The tools used by the researches through visitations to the professionals in a previously scheduled hour. The visitations realized by the researches and other collaborators, properly trained and identified. Privacy and free will of the interviewees guaranteed, as well as their working routines observed.

4.5 Tools

To identify and attribute qualities in a space is a complex task, for the meaning of the place, in most cases, comes from human intentions and experiences of the people who use the space. An APO (post-occupation analysis) is an interactive, systemized and rigorous evaluation process of the built environment performance, after some time of its construction and occupation [32]. On the field research it will be adopted an APO with cognitive approach, with the purpose of diagnosing, describing and analyzing the constructed environment, perception and environment cognition from the point of view of the users, the applied tools are:

- Exploratory Visit. Done without a previous course organization and with no influence of other people's opinion. It is part of the concept of incorporated observation, and it also can be defined as "an specific practice that incorporates an open approach of the experience" [32].

- Walkthrough—with Environmental Inventory. It might be defined as a discussed course, complemented by photographs, sketches, audio recording, in which physical aspects are suited to articulate the participants reactions in relation to the studied environment [32]. The tool enables the descriptive identification of positive and negative points of the analyzed environment, suiting the articulation of the reactions of the subjects in relation to the environment. Used by researcher.
- Questionnaire—Structured. A research tool that contains a group of questions related to a given topic or problem [32]. The tool will be used to enable the discovery or regularities and compare the answers related to a group of questions. Used for staff (coordinators, nurses and physicians).
- Visual Selection and Visual Map. The visual map allows the identification of the users' perception in relation to a given environment, with focus on the localization, appropriation, territory mark, inadequacies to existent situations, exceeding or improper furniture and barriers. The visual selection, allows the imaginary to come up, the symbols and cultural aspects, as well as assessing the impact caused by some architectonic typologies, spatial organizations, colors and texture about quality of life and people well-being [32] Used for companions.
- Wish Poem. It allows the users of an environment to declare, through drawings, their needs, feelings and wishes related to the analyzed environment, representatives of the demands and expectations of the users [32]. Used for patients.

The APO will be done with patients, companions, coordinators, nurses and physicians in order to understand the demands for the Pediatric admissions, which will allow us to understand the "profile" of the users, and also to comprehend the transformation that the "clients" of pediatric admission pass through. On the APO, it will be analyzed physical structures with notes about: green areas interaction, illumination, ergonomics, family and workers accommodation spaces, nourishment, spirituality, artistic space and if there are other alternative healing practices.

5 Expected Results

It is expected to prove that the spaces perception, from the users' view, reveals the valuation of humanization in pediatric environment as a proceeding capable of contributing to the therapeutic process, providing physical, psychical and spiritual well-being, contributing to reduce the time of admission permanence and reducing the medicine consumption. The research has also the pretension of recommending project guidelines for similar projects.

6 Final Considerations

To elaborate hospital architectonic projects is needed to build environments that attend all sides of health area, in a way that it may be above all functional, pleasant, proper to the needs and not only a structural environment, for, after all, it is an environment which is related to safety, besides beauty and efficiency. As affirmed by Goes [33], health environment architectonic projects go beyond particularities. The building architectonic project on the health sector is a complex challenge. The projects must consider the needs and preferences of the patients, users and relatives. The humanization appears as an ally of these aspirations; to the patients it is strongly bound to the right of health and access to services and not only to the technical character. It is necessary value the work on a more humanized way, which contributes to the well-being of the child and family, besides facilitating the development on the working process of the health professionals, making the admission experience less traumatic.

To discuss the fundamental implications to the project basis, based on the synthesis of records and evidences, makes easier the conceptual development, which may support and guide the conception and assessment of interventions, and as related by Benetti [34] "the well-solved and quality architecture may be a great medicine for health problems".

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Supporting Phobia Treatment with Virtual Reality: Systematic Desensitization Using Oculus Rift

José P. Monge, Gustavo López and Luis A. Guerrero

Abstract An irrational fear is called a phobia. Cognitive therapy teaches patients how to respond to triggering stimuli, by relaxing their mind and entering a state of reduced anxiety. Some of these methods depend on patient's imagination, since putting them in the situation or the object that triggers the anxiety (airplanes, spiders, public speaking, and dinosaurs) might be difficult. Our project proposes an interactive virtual reality system that enhances both the visual and hearing parts of the therapy, putting the patient in a virtual world where they can learn the proper techniques to learn how to respond to the anxiety triggers. We call our system VRPhobia. A prototype was created and it was evaluated with the aid of Cognitive Psychology therapists. The system takes into account the techniques used by the therapists and the training that the patient goes through. It works as a tool that enhances the therapy process.

Keywords Virtual reality · Phobia · Cognitive psychology · Healthcare

1 Introduction

Everyone is afraid of something. From children to fully grown adults, fear is a response from the human body that prevents us from being harmed. But when this fear takes control of us (our body, our mind, and our thoughts) this becomes

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unmanageable. This is what experts called a phobia: an unreasonable amount of anxiety produced by an object or a particular situation that produces a negative impact into our daily life, leaving the subject that suffers the effect of the phobia in a non-functional state.

In this paper, we present a virtual reality system that implements a systematic desensitization technique to improve and help patients with the therapy process to treat phobias. Introducing patients to a technique to treat phobias can be troublesome and in some cases expensive, unless we can use a virtual realty system as we propose.

Virtual Reality (VR) presents itself as a returning field that may be useful to overcome a lot of the challenges that are inherent to the cognitive psychological techniques used for phobias. VR is an affordable option that can be found in several forms, from consumer high performance units (Oculus Rift, Valve Vive, Playstation VR) to mobile implementation (GearVR, Google Cardboard). The ability for patients and therapists to have a system to enhance the therapy is now easier than ever. VR can also adds several stimuli for the patient that s/he would have to control externally otherwise. Music, visuals effects and narration guiding the therapy exercises are all parts of our system, which can be modularized and modified to be applied in different situations and for different phobias.

This paper presents our advances in the implementation of a system that enhances the systematic desensitization technique based on the evaluation of a cognitive psychology therapist. The paper is structured as follows: Sect. 2 presents the technical background, how we are implementing the therapy technique using virtual reality, and the kind of technology we are using. Section 3 we will describe the system. Section 4 presents the results of the evaluation performed. Finally on Sect. 5 concludes our paper and presents future work.

2 Background

This section presents the definition of virtual reality and phobia treatment. Also, it delves on the oculus rift and how VR has been applied in the treatment of phobias in the past.

2.1 Virtual Reality

A computer can generate virtual spaces that can provide sensory experiences, and this is called a virtual environment. Virtual environments are used to allow the user to interact with a computer-generated world [1]. Usually these environments are implemented using Head-Mounted Displays (HMD), which are devices attached to the user's head that can provide stereoscopic images and 3D sounds.

Virtual Reality integrates several technologies as real-time graphics, body tracking devices, visual displays, and other sensory input devices [2].

VR is composed not only by technology in the head-mounted display, but in the treatment of all the parts that make it a complete experience. Objects need to be built as realistic as possible: they must be fully 3D (stereo), and the lighting and the performance must be good enough (current standards show between 75 and 120 frames per second), in order to create an immersive experience [3].

VR is intended to alter the perception of the real world, creating sensations and situations that put the user in an unexpected place, while in the comfort and safety of his home. In turn, it creates a very immersive experience, and this experience can be as real as the existing world. As some studies point, this feeling leads to the patient actually experiencing the same sensations as if it was being applied directly into their bodies instead of a projected image (contrary to what happens in TV).

Researchers also need to take into account that VR can be presented using "desktop" VR [4], but the feeling of being there is always more intense when using a HMD as the Oculus Rift we used in this project. Besides, the use of visual and auditory feedback provokes even more immersion.

2.2 Phobia Treatment

There are different ways to treat phobias. The systemic desensitization, based on the principle of cognitive psychology, tells us that the body can not be in both an anxious state and a relaxed state.

The anxious state is induced in patients when a situation related to the phobia (or the phobia itself) happens. Thus the way to reduce the anxiety is to teach the patient how to relax his or her body. Zettle [5] proposes a way of administering a systemic desensitization [6, 7], where patients first learn about muscle relaxation, and then they learn relaxation by recall and cued relaxation. Following this technique the patients can create a hierarchy list with items that represent situations that produce them anxiety.

The feeling of anxiety uses a 1–10 scale to measure how much the situation or stimulus is affecting the patient. This is scaled relative anxiety. After the patients have entered in a relaxed state, and they have created the hierarchy, the final stage asks them to apply the relaxation techniques they have been taught while imagining the situations going from the one that causes the least anxiety to the one that produces the most anxiety. It is important to highlight here that patients don't go up the hierarchy unless they feel relaxed or comfortable with the current item. Another detail is that patients need to make sure they have properly succeeded on a previous level. So, it doesn't mean that the patients need to go through the whole hierarchy every time; instead they need to pass the last item in the hierarchy [8].

Acceptance and Commitment Therapy (ACT) is another technique to handle anxiety and phobias. It is a behavioral technique where the goal is to promote psychological acceptance and discourage experiential avoidance, thus it allows the

patient to commit to actions that enable her/him to reach the wanted goals (overcoming the phobia for example). But the ACT doesn't demonstrate improving results when compared with Systematic Desensitization, and it requires that the patient is actively trying to achieve the goal with an unclear structure [5].

Eye Movement Desensitization and Reprocessing [9], is a technique where the stimulus that cause anxiety or fear, is supposed to be "trapped" in the brain, associated to images of the disturbing or distressing events. When patients recall these memories the therapist can "redirect" the eye movements using a light or music. The theory then states that the brain will reprocess the thought but without the associated negativity or anxiety.

Another phobia treatment is the shock technique [10], where the patient has to face the source of anxiety, either in picture or the real object. This technique however, has several caveats since it has a psychological impact on the patients. Due to the impact that it causes when applied, is not recommended and it is not used by therapists. Another field where phobia treatment has been investigated is the pharmacological field. However, the results have been unsatisfactory since there is no medicine to treat specific phobias. Most of the drugs that are used in conjunction with therapy are benzodiazepines and beta-blockers, but the results of using them with other techniques actually decrease the effectiveness of therapy with no permanent changes in the patient's biology.

2.3 Oculus Rift

The oculus rift is the result of a Kickstarter campaign, from 2012, to create an affordable HMD for VR. This device allows most people to experience VR from the comfort of their home. It also allows creators and programmers to have access to HD graphics on a HMD with a larger field of view [1]. The company has released 2 different configurations: Development Kit 1, and Development Kit 2. The main difference is the image resolution. Oculus is expected to release their consumer version this year for $599 (Fig. 1).

2.4 Virtual Reality Applied to Phobia Treatment

As a reappearing technology, VR has had its fair share of implementation in the past, but some of these implementations suffer from the limitations found during those times. Previous authors have made several developments to deal with different phobias, for example, a system that utilizes low poly textures and graphics, with a low resolution HMD to treat claustrophobia [11]. It does, however, improve in some ways the work presented by Bruce and Regenbrecht [11], where the visual quality of the system and the cost (over $5000 per installation) made it very hard to justify. But they did take into account things that weren't by the previous studies,

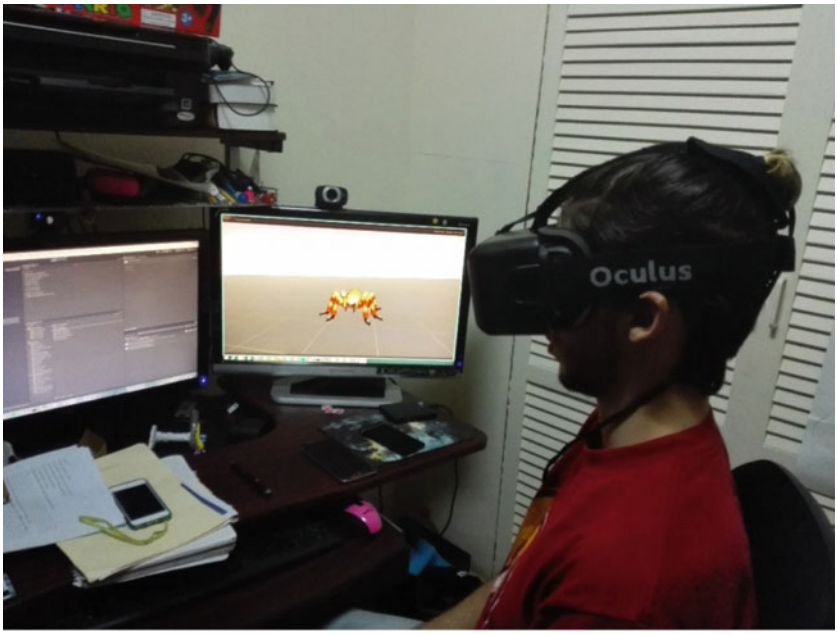

Fig. 1 Illustrative image of one of the authors using the prototype, the same image (*spider*) in the screen is visualized in 3D in the Oculus Rift DK2

for example making sure that the environments present to treat the acrophobia, where real enough that they could increase the feeling of being of the patients.

Perez et al. went for a mix of virtual reality and augmented reality to serve as treatment for Acrophobia (fear of heights). On their system they use different markers in a room to create different objects and the sensation of height. But this approach needs that therapist's office to have a lot of room, and then the illumination must also help the visualization of the markers that create the phobia scenarios [3].

Some authors defend the use of VR as a viable technique, even combining with other measurement instruments [12]. For example, on their study, Wiederhold et al. combined the use of VR with biofeedback instruments to compare if the amount of subjective anxiety that the patients where reporting when using the HMD was properly mapped to the amount the instruments where showing when treating fear of flying.

In another study, authors were trying to remap the real world to a VR HMD, creating a hybrid between (Virtual Reality and Augmented Reality). Their work (a smaller scale version of the one presented in [3]) was used to treat fear of small animals (insects for example), and it tries to solve a problem present in VR, which is the feeling of presence where limbs are not there [13].

The amount of phobias that can be treated using VR is evidenced by the work of North et al. [14], where HMD has been used in tests with patients with agoraphobia, acrophobia and even fear of flying.

However, most of these projects do not take into account the therapist's input, or the importance of the systematic desensitization relaxation section. Our system improves on the feeling of being by using high resolution images and by creating scenarios or environments that push forward the idea of being there. For example we added a body sitting down, so patients can be comfortable and can also look at their own body. Our system also works on the importance of going through the relaxation section. Instead of trying to make an outside section and trying to recreate the traumatic or anxiety triggering scenarios, we guide the patient through the relaxation exercises. This allow patients to have a module that guides their sessions to a safety point and even provide a selection of music, so they can chose things that help them to improve their relaxed state.

3 Prototype Implementation

In order to plan our prototype, we needed to set up a design session with one of the experts, a cognitive psychology therapist that could lead us about the systematic desensitization process. The first step was the definition of the stages the tool should go through. It should have a menu where the patient can select the actions s/he wants to take.

On the first menu, there are 3 options that can be chosen (see Fig. 2). The first option is the relaxing experience setting. Each of the settings is designed to play relaxing/meditation music, ambience sound and trying to guide the patient to reach a relaxed state. We proposed 3 initial settings: a beach, a forest, and a mountain. Each one has its own ambience sound and its own music. Besides to improve the immersion of the patients, each one of these scenarios has a "body", so the player can look at it and doesn't get disoriented.

On the main menu second option, a hierarchical list is presented with 15 different situations that can increase the anxiety up to 10. From this standard list the patient creates her/his own list. This is one of our design decisions for trying to make the tool more useful. The system has a set of scenes or stimuli and allows the patient to arrange it. This gives us the chance to reuse most of the scenes instead of creating specific scenes for each patient. Once the hierarchical list is done, we can continue with the next step.

Finally, the option where the main method of the therapy is applied starts in a menu where the patient selects the last events or scenes that s/he passed (either at home or at the therapist's office), or the events that s/he was able to keep the anxiety levels controlled. After this, the patient is taken to this scene and it is asked to try to maintain calm in front of the anxiety triggering stimuli. Again, being guided by the therapist (or a prerecorded guide in case of a training session at home), the patient tries to keep their anxiety levels down. Once the therapist has assessed that the

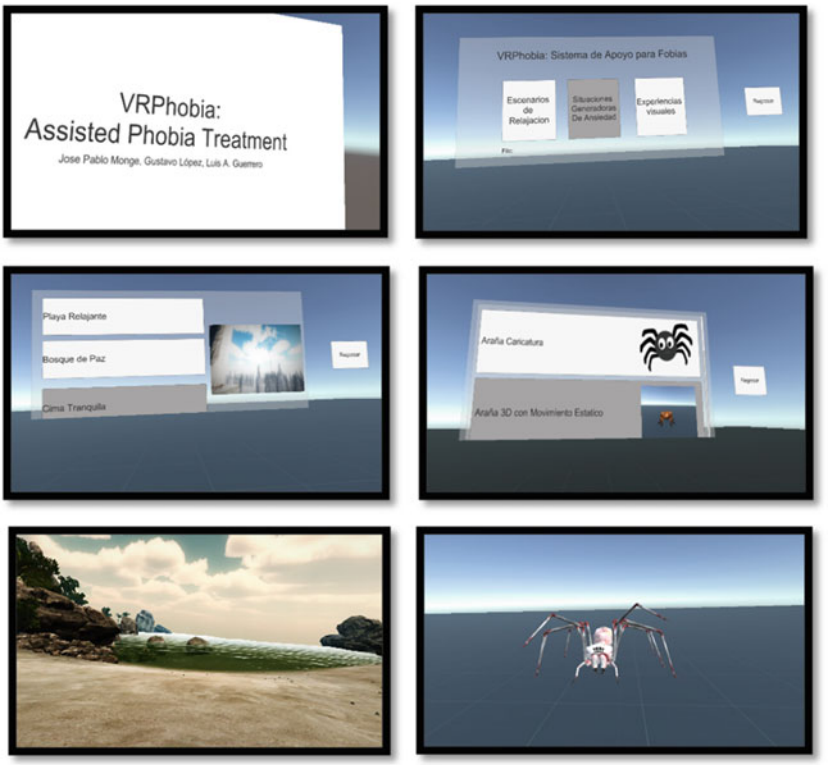

Fig. 2 VRPhobia prototype screenshots, *top left* shows the title and project collaborators. *Top right* presents the main menu from where the software is navigated. *Middle left* is the relaxing environments menu, *middle right* is the hierarchy of anxiety triggering situations. *Bottom left* and *bottom right* are the actual situations (relaxation and anxiety triggering respectively)

patient has rightfully gone through the situation or scene with no major issues, the next scene or situation can be introduced.

One situation that needs to be taken into account is that the patient may not always be in the same physical state. Lots of factors can weight in the anxiety management of the patient and one situation that was easily conquered previously might trigger an anxiety episode. We have made 2 adjustments to make the system safer for the patient and more effective.

First, the therapist must assess the previous section always and if the patient is going through one the scenes or situations, we have a "panic button". The panic button can take the patient, at any moment during all the exercise, to her/his "safe place". This safe place will be the last place where the relaxing section of the therapy occurred.

The second adjustment is: if the patient is having trouble moving forward with the scenes, it means that s/he didn't make the hierarchy assessment properly, so we gives always the chance for the patients to readjust their "subjective" anxiety to

each of the sections we have created. This in turn, will allow us to find out a "basic" hierarchy that could be suggested to patients and then improve the time it takes them to start with the therapy exercises.

4 Evaluation

Using a set of mock ups, we proceeded to meet with the experts to show them the screens that would map the different sections of the prototype that we planned with the therapist.

The expert group we used to evaluate our prototype design was made up by one cognitive therapist and four advanced students (5th year students) from the Psychology School at Universidad de Costa Rica. All of the experts have an understanding of the systematic desensitization technique and they all agreed to be part of the research in order to help improve the prototype.

Each one of the experts was shown the prototype images in the order that we defined the system flow, afterwards they were allowed to ask questions and inspect each of the screens they saw previously as many times as they had wished.

Once they had no more questions and they were done with the prototype screens, we applied the following questionnaire:

- Do you think the technique is properly applied?
- Do you like the idea of using VR assisted tools for therapy?
- Would you use the VR tool for therapy, or at least recommend it?
- Do you think it improves the way the therapy is currently applied?
- Can the system be used in the office next to the therapist, or must be used at home (training)?
- Do you think all phobias can be treated using this system? If not, which ones do you think can, or cannot be treated with this system? Why?
- Do you have any comments about the tool?

We succeeded in getting at least 5 experts involved in the evaluation process. After presenting the concept images, all 5 agree that the systematic desensitization technique is being applied and mapped properly in the system. One of them however brings to mind that the tone of the voice of the therapist (or the recording), brightness of the image and even the pitch of the sounds should also be controlled to make sure that the relaxation stage is indeed being improved instead of just barged in.

In the second question, 4 of the experts agreeing that therapy need to be updated. They said it needs technology to be better, especially making the relaxation section improved. One of the experts however doesn't believe that VR is going to have a meaningful impact in any near future.

The third question divided our experts. Three of them would use the system as a support tool to enhance therapy (one of them does an annotation regarding having

to be prepared properly before trying to use the tool). Two of the experts wouldn't use the system for therapy, nor would they recommend it.

Question number 4 came with 3 positive results with the experts stating that the tool updates the technique and improves it, either by making it more effective and less expensive, putting it in reach for therapists and patients alike. Two of the experts don't believe the tool improves the technique. However, they see potential to make the therapy have different results than when used only with imagination.

Regarding the place of use of the system, most of the experts agree that the system might be better suited for use in the therapist's office. The reasons go from the fact that patients may not have enough space to take advantage of the tool, to the patient not being able to handle an anxiety attack provoked by the situations or scenes presented by the system. One of the experts does believe that the patient can profit from having the system home, but it must be trained to do so beforehand.

The sixth question posed an interesting find, since two of the experts believe that most or all phobias could be treated in conjunction with the system. Another answer presents the fact that very specific phobias are difficult to treat with a generalized system like ours (for example, fear of yellow colored birds). Another one of the experts doesn't believe that all situations or anxiety causing stimuli could be approached in the way the system presents it. Finally, one answer states that the physical objects (animals, objects, situations) can be properly treated using the proposed system, but social anxiety or imaginary anxiety causing situations are more difficult to model, thus making it harder to treat using our system.

Among the comments we found that most of the experts enjoy the fact of including technology into the therapy technique. The feel of being inside the virtual worlds improves the chances of the therapy getting enhanced, this was also an important point for one the experts. Overall they found the idea and the flow of the prototype very interesting and they are looking forward to seeing more.

5 Discussion

VRPhobia is a great opportunity to attack an area which has not been enough attention. From our survey to the experts we state they appreciate the inclusion of technology into their field. Most of them were young professionals that have grown with technology so they are comfortable having technological tools.

The results of our validation indicate that the system fulfills its purpose of becoming a tool that implements parts of the phobias therapy, enhancing the work of the therapist, while allowing the patient to be able to train and keep working on the therapy from the comfort of their homes. Some details that were not taken into account showed up after analyzing the system with the experts. For example, the reason some of the patients need therapy is because they can't manage their anxiety, so we can't really just thrown them into the HMD straight away, because the fact that they are in therapy already might creates some anxiety. They need to be eased in the tool so we are sure that the anxiety that is being perceived is only coming

from the phobia and not from the situation surrounding the patient and the newly introduced tool.

The evaluation also presents us with a new limitation that we had not previously taken into account, which differentiating the phobias by their cause, since some of them can be related to real life objects and some of them can be related to social interactions, which are harder to model in VR than the former.

6 Conclusion and Future Work

We presented a prototype of VR for enhancing phobias therapy. This system diminishes costs, improves patient experience, and has a big potential of improving the therapy sessions. Besides, it allows the therapists to update their tools and techniques with the aid of technology. From our findings we can further improve our system to make it viable to be tested in actual patients.

The next step will be to conduct a pilot test with final users, using a case study for patients suffering from arachnophobia. These studies are to be conducted with 1st year students from the Psychology School at Universidad de Costa Rica. We also want to make the system more portable, so a version that uses mobile VR (instead of using a PC core for Virtual Reality) will be developed soon. We also plan to implement biofeedback into the system so instead of having to use subjective anxiety. The patients can connect to the system and then it will be controlled for them, allowing them to concentrate on how they are feeling instead of controlling the system.

Our prototype was evaluated by 5 experts in cognitive therapy and the assessment was positive. The feedback obtain during the evaluation session will be useful to improve our system. Moreover, once the final prototype is developed usability testing must be performed to assess its viability with final users.

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Intelligent Nano-Worlds: A New ICT Based Tool for Mental Health Care of Children Living Under Social Vulnerability

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Abstract The latest estimates of UNICEF and United Nations present a complex picture related with children living under social vulnerability. Approximately, one-half of the estimated 57.4 million people displaced by war around the world are children, most of whom have been separated from their families. In the same line, many countries (especially the developing ones) present a lack of specialized professionals and resources to provide mental care and rehabilitation services. Thus, children who are under institutional care, frequently present some kind of resistance to the psychological intervention. On those grounds, this paper presents a new proposal with the aim of providing support for infant psychotherapy (diagnosis and intervention) focused on this vulnerable population. Our approach relies on the new

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idea of incorporating the "interactive and ludic nano-worlds" (that are special sceneries inside a micro-world focused on the patient's profile). Likewise, the developed system uses intelligent ICT tools, and an expert system to generate automatically intervention guidelines. This proposal has been tested with 124 children and has reached encouraging results.

Keywords Interactive ludic Micro-worlds · Children under risk · Psychological diagnosis and intervention · Expert systems

1 Introduction

Global statistics estimate prevalence of 153 million children who have lost one or both parents [1]. According to The United Nations, about 8 million children are living under institutional care around the world [2]. Multiple factors contribute to this issue, as children who are under foster care have been separated from their parents, temporarily or permanently, due to orphan hood, child abuse or family neglect, domestic violence, war conflicts and natural disasters [3].

Foster care institutions' aim is to restitute the child's rights, which have been infringed. For this, they count with specialized staff, which attends to children in the most important areas for their integral development, in which psychological attention is included. Nevertheless, in this kind of institutions there might be some inconveniences related to a lack of resources or professionals, which causes a difficult attention. In addition, characteristics of the abused child interfere with the psychological work, due to resistance they might experience towards therapy or the therapist.

In this scenario, it is necessary to implement psychological tools to let professionals get closer to the child whose personal limits has been violated, in a respectful and non-invasive manner. An automatized and ludic tool would facilitate adaptation of the psychotherapy to own child's language, game activities, [4] and at the same time, it would satisfy the actual generational demands.

Thus, tools of this kind would optimize clinical work, by not only enhancing the rapport, but also contrasting subjective view the professional that may have with standardized data that could serve as a reference of "normality" (understanding this term as common behaviour according to a determined developmental age). Furthermore, when including an automatized instrument that the child is able to use by him/herself, the psychologist can temporarily take distance from the patient during the session to observe his/her behaviour towards tasks that he/she might resolve. Finally, organization and following of the patient's files are factors, which may represent drawbacks for the clinician within praxis, especially when they are treating with children. Computerized instruments are likely to help the professional to overcome these situations.

On those grounds, this research presents a novel approach for infant psychodiagnosis and intervention, based on nano-worlds, virtual spaces that contain various

activities to develop specific skills in a child. These spaces and activities are set over data obtained from an initial diagnosis stage, which consists in the creation of a personal avatar, and its corresponding family, using pre-designed graphics to evaluate the child's emotional state.

The rest of the paper is organized as follows. Some relevant researches related with psychological diagnostic and intervention of children under risk situations are described in Sect. 2. The general architecture of the system as well as the theoretical psychological basis are presented in Sect. 3. Section 4 describes the pilot experiment carried out with the aim of analyzing real feasibility of the system. Finally, Sect. 5 presents some ideas for discussion and future work.

2 Related Work

Various psychotherapeutic tools consisting on serious games have been implemented in clinical practice to support treatment of different disorders in children and adolescents, such as Posttraumatic Stress Disorders [5] or complicated situations like parents' divorce (ZIPLAND). These instruments have the enormous contribution of enhancing children's motivation to psychotherapy, help the professional to guide the development of sessions and facilitate understanding of important psychotherapy concepts [4].

Treasure Hunt, [4] is a serious game based on the principle of cognitive-behavioral therapy for treatment of various disorders in children going from eight to twelve years old. Initially, its main purpose was to be a channel through which a therapist could send electronic homework assignments to a child, so he/she could rehearse basic psychoeducational information given during the session. However, researchers have found recently that therapists are including it within psychotherapeutic session with enormous success. The game includes cognitive-behavioral therapy concepts, such as influence of thoughts on feelings and actions, and distinction between positive and negative thoughts, both important in treatment of internalizing and externalizing disorders.

The story takes place in a ship commanded by Captain Jones and his mates, a cat named Felix and a parrot, Polly. The game counts with six levels, in which several tasks are presented to the child. Every task is addressed to detect automatic thoughts that affect child's emotions and behavior. Therapists as well as children have shown positive reactions to the game, because of its attractiveness and useful contribution as a therapeutic session organizer and as a tool to explain cognitive behavioral treatment concepts.

SAGE—Storytelling Agent Generation Environment [6] is a digital interactive environment designed for children to create their own storytellers, and interact with them by telling and listening to stories. The storyteller is programmable by child, and consists in a stuffed animal, which presents comforting tales in response to child's narration of his/her own experiences. In addition, user is capable to include

his/her stories to a repertory of tales that wise storyteller may present to a different child, so he/she can interact with them.

The system "enables exploration of one's inner world and requires flexing one's language skills". Results showed that children could show their own fears, feelings, necessities and interests through their stories, and overcome breakdowns in conversational interaction by designing their storytelling characters.

3 Intelligent Nano-Worlds: A New Approach for Psychological Diagnosis and Intervention with Children Under Social Vulnerability

3.1 Theoretical Psychological Basis: The Draw-A Person Test and the Draw-A-Family Test

The micro-worlds system has its basis on some psychological concepts, used very frequently in children's therapy. The main construct is *projection*, which is attribution of self-perceived characteristics to external realities [7]. This mechanism appears in subject's daily life, including decision making, which is the basic mode of the application [8].

To build the diagnosis phase, we took two projective graphical tests: the Draw-A-Person test (DAP) and the Draw-A-Family test (DAF). These two classical instruments are used within the psychotherapy to evaluate child's emotional traits. The first one gives to the clinician information about child's self-image, through the analysis of human figure traits, using different criteria, such as size, space disposition or inclusion of details [9]. The second test evaluates emotional relationships within the child's family, by examining distances among represented characters, space disposition and different elements included in the drawing [10].

Play therapy foundations were also considered to create different virtual games, which constitute the intervention phase. This psychology orientation proposes that child will communicate in a better way through a play activity, due to difficulties to verbalize his/her own conflicts [11].

3.2 Psychological Profiles

On these theoretical foundations, four psychological profiles have been proposed as guidelines to detect child's affective and behavioural traits, considering criteria used in traditional paper and pencil test. Different DAP criteria were grouped according to their similarities to conform patterns that describe a child's behavior. Three of them show different tendencies to certain behaviour, which are frequent in infant population and are: aggressiveness, inhibition and deficits in social skills. Furthermore, a

fourth profile has been set to represent normality, referring to a lack of emotional conflicts. On those lines, by selecting certain characteristics in avatar's elements (parts of the human body), child may project psychological traits such as reticence, social anxiety, anger, among others. These profiles or patterns are determined automatically by the expert system implemented in the tool.

3.3 General System Design

The proposed system consists of three main layers that are aimed to support the different activities that must be carried out during the psychological diagnosis and intervention of children under social risk (Fig. 1). Below are described the most important services and elements that make up the system.

- In user interface layer are provided services and applications that allow psychologists conducting the initial screening/diagnosis, and intervention with each patient according to his/her psychological profile. With this aim, this layer incorporates several applications to present intervention plans generated by the expert system, as well as generating reports, or providing remote support for family/caregivers. These activities can be performed using mobile gadgets (tablets and smartphones), desktop computers or through an intelligent interactive multi-touch desktop. The last tool is especially useful for those activities in which mobile gadgets present some limitations (collaborative work, exercises that require fine motor skills, among others).
- Information collected through user's layer device feeds the **expert system** and includes the following features: **patient's personal information** (age, sex, and some psychological features described in the next section), and results obtained by the patient in the DAP and DAF tests. Based on these data, the expert system is able to perform the following processes: (a) **to learn and analyze the patient's psychological profile** with the aim of providing an adequate set of **intervention guidelines**; (b) **to build scripts for a microworld** according to the patient's profile and his/her psychological diagnosis; and (c) **to generate automatically academic contents** to teaching different concepts to patients (adequate behavior, self-care, etc.). Likewise, the system contains an **avatar and characters** to guide patients across intervention process. Nano-worlds are small games, and/or activities that can be adjusted to carry out intervention guidelines, according to patient's psychological profile.
  Each micro-world and its corresponding nano-worlds are modified (in real time), according to patient's profile and also the manner how child is introduced to these worlds, which is presented as an animation containing situations related to some characteristics that patient needs to develop. For example, if a patient obtains a profile characterized by inhibition, the micro-world will adapt to present a special introduction in which the avatar that represents the patient appears from a crowded place.

Nano-worlds are distributed within different areas of a micro-world and according psychological meaning that they may have. In this manner, in the micro-world House, the child's bedroom, which contains personal objects, is associated to a self-image that will be the scenario to work with an Inhibition profile.

As a micro-world contains various nano-worlds per profile, when child has completed the activities corresponding to his/her profile, he/she passes to next micro-world (a different space that is common to child's daily life), being situated in the nano-worlds corresponding to his/her profile again. This transition is proposed as an increasing level system, which can enhance development of assertive responses, providing continuity to psychogical work.

- The **knowledge layer** stores all information that is used in the system. The **clinical repository** contains personal data of the patient, and his/her psychological profile, while activities carried out during psychological diagnostic and intervention are stored on a specific database. Likewise, this layer allows to store **intervention guidelines** generated by the expert system for each patient, and add other **projective graphic** tests, **vocabularies** (like DSM-5), and observations made by psychologist when patient executes the proposed nano-worlds or games freely during psychological session (psych diagnosis through games).

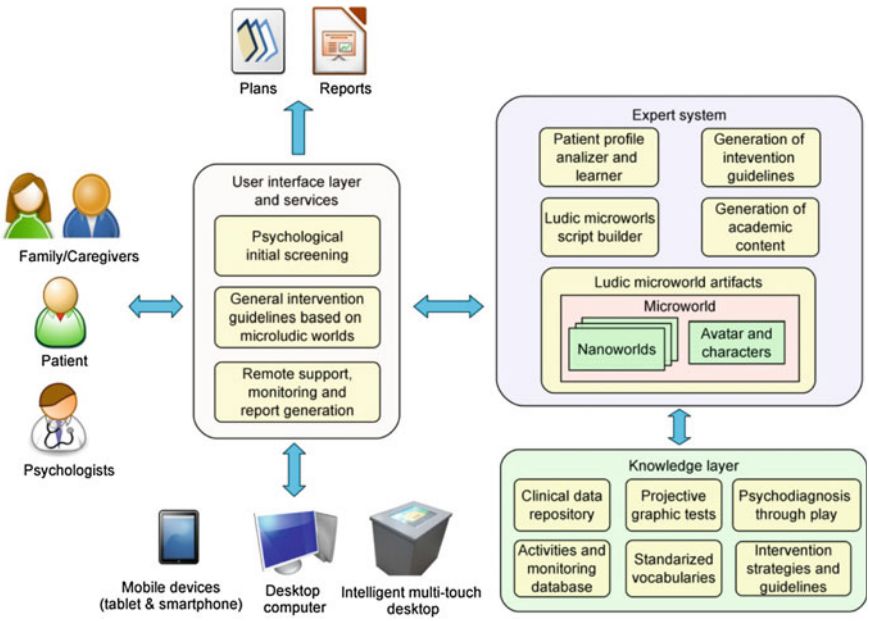

Fig. 1 General architecture and main components of the proposed approach

3.4 Diagnosis and Intervention Process

Initial diagnostic phase was built over two tests mentioned above, and it consists in creation of a personal avatar and a family, by selecting different predesigned graphics. Meanwhile, intervention phase focuses on developing of some skills in which child may present difficulties. This process would be done by using virtual games, which present different tasks aimed to stimulate assertive responses in child.

Once child has created his/her personal avatar and family, the system automatically throws a psychological profile from which a specific intervention plan is proposed. This plan relies on various micro-worlds, which consist on a simulation of real environments, common to the subject. Some nano-worlds have been included in each micro-world, as reduced virtual spaces, which focus on specific skills that patient needs to develop. This way, a general scenario represented in a micro-world is fractioned so behavior expected within it can also be divided into smaller steps or reactions.

Nano-worlds are distributed in different areas of the general scenario, and they have continuity through all the presented micro-worlds. In other words, one child will work on the same skills through various micro-worlds presented, but in different and increasing levels. With all the information obtained in the diagnosis phase and during the intervention one through nano-worlds, psychologist can complement work made in order to support child's recovery.

4 Intelligent Nano-Worlds: A New Approach for Psychological Diagnosis and Intervention with Children Under Social Vulnerability

With the aim of analyzing whether the developed approach (mobile application and expert system) can provide an adequate set of guidelines of patient's profile, we have conducted a pilot experiment with 124 children (93 assisting to regular elementary schools and 31 living in foster care institutions). Regular school students were selected through some criteria such as not having suffered any kind of violence or presented significant emotional conflicts to mark a difference from vulnerable children's group. For this initial stage, we have trained and tested the expert system to determine the presumptive automatically psychological profile of each patient.

In this line, a team of three expert psychologists have conducted two evaluation processes in all children, one using the traditional version of the DAP test (using pencil and paper), and another one using the mobile application (Fig. 2). For the second evaluation, the expert team has asked each child to create an avatar combining the different parts of body (head, neck, torso, hands, arms, eyes, mouth, ears, legs, feet, and clothes). For each body part of the avatar, the mobile application presents several alternatives and each one has a psychological significance

Fig. 2 The *left side* shows a screen capture of some body parts that can be used by children during the avatar's creation. In the *right side* it is presented a picture of two children playing a "drawing game" with the multi-touch desktop

(for example, small feet represent inferiority feelings). Currently, the mobile application and expert system are able to determine psychological traits that belong to three profiles, mentioned above: Inhibition (23 features), Aggressiveness (20 features), Social Skills Difficulties (19), and Non Significance/Normal (25 features).

Currently, the expert system implements two algorithms to learn answers provided through mobile application: an Artificial Neural Network (ANN), and Random Forest (RF). Configuration and results achieved by each algorithm are described below.

- ANN with two hidden layers of 11 and 6 neurons, respectively. The sample was selected as follows: 70 % of children of schools and 70 % of children in foster care institutions for training, and the rest for testing the system. The accuracy reached with this algorithm was 80 %.
- RF: the sample was selected in the same way as in the previous case. The accuracy reached with this algorithm was 60 %.

Finally, we have performed an analysis of "means" for each profile. This data refer to the average number of items selected by the sample per profile, in both applications (informatics version and the original tests). As is shown in the Fig. 3, in the Inhibition profile, we appreciate similarities of data distribution between both versions, as well as in the Aggressiveness profile, which curves are very close. On the other hand, this tendency differs for the Social Skills and the Non significance profiles, which means they are separated by a higher distance. These results suggest

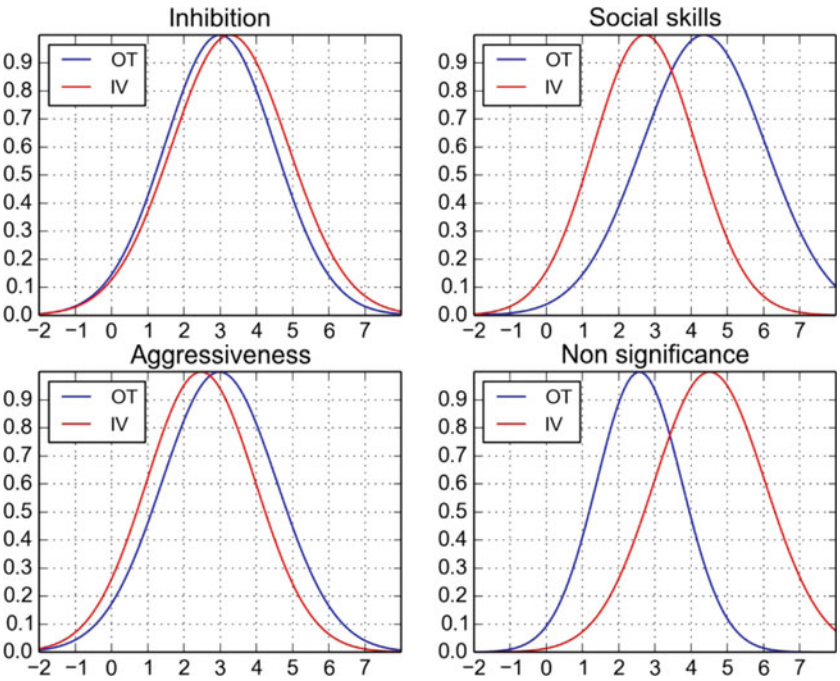

Fig. 3 A comparison of means in every psychological profile. Each graphic shows *curves* for each profile, in both versions: the original paper and pencil test (OT) and the informatics version (IV)

that the informatics system works very similarly to the original paper and pencil test in relation to the Aggressive and the Inhibition profiles. Nevertheless, the Social Skills and the Non significance profiles may be theoretically reviewed.

5 Conclusions and Future Work

The present research showed that the micro-worlds system enhances the therapeutic relationship with children under social vulnerability, because it reduces some resistance that kids may have towards mental health professionals. Data obtained in relation to profiles, which correspond to creation of the personal Avatar, are also encouraging, as they are similar to the original paper and pencil test.

The creation of the family showed similarity as well, as children were able to project their ideas about their own families. This version of family representation is able to measure differences between samples within the present research (regular students and children under foster care), which have diverse realities related to concept of family.

The use of pre-designed images to create figures that child is generally asked to create with his own hand, allows him/her to express feelings and desires that find their limits in developing abilities of graphism. In this sense, interpretation of child's representation can focus on emotional aspects, which in the traditional paper and pencil tests are combined with those aspects of motricity.

As lines of future work, we propose the following ones:

- To design ontologies to represent inherent relations of psychological traits, avatar images, and profiles.
- Analyze the real feasibility of using other technologies as robotic assistants, or multisensory environments to motivate children to participate on psychological diagnosis and intervention.
- To design new interaction activities and exercises in which can interact two or more children.

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Part VIII
Healthcare Communications and Logistics

Application of the Delphi Method in the Development of a Triage Method for Vulnerable People in Disaster

Taro Kanno, Chie Ishida, Yuko Kubo, Masako Saito, Mariko Ohara, Kayoko Kawahara, Takuya Yamamto and Kazuo Furuta

Abstract This paper introduces a new triage simulation method for use in the design phase of disaster triage method for vulnerable people. The proposed method is an online scenario-based triage simulation incorporates the Delphi method. The method was assessed to determine its effectiveness for obtaining knowledge to improve the design of a new triage method. The result showed that the method is effective for identifying the appropriate triage, consideration points, and the cases for which the appropriate triage is difficult to determine.

Keywords Evacuation shelter · Triage · Vulnerable people · Delphi method

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1 Introduction

One of the biggest concerns in disaster medicine and nursing is the lack of an established method for triage of vulnerable people such as babies, the elderly, bedridden people, and people with severe chronic diseases. In extreme disaster such as the Great East Japan Earthquake in 2011 and the Great Hanshin-Awaji Earthquake in 1995, medical resources and efforts are usually allotted based on the criteria to save the lives of people with serious injuries, resulting in less attention being paid to vulnerable people. Among these people, however, some would be at the risk of death under the poor living conditions, such as evacuation shelters, although they are categorized "green" according to the typical emergency medical triage. That is why a different type of triage is necessary for vulnerable people.

A triage method for vulnerable people in disaster is being developed in our research project [1–3] and only a prototype triage method consisting of four categories has been proposed thus far. One of the problems in the development of the new triage method is the difficulty of predicting and determining the appropriate triage for various types of vulnerable people with different physical, mental, and cognitive problems. In the early stage of the project, we tried to develop a triage method based mainly on trial and error through participatory simulations and workshops. It requires, however, much time and effort, and is not so efficient for obtaining reliable and important knowledge for improving the triage design [3]. In order to make the triage design process more efficient and effective, we are currently applying the on-line Delphi method in the participatory triage simulation. This paper introduces and discusses the first result obtained from the Delphi method-based simulations.

The next section explains the proposed triage category that has been developed in the project thus far. In Sect. 3, details of the triage simulation that incorporates the Delphi method is introduced. In Sect. 4, the result of the simulation and discussion are presented, followed by the conclusion in Sect. 5.

2 A Proposed Triage Method

A triage method for vulnerable people in disaster is currently being developed. This triage method is assumed to be used at an evacuation shelter after major disasters. The current version of the proposed triage has four categories corresponding to the place where the vulnerable person should be transferred from or moved in the shelter. The summary of the triage category is shown in Table 1.

The first category is for the people who should be sent to hospitals, such as severely wounded people who fall under the red and yellow categories of the START method [4], patients undergoing dialysis, people with high fever, patients receiving home oxygen therapy (HOT) who have a little oxygen left in the bottle, and so on.

Table 1 Triage categories and example cases

Category	Place to transfer or move	Examples
I	Hospital	severely injured persons, patients undergoing dialysis, HOT patients with a little oxygen, persons with high fever, etc.
II	Emergency nursing care center	total assistance, high medical or nursing care needs, etc.
III	Small isolated room	persons who require special attention required from caregivers, persons with mental or cognitive disorder, etc.
IV	Gymnastic hall, or large room	others, healthy people

The second category is for people who should be transferred to "*Fukushi-Hinanjyo*", or emergency nursing care centers. Emergency nursing care centers are intended for people who need relatively intensive but not urgent medical or nursing care. In Japan, installation of these centers is required for each municipal government, according to the national and local disaster preparedness plans. Nursing homes and facilities for disabled people usually become these centers in disasters. People who are classified under these two categories are not suitable to stay at an evacuation shelter for a long time because of the high probability that their lives will be in danger under the poor living conditions in the shelter.

The third category is for people who need special attention from caregivers, such as people with mental or cognitive disorder, babies and small children, people with low performance in activities of daily living (ADL) but have no attendants, and so on. They should be assigned a small and separate room in evacuation shelters.

The last category is for the rest of the persons who do not fall under the aforementioned categories. They are assigned a large room or the gymnastic hall to be shared with many other people. The category is ready for implementation, and its applicability was partly validated through the past simulation thus far [3]. It seems a good approach to design a category from the view point of response options for vulnerable people. However, the criteria for the triage are still tentative, and providing clear and concrete criteria easily applicable to any vulnerable people under any situations seems difficult.

3 Online Triage Simulation with Delphi Method

In this section, the triage simulation that incorporates the Delphi method is introduced. After a brief explanation about the scenario-based triage simulation and Delphi method, the details of the proposed method, which is the on-line triage simulation using the Delphi method, is explained.

3.1 Scenario-Based Triage Simulation

A scenario based participatory simulation of triage for vulnerable people has been adopted so far. In the simulation, after the instruction on a triage method, text descriptions of some vulnerable people which include demographic information, physical conditions, observable symptom and so on are presented to each participant, and then the participant is asked to triage the vulnerable people based on the given information by using the triage categories and criteria such as those listed in Table 1. After the simulation, they are asked to discuss each result with other participants and to answer the questionnaire to obtain general comments on the triage method. Important knowledge to improve the design was obtained from past simulations, such as triage categories and criteria. However, these simulations were not so efficient, as in some cases, the discussion would be inconclusive and the issue remained unclarified. One problem is that not all participants could present their opinions because of the limited time and the lack of interpersonal communication skills. In addition, such discussions require much time and effort to record and analyze.

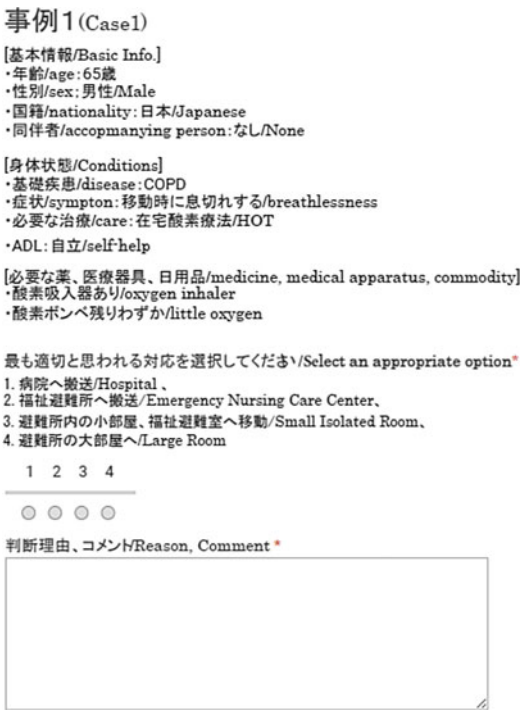
3.2 The Delphi Method

The Delphi method is a structured group communication technique originally developed as a forecasting method [5], such as for forecasting the impact of the implementation of a new technology. The method entails several participants who anonymously answer questionnaires and subsequently receive feedback regarding the summary of the answers, which is repeated in two or more rounds for each question. After each round, participants are encouraged to revise their previous answers in consideration of the feedback of the previous round. This process is believed to be useful in efficiently attaining convergence of opinions and to clarify the key issues for decision making.

3.3 Online Triage Simulation Using the Delphi Method

The method of incorporating the Delphi method in scenario-based triage simulation is easy and simple, that is, conducting a triage simulation along with the process of the Delphi method. The main modifications from the past simulations are listed as follows:

- The simulation is conducted under the condition of anonymity. Online questionnaires are adopted for maintaining anonymity, and efficient recording and analysis. The online questionnaires are developed by using Google Form. Figure 1 shows an example of a triage question presented to participants.


事例1(Case1)

[基本情報/Basic Info.]
・年齢/age:65歳
・性別/sex:男性/Male
・国籍/nationality:日本/Japanese
・同伴者/accopmanying person:なし/None

[身体状態/Conditions]
・基礎疾患/disease:COPD
・症状/sympton:移動時に息切れする/breathlessness
・必要な治療/care:在宅酸素療法/HOT
・ADL:自立/self-help

[必要な薬、医療器具、日用品/medicine, medical apparatus, commodity]
・酸素吸入器あり/oxygen inhaler
・酸素ボンベ残りわずか/little oxygen

最も適切と思われる対応を選択してください/Select an appropriate option*
1. 病院へ搬送/Hospital 、
2. 福祉避難所へ搬送/Emergency Nursing Care Center、
3. 避難所内の小部屋、福祉避難室へ移動/Small Isolated Room、
4. 避難所の大部屋へ/Large Room

1 2 3 4

判断理由、コメント/Reason, Comment *

Fig. 1 An example of triage question

- In answering triage question, participants are asked to write the reason for the triage as well.
- The participants answer the triage question in two or more rounds, and are allowed to revise the previous triage, with consideration of the summary of the answers from all participants.

4 Results and Discussions

Triage simulations according to the procedures explained in the previous section were conducted to determine whether the Delphi method is effective for obtaining knowledge to improve the design of the disaster triage of vulnerable people.

4.1 Setting

In the simulation, 21 professional nurses (with career length ranging from <1 year to 30 years, mean [SD] career length, 13.7 [8.0] years) participated were randomly

divided into groups A and B. Group A consisted 11 participants, and 20 vulnerable people were included in the simulation. Meanwhile, group B consisted of 10 people, and 19 other persons were included in the simulation. A web-based online questionnaire was used in all three rounds of the simulation. The triage categories and criteria explained in Sect. 2 were used for both groups. As feedback, a bar-chart showing the distribution of the answers to the triage question and a table of comments were presented in the second and third rounds. The research ethics board of the University of Tokyo approved all of the methods used in this experiment.

4.2 Convergence of Answers

Shannon's entropy defined by Eq. 1 is calculated to quantify the degree of convergence of answers. In Eq. 1, p_i is the probability with which triage category i is selected. The smaller the entropy, the bigger the convergence; and if all the triage answers are the same, the value of entropy becomes 0.

Figure 2 shows the average convergence of answers obtained from each group. The both graphs show that entropy gradually decreases as the round is advanced, which suggest that the answers are reaching an agreement on average.

Figure 3 shows one case example of a patient undergoing dialysis in which complete agreement was attained in the third round. The upper graph shows the trend of entropy and the lower graph shows the actual answer distribution in each round. From these results, we can infer that in general the Delphi method functioned as expected in terms of convergence of answers in the triage simulation.

$$\begin{aligned} \mathrm{H(P)} &= -\sum_{i=1} p_i \cdot log_2 p_i \\ \mathrm{P} &= (p_1, p_2, p_3, p_4) \end{aligned} \tag{1}$$

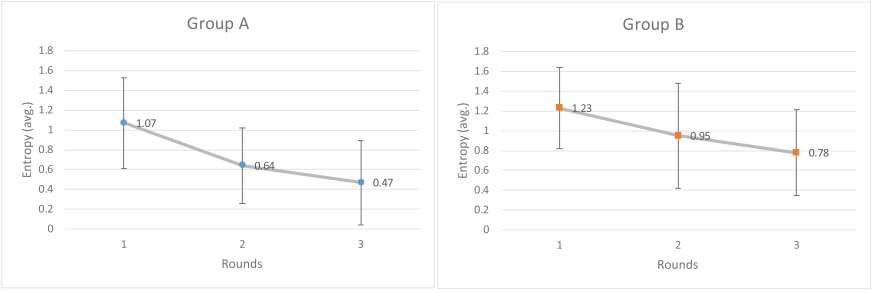


Fig. 2 Convergence of answers

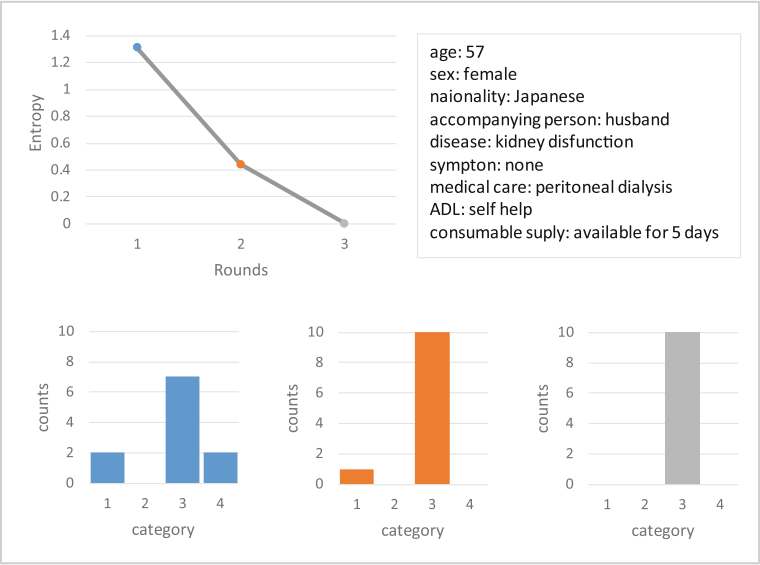


Fig. 3 A case example with complete agreement of answers

4.3 Exceptional Cases

If we look at the details of the result of each case, however, a few cases did not show the decreasing trend in entropy value. Figure 4 shows the result of an example of such cases. Note that the answers in the first round were very dispersed. Even if the answers were converged in the second round, the final answers were still split between categories 1 and 3. In the past simulations, obtaining an agreement in the triage of such vulnerable people with mental or cognitive disorder was found to be difficult because the disease presentation differs substantially between individuals and is significantly affected by the surrounding conditions. The present result is consistent with this finding. The excerpts of reasons and comments about the example case in answered to the triage question in the simulation are shown in Table 2. The number in the left column shows the selected triage category, and that in the right column describes the reason or comment for the selection. From the table, it is considered that the more concrete situation- and individual-dependent information is required for a more reliable triage. Furthermore, we observed that several common points were referred by the participants, such as the lack of medicine, husband's support, and isolation form others, which are considered important points for the appropriate triage for the example case. This indicates that the proposed method is more effective and, at least, more efficient to obtain useful knowledge for triage design that the past scenario-based participatory simulations.

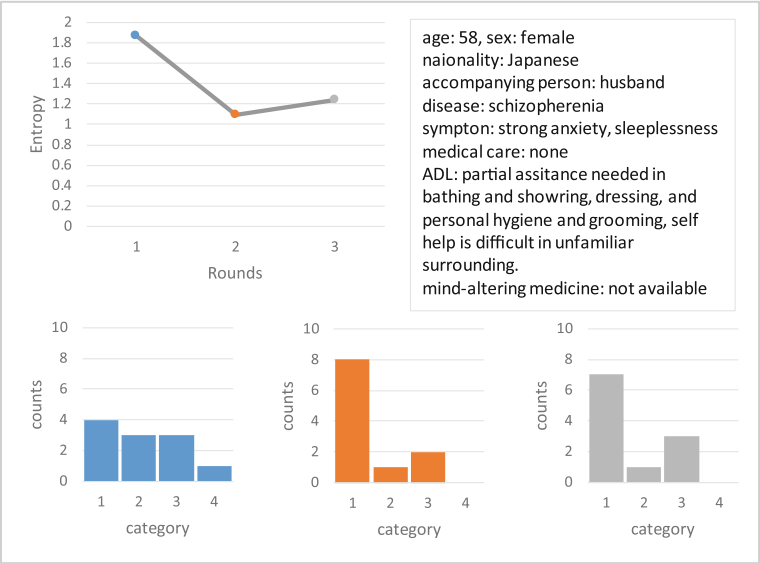


Fig. 4 Case example with high entropy

Table 2 Reasons and comments on the case presented in Fig. 4

Triage	Reasons and comments
I	She does not have the necessary medicines
I	She needs to go to hospital to receive medication. After that, she can stay at III
I	It is difficult to respond to her problem by II to IV immediately after the disaster, because she is not taking medicines even though she is highly anxious
I	Without medication, her mental instability will affect not only herself but also others in the evacuation shelter
II	I, If the hospital provides psychiatric service. If not, she should go to II because anxiety becomes stronger under disaster situation. II is the best option for watching over and taking care of her
III	We can expect the condition to stabilize if she is isolated. If something happen, she can cope with the situation because she can rely on her husband for support
III	She has her husband and no major problems in ADL, even though she needs medication
III	Supposing she usually stay at home, it is rather good for her to stay at an isolated room
IV	Support from her husband is available. It is best that she goes to the hospital for treatment before her condition worsens

5 Conclusions

This paper introduced an online disaster triage simulation for vulnerable people based on the Delphi method and presents the results obtained from the first trial of the proposed method. The result show that the Delphi method was effective for attaining convergence of answers even in triage simulation and for clarifying important points and criteria for the appropriate triage. This suggests that the Delphi method is applicable for discussing better triages in the design phase of a new triage method and in training and education. The results also suggest that the entropy of the convergence of answers can provide numerical metrics not only for the degree of convergence but also for the difficulty level of the cases used for triage simulation. This information is useful for simulation design for education and training.

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Usability Testing an Electronic Health Record: Lessons Learned and Ethical Considerations

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Abstract Interface design professionals frequently conduct usability tests to measure how well users can accomplish certain tasks with a given interface and to identify areas of improvement for redesign efforts. Much of the literature on electronic interface usability tests relates to consumer products, but there are special considerations when performing a usability test on an interface used in health care such as an electronic health record. A recent project involved a usability test of the existing electronic health record in the Veteran's Health Administration by 30 clinicians. Notable issues were the development of an appropriate clinical scenario, recruiting of representative clinicians, and determining how to address unexpected usability findings. The health care environment adds a particular ethical challenge that may not be present in other usability tests, because it is necessary to balance considerations of patient safety with protection of the clinician participants.

Keywords Human factors · Human-computer interaction · Usability · Usability testing · Electronic health record · Patient safety

1 Introduction

Recent publications have identified usability and safety concerns with electronic health records (EHRs) [1, 2]. Based on reports of possible patient harm, the American Medical Informatics Association (AMIA) convened a Task Force on Usability that developed ten recommendations for EHRs [3].

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The purpose of this usability test was to establish a baseline of usability and user satisfaction for the current Health Information Technology (HIT) system used in Veterans Health Administration (VHA) for use as a reference for evaluation of future EHRs in the VHA.

Areas of interest for this study, as defined in ISO 9241-11 [4] included:

- *Effectiveness*—the accuracy and completeness with which specified users can achieve specified goals in particular environments;
- *Efficiency*—the resources expended in relation to the accuracy and completeness of goals achieved;
- *User Satisfaction*—the comfort and acceptability of the work system to its users and other people affected by its use.

This paper will focus on findings associated with the process of conducting a usability assessment of an EHR rather than on the usability results. There were challenges associated with developing user tasks, selecting participants, and responding to errors that are unique to the health care arena. The lessons learned from this study may be useful in the design of future usability testing in health care.

2 The Usability Assessment

2.1 Method

For this study, 30 participants individually completed the entire test scenario, consisting of six tasks. All participants were practicing VHA physicians, physician assistants, or nurse practitioners who had experience with electronic prescribing, clinical information reconciliation, and clinical decision support. Some of the physicians were completing a residency in quality and safety, a one-year program that follows a traditional residency.

Years of clinical experience in the VHA served as a marker for experience with the EHR. Less experienced clinicians were those who had four or fewer years of experience in the VHA, while more experienced clinicians were those with five or more years of experience (Fig. 1).

The testing occurred remotely via Microsoft Lync®. The test facilitator ran a national version of the VHA's EHR on his computer. Participants used their own computers and phone lines and connected to the facilitator's computer. Participants signed an audiotape and screen capture release form. They also completed a questionnaire on demographic information.

The six usability tasks and the test patient characteristics were derived with the assistance of subject-matter experts with consideration for the ONC Safety-enhanced Design 2014 Edition criteria on electronic prescribing [§170.314 (b)(3)], clinical information reconciliation [§170.314(b)(4)], and clinical decision support [§170.314(a)(8)] [5]. These criteria were used because they describe

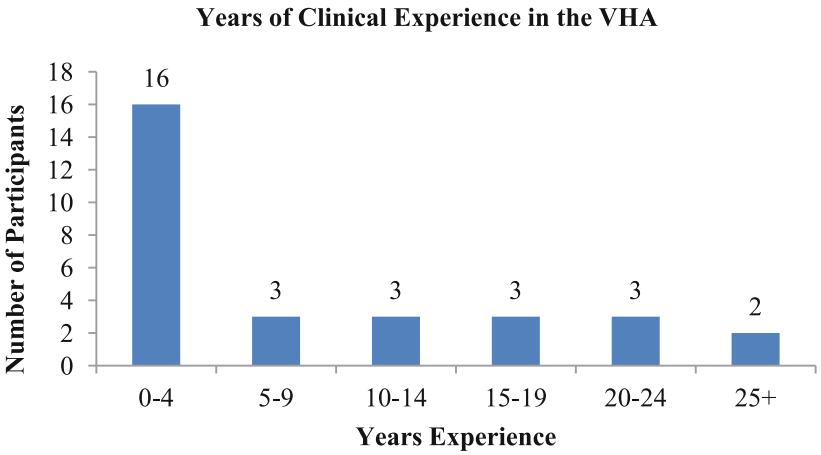

Fig. 1 Participants' clinical experience in the VHA

common and important clinical tasks. The scenario and tasks were identical for all study participants. Clinical staff reviewed the task descriptions to ensure that the content, format, and presentation were representative of real use and substantially evaluated the required functionality. The tasks, which represented common and relatively complex functions, were as follows:

1. *Review Lab Results*: Please review the lab results from September for the patient. Tell me which results are not in the normal range.
2. *Locate Clinical Guidelines*: Assume you want to find clinical guidelines for cellulitis. Please show me how you would do this. State verbally the source and publication date of the information.
3. *Order Medication* (*Alert*): Next, we will ask you to order a medication. You decide to order Bactrim for this patient's cellulitis. Please place this order using CPRS as you would normally with regard to dosage, route, etc. [Note: In this task, the provider receives an alert that the patient has a previous adverse reaction to Bactrim and that Bactrim interacts with another medication the patient is taking. The expected response is for the provider to refuse to order the medication.]
4. *Order Medication* (*No Alert*): Because of this patient's allergies, you decide to order Clindamycin. You have reason to believe this antibiotic is appropriate in this situation. Please place the order using CPRS.
5. *Locate Patient Education Material*: Please provide the patient with education material related to warfarin. State verbally the source and publication date of the material.
6. *Locate Patient Alerts*: The patient's daughter expresses frustration that her dad could do more to take care of his health and says she and her brother are going to help stay on top of things. She wants to know if he is due for any preventative

testing. Please locate patient alerts and reminders and tell me if any clinical actions need to be taken.

In addition, each participant was asked to describe how s/he performs medication and problem list reconciliation, what works well about this method, and what does not work well. Each participant answered these questions for several different scenarios, including for a patient who is only seen at the local medical center, for a patient who is seen at different VA medical centers, and for a patient who is seen at a clinic outside the VA system.

2.2 Test Metrics

After the participant completed each task and each set of interview questions, s/he was asked to answer the rating questions listed in Table 1. For each task, the metrics described in Table 2 were collected.

2.3 IRB

Because this research effort was considered Quality Improvement, IRB approval was not required. The project adhered to the following ethical guidelines:

Table 1 Task rating questions and scales

Question	Rating Scale
1. Overall, this task was:	Very difficult ☐ ☐ ☐ ☐ ☐ Very easy 1 2 3 4 5
2. The way this system works fits well with my desired workflow when seeing patients	Strongly disagree ☐ ☐ ☐ ☐ ☐ Strongly agree 1 2 3 4 5
3. How many times a day do you [perform this task]?	0 ☐ 1-6 ☐ 7-13 ☐ 14-19 ☐ 20+ ☐ 1 2 3 4 5
4. How critical do you think [performing this task] is to patient care?	Not at all critical ☐ ☐ ☐ ☐ ☐ Very critical 1 2 3 4 5

Table 2 Usability metrics collected for each task

Metric	Measure of…	Type of metric
Task success/failure	Effectiveness	Objective
Number of errors	Effectiveness	Objective
Task time	Efficiency	Objective
Number of mouse clicks	Efficiency	Objective
Number of programs used	Efficiency	Objective
Task rating ("Overall, this task was…")	User satisfaction	Subjective
Utility ("The way this system works fits well with my desired workflow when seeing patients." "How critical do you think performing this task is to patient care?" "How many times a day do you perform this task?")	User satisfaction	Subjective

- The performance of any test participant must not be individually attributable. The individual participant's name should not be used in reference outside the testing session.
- Information about the participant's performance should not be reported to his or her manager.

3 Lessons Learned

3.1 Test Plan

Initially, the intention was to conduct a summative usability evaluation of the VHA's EHR. Due to technical limitations with the test environment, however, it was not possible for participants to access all of the programs that providers normally use. Therefore, formative usability evaluation techniques were used for the "medication reconciliation" and "problem list reconciliation" tasks. Rather than performing the information reconciliation tasks, the participants answered a series of questions about how they would normally perform these tasks.

Using formative evaluation techniques when it was not possible to perform a full summative evaluation allowed the investigators to learn about how clinicians perform these tasks and what difficulties they encounter, but there may have been additional findings had they actually observed clinicians performing the tasks.

3.2 Scenario Development

Scenario development began by identifying relevant tasks from the ONC Safety-enhanced Design 2014 Edition criteria [5]. The initial draft of the tasks was composed with the help of a clinician. Multiple iterations of the scenario with clinicians with different areas of specialty were completed to ensure the tasks were written in such a way that clinicians agreed on the correct response.

Lack of realism is often a concern with simulated task environments. In cases where the correct answer is to halt a task, there is always a concern that a participant will proceed simply because the moderator has given a direction. For the medication ordering task with the alerts, one participant entered "CPRS Test" as the reason for the alert override, indicating she was not acting as she would in a normal clinical setting. After this occurrence, the moderator added an instruction to participants to complete tasks as they would normally, and questioned any participants to determine if they thought they had acted as they would with an actual patient.

3.3 Participant Recruitment

Participants were recruited from a variety of clinical areas, with a result that some participants did not commonly perform all the tasks in the test scenario. Several participants who worked in specialty areas noted that they did not commonly prescribe antibiotics, and they had to spend additional time locating information on the correct dose. For future studies, it may be best to limit participants to one practice area or create different scenarios for each clinical specialty. In addition, it may be best to consider within-subject differences in task times for the same task performed using different EHRs rather than drawing conclusions based on aggregate task times on a single EHR, because a participant who does not often perform a particular task may artificially inflate the total.

Investigators recruited participants with a variety of experience, but it was difficult to locate true novice users for this study. Residents in health care settings generally begin their residency during July, and testing was conducted in the late fall and winter. Therefore, all participants had been using the EHR for at least several months. In addition, many physicians are initially exposed to an EHR during medical school. Future studies may wish to consider this timeline and conduct testing during the summer in order to target new users of an EHR.

One goal for this usability assessment was to obtain a geographically distributed test sample to reflect the diversity present in the VHA, which has over 1500 sites of care located around the country [6]. Therefore, all tests were conducted remotely. In addition, there was no eye tracking software available. Due to this, it was impossible for investigators to know where participants were looking as they performed the tasks. During a medication ordering task, one participant noted that he was using an app on his cell phone to look up dosage guidelines. It is impossible to tell

if any other participants did this as well. One solution could be to ask participants explicitly at the end of each task if they used any additional reference material during the task.

3.4 Ethical Considerations

It is generally possible to protect participants in a usability test by consolidating the data. There may be a problem if the study identifies in some way a participant who has made an error. This identification could occur if the authors are too specific about a participant's job title, role, and/or location.

3.5 Unexpected Findings

One participant made an unanticipated error during the medication prescribing task. During the debrief period following the test session, the moderator explained the error and the correct procedure to the participant. After discussion with team members and patient safety experts, it was determined that there was no patient safety concern associated with this error. Therefore, the team took no additional action until all testing was complete in order to avoid altering the outcome of future test sessions. The results of the testing will be incorporated into future training to correct this error.

4 Discussion

A key finding from this usability assessment is that flexibility is essential when evaluating a complex tool in a changing environment, such as an existing EHR in an active health care setting. Evaluators may wish to consider employing a mixture of usability evaluation techniques if technical issues prevent a purely summative test. Valuable findings can come from methods such as structured interviews, even if these do not yield direct quantitative measurements.

It is important to call upon the experience of multiple clinicians with diverse backgrounds when developing a usability scenario, because there can be significant differences in practice between professionals depending on area of clinical expertise and typical practice environment.

Having participants with varying amounts of experience can be useful when attempting to identify usability issues. Often, novices will commit more errors, and it may be possible to learn more about workarounds with super-users. In addition, users who have trained others may have anecdotal accounts of usability issues they observed with trainees.

When conducting a usability assessment of a system that is currently in use in a health care setting, it is important to consider how to proceed when there are unexpected findings. Ideally, the investigators will be able to avoid any actions that would compromise findings from the remaining participants.

In most usability tests, protection of the participant is the ethical imperative. However, with health care, it is always necessary to consider patient safety as well. If there is a clear and imminent patient safety concern, one must consider how to address that, but confidentiality is still necessary, both to protect the participant and to promote future patient safety. Consider the case of New Zealand's Independent Safety Assurance Team (ISAT), which established a confidential aviation safety information sharing program in 1988. After an analyst knowingly released the name of a reporter, industry lost confidence in the system and ISAT subsequently failed [7]. Without protections for reporters and usability assessment participants, safety will be compromised.

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Demographics, Military Status, and Physical Health as Indicators of Personal Resilience Among U.S. Active Duty Service Members and Veterans

Valerie J. Rice and Baoxia Liu

Abstract Personal resilience refers to the ability to constructively adjust and move forward with ones' life following tragic events or situations. However, few studies have examined the characteristics of highly resilient active duty military or veterans. This study examined the relationships between personal resiliency scores (The Resiliency Scale), demographics, general Self-Reported Health (SRH), and health symptomatology (Patient Health Questionnaire-15) among 263 U.S. active duty and veteran service members. Pearson Product-Moment Correlations, an Analysis of Variance, and Regression Analysis were used with a significance level of 0.05. Results showed that active duty service members were more resilient than the veterans in this population ($p < 0.05$). Findings also demonstrated that a higher education level, longer time on active duty, higher SRH, and lower symptomology were correlated with ($p < 0.05$) and contributed to greater resilience [$F(4, 258) = 26.18$, $p < 0.01$), $R^2 = 0.54$]. These results demonstrate the importance of health and education, perhaps pointing toward a protective qualities that may also include longer service time.

Keywords Resilience · Military · Health · Symptomology · Time-in-service · Education

1 Introduction

When describing material that is 'resilient', it is said that it has the quality of being able to return to its' original shape after being stretched, pulled, or otherwise manipulated into a shape different from its' normal state. Using this description, a

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rubber band is resilient. The term resilience has been adapted to refer to individuals, teams, organizations and governments [1]. Personal resilience refers to an individuals' capacity to return to one's original state, or close to it, by positively adjusting and continuing forward momentum in one's life following trauma or significant hardship [2, 3], and to do so while maintaining acceptable functional, social, and psychological capabilities [3].

Personal resilience is of great interest to the U.S. military [4]. Military service members face adversity during deployments into harms' way, including possible death and physical injury (their own or that of others), as well as long durations away from family and support systems, dealing with different cultures, and austere climates and living conditions. The families of service members also face challenges as they confront the possibility of the death or injury to their family member, handling daily life stressors without one parent, and frequent "starting over" in making new friends, finding new housing, and entering new schools during military moves. Family stress naturally translates to additional stress for the active duty service member. Both the service member and his (or her) family members also must confront the realities of the reintegration of the service member back into the family after long absences. This reintegration may entail the return of a family member who is injured and irrevocably changed from the person they were when they initially left on deployment. Building resilient service members may prevent deleterious outcomes of exposure to war such as post-traumatic stress, depression, mood disorders, marital difficulties, or dysfunction in the family or military units.

Resilience can be developed or enhanced [5–9] in a number of ways (experience, training, sharing of experiences) in ones' lifetime [1, 10, 11]. Therefore, the U.S. military services offer a variety of training approaches thought to enhance resiliency to their service members [12, 13]. However, there may be characteristics of those who are shown to be resilient that could be identified and perhaps considered when developing resiliency training programs.

The purpose of this research was to examine the relationships between resiliency scores and demographics, self-reported physical health and self-reported health-related symptoms among U.S. active duty and veteran service members. This information could offer initial information about potential protective factors that may enhance personal resiliency.

2 Methods

2.1 Participants

Active duty U.S. military service members and veterans were recruited as research volunteers from Joint Base San Antonio, Fort Sam Houston and the surrounding vicinity through information booths, briefings, fliers, and email advertisements. Volunteers were recruited for a larger study focusing on the effectiveness of

Mindfulness-Based Stress Reduction offered in-person and over a virtual world. The data for this study was collected prior to mindfulness training interventions. An oral and written explanation of the study was presented to all potential volunteers as part of the informed consent process, and individuals who wished to participate signed an informed consent form. Participation in the study was voluntary and volunteers were able to terminate their participation at any time during the study. Participants were not compensated for their participation.

2.2 Surveys

Research volunteers completed pre and post-training evaluations as part of the larger study. This paper includes information from the pre-training surveys only.

Demographics. The volunteers were asked to complete a demographic questionnaire including information on their age, gender, weight, height, marital status, education level, military status, number of deployments in harms' way, and time-in-service. Body Mass Index (BMI) was calculated for each volunteer based on the individual's self-reported weight and height, and BMI was consequently used for analysis.

Self-rated Health (SRH). Volunteers rated their present, overall health on a 5-point Likert scale (poor, fair, average, good, excellent), responding to the question "Overall, how would you rate your health?" [14, 15]. Similar ratings of health, used during Behavioral Risk Factor Surveillance, demonstrate a test-retest reliability of 0.92 [16].

Patient Health Questionnaire (PHQ-15). Volunteers completed the PHQ-15, a self-administered version of the PRIME-MD diagnostic instrument [17]. The PHQ-15 is an abbreviated somatic symptom subscale derived from the full Patient Health Questionnaire [17]. The PHQ-15 includes 14 of the 15 most prevalent DSM-IV somatization disorder somatic symptoms and is rated on a three point scale (0 = not bothered at all; 1 = bothered a little; 2 = bothered a lot). The questionnaire asks participants to rate the extent to which they have experienced somatic symptoms "during the past 4 weeks". Symptoms in the survey include stomach pain, back pain, pain in the arms, legs or joints, headaches, chest pain, dizziness, fainting spells, etc. [17]. The questionnaire has been shown to be a valid instrument [18, 19]. The agreement between PHQ diagnoses and those of independent mental health professionals was high (0.65) and the PHQ has an overall accuracy of 85 % and sensitivity of 75 % [18].

Resilience Scale (RS-14). The 14-Item Resilience Scale (RS-14) [20] is a shortened version of the Resilience Scale (RS) [21]. The RS-14 includes 14 items with a 7-point scale for each item (1 = strongly disagree, 7 = strongly agree). The total score serves as an indication of a person's resilience, measuring an individual's ability, strength, and resources to manage and respond to life events. The RS-14 has high internal consistency reliability (0.93) and convergent validity (r = 0.63) [20].

2.3 Statistics

Descriptive analyses included identifying frequencies, means and standard deviations for outcome measures. T-tests were used to discover the difference in resilience among the demographics for two groups (i.e. gender) and one-way ANOVAs were used for groupings larger than two (i.e. race, marital status, education level, and military status). Pearson Product-Moment correlations were used to examine the association between the RS-14 resilience scores and demographic measures, the SRH, and PHQ-15 scores. A linear regression was carried out to investigate how the associated factors contribute to resilience scores. Data analyses were conducted with the IBM SPSS Statistics for Windows (Version 22, Armonk, NY: IBM Corp, Released 2013) using a significance level of 0.05.

3 Results

3.1 Descriptive, Correlation, and Group Comparisons

A total of 263 volunteers participated in the study. Volunteers' demographic data are shown in Table 1. Volunteers ranged in age from 24 to 74 (M = 47.78, SD = 12.13), 53.6 % were male and 66.2 % were veterans (66.2 %). The majority were Caucasian (53.2 %), married (56.7 %), and had attended some college (93.9 %).

The means and standard deviations of age, BMI, SRH, PHQ-15, time in service and the number of deployments in harm's way are shown at the bottom of Table 1. The SRH mean for all volunteers was 2.53, between average and good health. The percentages of volunteers falling into each of the SRH rating are shown in Table 2, showing the majority of volunteers rated their health as good.

The mean value for all volunteers on the PHQ-15 of 10.07 is in the medium range for symptom severity. Table 3 shows that the majority of volunteers fell into the low range for symptom severity.

The average resilience score of all participants was 75.13, which falls in the moderate range for resilience. The frequencies and percentages of those participants who fall into each of the resilience categories are shown in Table 4, showing most of the volunteers' resilience scores were in the moderately high range.

The resilience scores of the demographic groups are listed in Table 1. Resilience scores were not found to be different for gender, race, or marital status ($p > 0.05$). Resilience scores were different for military status [$F(3, 259) = 3.48$, $p < 0.05$]. A Tukey HSD post hoc analysis showed that active duty service members scored higher in resilience than veterans ($p < 0.01$). Reserves and Guard were not significantly different from active duty or veterans in resilience. Resilience scores were

Table 1 Descriptive results for demographic groups and resilience scores for each group, and correlations between resilience and demographic features

	N	(%)***	RS-14 Scores	(SD)
Gender				
Male	141	(53.6)	74.09	(17.64)
Female	122	(46.4)	76.33	(15.65)
Education**				
GED/High school	16	(6.1)	64.25	(15.47)
Some college/associate's	85	(32.3)	70.05	(18.90)
Bachelors	67	(25.5)	77.24	(14.90)
Masters/Doctorate	77	(29.3)	80.94	(13.47)
Other professional	18	(6.8)	76.06	(16.18)
Race				
African American	66	(25.1)	78.12	(14.37)
Native American	4	(1.5)	77.25	(14.84)
Caucasian	140	(53.2)	74.21	(17.11)
Hispanic	46	(17.5)	72.52	(19.13)
Asian	5	(1.9)	80.80	(15.68)
Other	1	(0.4)	84.00	–
Marital status				
Married	149	(56.7)	76.43	(16.05)
Divorced	56	(21.3)	74.13	(19.41)
Widowed	3	(1.1)	72.33	(10.02)
Single/Separated	45	(17.1)	72.89	(15.08)
Living with significant other	10	(3.8)	72.20	(20.50)
Military status*				
Active duty	79	(30.0)	80.11	(14.53)
Reserve	6	(2.3)	73.67	(8.62)
Guard	4	(1.5)	70.00	(16.59)
Veteran	174	(66.2)	73.03	(17.50)
	M	**(SD)**	**Correlation with RS-14**	**(N)**
Age	47.78	(12.13)	0.048	(263)
BMI	28.10	(4.64)	−0.056	(263)
SRH	3.47	(1.02)	0.453**	(263)
PHQ-15 total score	10.07	(5.76)	−0.384**	(263)
Time in service	14.89	(8.63)	0.264**	(263)
Number of deployments in harm's way	1.52	(2.23)	0.081	(177)

*Significant at the 0.05 level

**Significant at the 0.01 level

***The categories with a total of less than 263 have missing values, the total percentage may not be exactly 100 due to missing data or rounding

Table 2 Self-reported health by category (n = 263)

	Frequency	Percent (%)	RS-14 score	SD
Poor (5)	9	3.4	46.56	11.76
Fair (4)	47	17.9	68.81	18.08
Average (3)	48	18.3	69.21	17.27
Good (2)	130	49.4	78.70	13.69
Excellent (1)	29	11.0	88.00	8.00

Table 3 Patient health questionaire-15 score frequencies and percentages (n = 263)

Symptom severity	Frequency	Percent (%)	RS-14 Score	SD
Minimal (0–4)	52	19.8	85.06	10.83
Low (5–9)	80	30.4	78.49	15.72
Medium (10–14)	65	24.7	69.65	17.03
High (15 and above)	66	25.1	68.62	16.95

Table 4 Resilience scale frequencies and percentages for volunteers (n = 263)

	Frequency	Percent (%)	RS-14 score	SD
Very low (14–56)	36	13.7	43.50	10.54
Low (57–64)	25	9.5	60.24	2.54
On the low end (65–73)	40	15.2	69.08	2.53
Moderate (74–81)	44	16.7	77.68	2.22
Moderately High (82–90)	72	27.4	85.60	2.53
High (91–98)	46	17.5	94.39	2.47

higher for participants with higher education [$F(4, 258) = 6.79$, $p < 0.01$]. A Tukey HSD post hoc analysis showed that participants with GED/High School diploma had lower resilience than those with Bachelor's, Master's or doctoral degrees ($p < 0.05$); the participants with Master's or doctoral degrees showed higher resilience than those with some college experience or an associate degree ($p < 0.01$).

Pearson Product Moment correlations showed positive correlations between resilience and SRH and between resilience and time-in-service ($p < 0.01$, see Table 1). That is, higher scores on SRH and a longer time spent on active duty were associated with higher resilience. Resilience was negatively correlated with PHQ-15 scores, demonstrating that the more somatic complaints reported, the lower the resilience. Age, BMI and number of deployments in harm's way were not significantly correlated with resilience ($p > 0.05$).

Table 5 Linear regression predicting resilience

	Unstandardized coefficients		Standardized coefficients	t
	B	Std. error	Beta	
Constant	50.105	5.563		9.007
Time in service	0.368**	0.105	0.189	3.486
Education level	1.766*	0.877	0.112	2.012
Health rating	5.419**	1.032	0.329	5.253
PHQ total score	−0.448*	0.184	−0.154	−2.443

*Significant at the 0.05 level
**Significant at the 0.01 level

3.2 *Regression*

A simple linear regression was calculated to predict resilience scores based on measures that were significantly correlated with resilience, including education level, SRH, PHQ-15 total score and time-in-service. A significant regression equation was found [$F(4, 258) = 26.18$, $p < 0.01$], with an R^2 of 0.54, thus accounting for 54 % of the variability. The results from the regression are shown in Table 5.

4 Discussion

The majority of the active duty service members and veterans who volunteered for this study were highly educated, reported their health as good, and their resilience as moderately high. Approximately 62 % of the volunteers for this study had a bachelors' degree or higher and 93 % had attended some college. A 2008 report using manpower and personnel files from the Defense Manpower Data Center noted that among enlisted personnel from all services, that 93 % had a high school diploma or above, and 90 % of officers had a Bachelor's degree. Approximately, 1 % of enlisted personnel lack a high school degree, compared to 21 % of men in the civilian sector between the ages of 18–24 years of age [22]. As the education level in our population increased, resilience increased, demonstrating that knowledge appears to enhance resiliency. Although we did not find information on this relationship in the resilience literature, the idea that greater knowledge resilience speaks to characteristics associated with resilience, such as cognitive fitness, adaptability, and active problem solving [1].

Responses to the general SRH question are indicative of one's physical [23] and psychological health [24]. This supports the literature in which physical fitness is associated with resilience [25], as is emotional fitness [4, 25]. Emotional fitness related to resilience includes self-regulation, stability, and flexibility [1].

Somatization occurs when an individual has vague or recurring physical symptoms with no discernable physical or medical explanation. The symptoms are not being falsified, however, and the symptoms may cross various systems in the body, such as digestive, visual, neurological, and orthopedic pain symptoms. The symptoms are most often associated with individual psychological distress, such as anxiety or depression. Higher somatization symptoms are seen in those with high scores on the Post-traumatic Stress Disorder Checklist [26] and somatization has been added to the DSM-V symptoms of PTSD [27]. Individuals with somatic symptoms are often seen in primary care clinics and somatization is associated with impaired function and heavier healthcare use [10]. Hence, our findings that higher somatization is associated with lower resilience further supports the above mentioned concepts of resilience being associated with physical and emotional health [4, 25].

Longer time spent on active duty was also indicative of greater resilience. There are a number of possible rationales for this. Individuals who remain on active duty receive additional education to prepare them for each new increase in their military responsibilities. In general, over a full career a person in the enlisted ranks would attend basic training, advanced individual training, basic and advanced leadership courses, senior and master leadership courses, and the Sergeants Major Course. An officer could attend Officers Basic Training, the Captains Career Course, Intermediate Level Education, the School of Advanced Military Studies, School for Command Preparation, and Senior Service College. In addition, individuals are often sent to other training that may pertain to the military and/or training specific to their occupational specialty or to their next duty station (such as training to take a command position). The longer an individual spends on active duty, the more training and education they are likely to receive. However, in our population, although the active duty service members spent slightly longer on active duty than the veterans, the difference was relatively small (active duty time in service = 15.80 $\pm$ 8.61; veteran time on active duty = 14.52 $\pm$ 8.83. A second possible explanation is that military service encourages adaptability and flexibility, as they move to new locations and assignments, deploy, and take on new jobs of ever increasing responsibility. With each new duty station comes new supervisors, new co-workers, physical locations, and job duties. Also, should there be disagreements between co-workers or between a supervisor and supervisee, there is not an option to leave. Therefore, the active duty service member must learn to adapt to the situation and make it as acceptable and productive as possible. Overall, the lifestyle of an active duty service member provides experiences that are likely to increase the following characteristics associated with resilience: accepting reality and situations they cannot directly alter [4, 25, 28]; a "can do" attitude (initiative taking and perseverance) [29, 30]; flexibility [29, 31]; and physical fitness [4, 25]. Again, while the time in service was only 1.28 years greater among active duty service members when compared with veterans, they are still embedded in the military culture. Third, social support systems are also associated with resilience [32] and remaining on active duty may lend social support through continued contact with others who have had similar experiences.

In order to have a more resilient military force, the information gained from this study could be applied in the following ways:

- Recruit individuals for military who have higher levels of education.
- Provide additional education, earlier in the service members' careers.
- Promote physical, cognitive, and emotional health.
  - Continue to provide physical fitness training, along with early assessment of physical injury, and provision of physical rehabilitation, when needed.
  - Provide mental fitness training that touches on both cognitive and emotional health.
  - Consider combining fitness training, giving equal consideration to both physical and mental fitness or combine combatant training with mental fitness training in a manner similar to martial arts training.
  - Reinforce concepts and actions that promote cognitive adaptation.
- Emphasize the characteristics of resilience during military training to include those not mentioned in this paper, but delineated elsewhere [1].
- Continue to assess and identify characteristics of resilience important for military service members.

5 Limitations

The data collected in this study were from a cross-section of a population at a particular point in time, thus additional longitudinal research is needed to further investigate the relationship between resilience and demographic features over time. Self-report measures used in this study made it possible for the participants to respond with a bias of making a better impression on other people (even though volunteers were aware than only the researchers would see their data). Additional performance based measures, if available, could be beneficial for future investigations. Finally, the results in this study are from active duty military and veteran volunteers, under non-deployment conditions. Caution should be used in applying these results to other populations.

6 Conclusions

Among this population of military active duty and veterans, a higher level education, more time spent on active duty, a higher rating of self-reported health, and lower somatization predicted higher personal resilience, accounting for 52 % of the variability. In addition, those on active duty were more resilient than those who were military veterans. It appears that improving resilience among service members

should entail fostering education, physical and mental fitness, and the experiences and training that encourage development of characteristics associated with resilience.

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Language Sample Analysis Framework Utilizing the Natural Language Toolkit and Social Media

Ahmad Abualsamid and Charles E. Hughes

Abstract In this paper we present the Analysis of Social Discourse Framework (ASDF), which utilizes the Natural Language Toolkit [1] (NLTK 3.0 documentation. http://www.nltk.org) to analyze language samples from children on the Autism Spectrum. For those whose anxiety prohibits them from providing speech samples in response to guided elicitation we utilize free form social media posts to obtain the language samples. To demonstrate the value of ASDF, we present a formative case study illustrating the collection of samples via social media posts and the resulting analysis. In addition to providing metrics traditionally used in speech sample analysis, ASDF provides new metrics made possible through natural language processing. ASDF is open source so it can be extended by researchers to include additional metrics and additional means of acquiring the data associated with these metrics.

Keywords Fragile X syndrome · Human factors · Language sample analysis · Autism spectrum disorders · Natural language processing

1 Introduction

Children on the Autism Spectrum Disorder often require intensive speech and language therapy at a young age [2]. In order to conduct effective therapy, Speech and Language therapists conduct one-on-one or small group sessions to work with these children. Pre-assessments are required to evaluate each child's current abilities in order to create a proper plan of care [3]. However, a large number of children on the Autism Spectrum Disorder also suffer varying levels of social and other anxi-

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eties [4] making it difficult to conduct a valid pre-assessment of the children's language and speech abilities, which in turns makes it impossible to curate an effective plan of care. The challenges are compounded in the subset of children on the Autism Spectrum Disorder who are concurrently cognitively impaired. Unfortunately, those children wouldn't understand the importance of the pre-assessment, an understanding that may lead an otherwise anxious child to try to overcome her anxiety. Further complicating matters is the therapist's inability to distinguish between whether the lack of response from the child is due to the child's speech and language deficit versus lack of response due to social anxiety versus lack of response due to cognitive impairments. As speech and language sessions are not affordable, neither in terms of time nor money, the built-up frustration often leads to ineffective services or worse yet to discontinuation of services.

In this paper we present a formative case study of a teenager who has the Fragile X Syndrome [5], the most common single gene cause of autism and the leading cause of inherited intellectual disability [6]. The child presents with cognitive impairments, inability to read social situations, and severe social and anticipatory anxieties. The child is verbal and interacts normally with her family, her peers at school and her teachers. However, the context of her speech and complexity of her language is well below grade level and thus she requires language therapy. While the child exhibits typical interactions in familiar situations, she exhibits selective mutism in unfamiliar situations and fails to converse with others. Anticipatory anxiety triggers selective mutism even in familiar environments when she senses that she is being tested or that there are expectations placed on her. At the age of five she spent a whole grade year at school without saying a single word in her classroom. The child has not been able to receive effective speech and language therapy in a clinical setting due in part to her selective mutism, which makes it impossible to perform a valid assessment of her current language abilities.

Language Sample Analysis is a tool used by Speech and Language therapists to assess clients' language abilities [7]. The therapist elicits language samples from children (or adults) through guided conversations. Often showing a picture (Fig. 1 depicts a very common example) and asking the child for a description of the picture [8].

The conversation with the child is recorded via an audio recording device. The therapist then transcribes the conversation and finally uses a PC based software to analyze the language sample [8]. Studies have shown that, while the approach is academically popular, it is not commonly used in practice. The current procedure involves recording devices, commercial PC-based software that is not straightforward to use, and manual transcriptions, all of which add overhead to the process and can lead to errors [9].

In lieu of using legacy commercial software and voice samples we present an open source extensible framework, the Analysis of Social Discourse Framework (ASDF), for analyzing text samples. The open source software is built on the popular Natural Language Toolkit [1] and is available for researchers to expand. Instead of eliciting voice samples from children, recording them, and then transcribing them, we utilize social media posts. It can be argued that spoken language

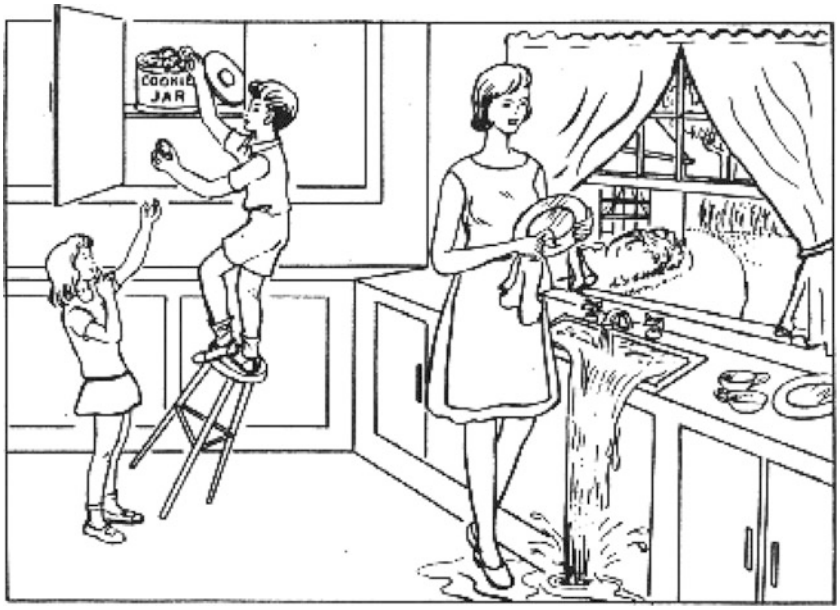

Fig. 1 The famous cookie theft picture often used to elicit speech in speech-language assessments

and written language provide us slightly different representations of a child's language ability. That is true, and our system does not prohibit the use of spoken and transcribed speech samples. However, for children exhibiting selective mutism the spoken language option may simply not be available, as has happened in our formative case study. It can also be argued that free-form social media posts convey more information about the child's language skills than a structured, manufactured, elicit of speech samples based on describing stock pictures.

In the remainder of this paper we present an overview of the Fragile X Syndrome, a discussion of the Natural Language Toolkit, introduce our Python-based open source framework, ASDF, that can be used to conduct language sample analysis, and finally present a formative study of analyzing language samples from the teen's social media posts.

2 Background

2.1 Fragile X Syndrome

The Fragile X Syndrome is an inherited genetic disorder on the X chromosome that causes intellectual disabilities, learning disabilities, seizures, working memory problems, visual processing problems, behavioral challenges, speech and language

impairments and various physical characteristics affecting as many as 1 in every 3600 males and 1 in every 5000 females. It is the leading cause of inherited intellectual disability and the most common genetic cause of autism [10, 11].

Due to the fact that males have a single X chromosome they are more severely affected than females, with the vast majority unable to speak clearly, read, write, attain education or live independently. Females exhibit milder effects, though they present with a spectrum of cognitive impairments, social anxiety and social deficits, and great difficulty processing sequences and abstract concepts such as time and money.

Fragile X has no known cure. While efforts to provide a drug treatment continue, none have been successful to date. As such, caregivers are left trying to manage the symptoms through drugs aimed at specific symptoms, and through behavioral, speech and language, and occupational therapies.

2.2 *Natural Language Toolkit*

The Natural Language Toolkit [6] is developed in Python and is a leading platform for working with human languages. The NLTK provides easy access to more than 50 corpora. It has an idiomatic Python API that allows Python developers to easily build and integrate software that utilizes the NTLK's numerous natural language processing abilities. The authors of the NLTK, Steven Bird, Ewan Klein and Edward Loper have also written an excellent book [12] titled "Natural Language Processing with Python—Analyzing Text with the Natural Language Toolkit," which was the inspiration for the framework presented in this paper. The NLKT works with Python 3 as well as Python 2.6/2.7. Our development efforts have been done in Python 3.

2.3 *Language Sample Analysis*

Language Sample Analysis (LSA) is a tool that allows Speech and Language Pathologists (SLP) to elicit spoken language from a client in order to conduct an evaluation [7]. LSA is not the only evaluation tool; in fact, other standardized assessments are used in the evaluation [3]. However, the LSA provides a great deal of useful information about the client's language ability including conversational skills, grammar, word meanings, social skills and morphology [8]. The language sample is either recorded and then transcribed, or immediately transcribed. The SLP requires great effort to have a faithful transcription of the spoken text, including all mistakes. The transcription process itself can introduce human errors on the part of the SLP; thus, the final transcription may not be exact due to transcription errors and subjective errors in interpreting mispronunciations, unclear speech and stops in the spoken language.

Once the sample is collected, the SLP can perform manual or computer-aided analysis on it [8]. A manual analysis typically involves counting the morphemes, which are the smallest units of language that have meaning, and dividing that count by the client's total number of utterances to derive a mean length of utterance (MLU). The MLU number is then looked up in standardized charts to identify the client's performance compared to peers. This analysis is not limited to children; it can also be used in the cases of Aphasia in stroke survivors, for example, to identify the type of Aphasia based on the patient's MLU.

Computer-aided analysis is typically conducted using the SALT PC software, which provides additional information such as total number of words, a count of mazes and abandoned utterances [8]. Mazes are series of utterances that do not contribute meaning to the flow of language [13].

The SALT PC-based software has access to standardized data and thus allows the SLP to compare their client's results against standardized results in their database [8, 9].

3 Framework

The open source framework, ASDF, that we have developed is available at https://github.com/abualsamid/lsa, it has a permissive license allowing it to be used for any research purpose, as well as allowing for pull requests if contributors want to improve the software. The Python program can be pointed to a data folder that contains individual text files with language samples in them. The program will loop through the files in the folder, and, for each file, will provide analytical metrics that can be used by the SLP to assess the child. The rest of this section will describe the different metrics and statistical data generated by the software.

3.1 Tokens, Words, Sentences, Stems and Lemmas

The framework uses the NLTK to tokenize the input text into words, sentences, stems and lemmas as shown in the sample Python code, which is incorporated from examples in the NLTK book [12], below:

```
import nltk
from nltk.corpus import PlaintextCorpusReader
from nltk import word_tokenize
corpus_root = '/sla/data'
wordlists = PlaintextCorpusReader(corpus_root, '.*')
for fileid in wordlists.fileids():
    raw = wordlists.raw(fileid)
    sents = wordlists.sents(fileid)
    tokens = word_tokenize(raw)
    words = [lower() for w in tokens]
    vocab = sorted(set(words))
    porter = nltk.PorterStemmer()
    stems=sorted(set([porter.stem(t)
                  for t in tokens]))
    wnl = nltk.WordNetLemmatizer()
    lemmas = sorted(set([wnl.lemmatize(t)
             for t in tokens]))
    num_chars = len(raw)
    num_words = len(words)
    num_sents = len(sents)
    num_vocab = len(vocab)
```

In few lines of code, we have examined a sample text, tokenized it into words, split it into sentences, found the unique set of vocabulary used in the text, found all the stems the child produced in the text as well as all the lemmas, and produced various statistics regarding the length of the raw text, the number of words, the number of sentences and the number of unique vocabulary words used. The stems and lemmas are important from a morphology point of view in giving us more insight into the child's language breadth and depth.

3.2 Complexity and Diversity

In addition to discovering the information above regarding the raw data, the framework uses the NLTK to produce the average length of words used, the average length of sentences (aka MLU in language therapy) as well as the lexical diversity of the text, which is defined as the number of unique words, i.e. vocabulary, divided by the total number of words used in the text.

3.3 Frequency Distribution

An important element in measuring the quality of language production, and more importantly in measuring the progress of language production over time is the

frequency distribution of words used and the frequency distribution of lengths of words used in language production. For example, we present the frequency distribution of words used in a Facebook post sample from our formative study describing what the teen did that day. The distribution shows words and punctuation symbols along with the frequency of usage of each, ordered from most frequent to least frequent.

```
[('we', 15), ('to', 10), ('.', 8), ('the', 6), ('after',
6), ('and', 5), ('went', 5), ('some', 4), ('left', 3),
('had', 3), ('items', 3), ('publix', 3), ('mommy', 2),
('truck', 2), ('done', 2), ('were', 2), ('cookies', 2),
('market', 2), ('buy', 2), ('mall', 2), ('food', 2),
('oviedo', 2), ('shopping', 1), ('today', 1), ("'s", 1),
('i', 1), ('asian', 1), ('rice', 1), ('for', 1), ('way',
1), ('money', 1), ('raise', 1), ('fresh', 1), ('lunch',
1), ('bought', 1), ('side', 1), ('selling', 1),
('return', 1), ('came', 1), ('shopped', 1), ('home', 1),
('brought', 1), ('at', 1), ('girl', 1), ('unloaded', 1),
('east', 1), ('finished', 1), ('cedar', 1), ('then', 1),
('get', 1), ('unloading', 1), ('all', 1), ('ate', 1),
('would', 1), ('so', 1), ('scouts', 1), ('sell', 1),
('clothes', 1), ('this', 1)]
```

The distribution is skewed towards functor words and towards the speaker's point of view. The latter is understandable since the teen was asked to describe the events of her day, but it also highlights a trait of persons on the Autism Spectrum Disorders who typically view the world mostly from a first person view. For contrast we provide the frequency distribution of the paragraph that started this sub-section (An important element in measuring …).

```
[('of', 8), ('the', 7), ('frequency', 4),
('distribution', 4), ('in', 4), ('words', 4), (',', 3),
('language', 3), ('production', 3), ('and', 3), ('used',
3), ('.', 3), ('from', 2), ('frequent', 2), ('measuring',
2), ('usage', 1), ('lengths', 1), ('our', 1), ('teen',
1), ('importantly', 1), ('study', 1), ('progress', 1),
('symbols', 1), ('is', 1), ('over', 1), ('more', 1),
('to', 1), ('ordered', 1), ('along', 1), ('important',
1), ('for', 1), ('a', 1), ('present', 1), ('sample', 1),
('with', 1), ('facebook', 1), ('punctuation', 1),
('their', 1), ('example', 1), ('least', 1), ('quality',
1), ('time', 1), ('post', 1), ('shows', 1), ('what', 1),
('formative', 1), ('element', 1), ('day', 1), ('did', 1),
('most', 1), ('an', 1), ('describing', 1), ('we', 1),
('each', 1), ('that', 1)]
```

Another frequency distribution of interest to us is the distribution of lengths of words. For our case study example above, the frequency distribution of the length of words used is:

```
[(4, 29), (2, 28), (3, 21), (5, 21), (6, 10), (1,
9), (7, 6), (8, 3), (9, 1)]
```

What this tells us is that 4, 2 and 3 letter words make up the vast majority of the sample. A single sample is not adequate to draw conclusions but this is another metric that can be very useful in longitudinal studies to understand changes over time to the child's language production.

Other frequency distributions provided by the framework are the frequency distribution of individual letters, which may be helpful in studying the use of vowels in text. Usage of letters such as v and w may indicate more breadth of language usage. Hapaxes, which are a special frequency distribution of one occurrence, are also generated by the framework as a separate metric.

3.4 Part of Speech Tags

The NLTK includes a parts of speech (POS) tagger [12]. A POS tagger processes words in text and assigns a part of speech to each word such as a noun, an adjective, coordinating conjunction, adverbs, etc. Part of speech tags are not used in sample language analysis by SLPs. Like frequency distributions of words and length of words, the Part of Speech tags can provide insight to the content and depth of language samples.

Similar to Frequency Distributions, the Part of Speech tagging may not be insightful for a standalone language sample; however, it can provide insight into the evolution of language ability over time in longitudinal studies. The framework uses the NLTK to tag parts of speech and provide an output describing the part of speech tag of every word in the input sample as well as the list of words associated with each tag. For example, it provides lists of nouns, verbs, adverbs, etc. used in the input sample.

3.5 Misspellings

The NLTK employs the Words Corpus that is available on most Unix like systems at/usr/share/dict/words. By using this corpus, we can test for misspelled or unusual words in the sample text by looking for words in the text that do not appear in the Words Corpus. This, however, is system dependent. For example, on Mac OSX the default Words Corpus is based on the Webster's 2nd International dictionary which

spells cookie as cooky. On Ubuntu the "wamerican" dictionary can be installed, which provides for less than half the words of the version on Mac OSX, but includes more commonly spelled American English words such as cookie. Our framework uses the default system Words Corpus to provide a list of misspellings in the language sample. This is helpful in both judging the child's current spelling ability as well as her progress over time.

3.6 Stopwords

Similar to Functor words, Stopwords refer to high-frequency words that usually have no lexical content. The two lists overlap greatly. The NLTK has a corpus of Stopwords. The English list is reproduced below for reference directly from the NLTK:

```
['i', 'me', 'my', 'myself', 'we', 'our', 'ours',
'ourselves', 'you', 'your', 'yours', 'yourself',
'yourselves', 'he', 'him', 'his', 'himself', 'she',
'her', 'hers', 'herself', 'it', 'its', 'itself', 'they',
'them', 'their', 'theirs', 'themselves', 'what', 'which',
'who', 'whom', 'this', 'that', 'these', 'those', 'am',
'is', 'are', 'was', 'were', 'be', 'been', 'being',
'have', 'has', 'had', 'having', 'do', 'does', 'did',
'doing', 'a', 'an', 'the', 'and', 'but', 'if', 'or',
'because', 'as', 'until', 'while', 'of', 'at', 'by',
'for', 'with', 'about', 'against', 'between', 'into',
'through', 'during', 'before', 'after', 'above', 'below',
'to', 'from', 'up', 'down', 'in', 'out', 'on', 'off',
'over', 'under', 'again', 'further', 'then', 'once',
'here', 'there', 'when', 'where', 'why', 'how', 'all',
'any', 'both', 'each', 'few', 'more', 'most', 'other',
'some', 'such', 'no', 'nor', 'not', 'only', 'own',
'same', 'so', 'than', 'too', 'very', 's', 't', 'can',
'will', 'just', 'don', 'should', 'now']
```

For our purposes we define content words as words in our sample that are not Stopwords. Our framework provides a metric for the percentage of content words relative to the whole text. In the US English language speakers use Stopwords for roughly 60 % of their speech. The Framework allows us to understand what percentage of the language sample is content and what percentage is Stopwords which would give us insight to how the child performs against the average English speaker in the country.

4 Case Study

4.1 Overview

Our formative case study is based on a teenage female who has Fragile X syndrome with comorbid autistic characteristics. The child started exhibiting delays in crawling, walking and talking at her early years. She was diagnosed with Fragile X at the age of 9, at which time she started receiving occupational therapy and speech and language therapies at her school. She currently receives private speech and language therapy at home; this therapy only became possible after the child became very familiar with the therapist over the course of numerous sessions. Attempts to enroll the child in clinic-based speech and language therapy have not been successful over the yeas, as failure to conduct assessments and limited familiarity with therapists continuously hamper their efforts.

The child owns an iPhone and an iPad and is familiar with Facebook, blogs, messaging apps and educational apps and websites. In order to explore alternative assessment strategies, a private Facebook group was created for the child and her family. The child was then asked to post periodically to the private Facebook group. The child was asked to describe her day in the posts but not given specific instructions otherwise. The child has been posting 1 to 2 times a month for several months. It is difficult to judge a change in the quality of the text just by reading it. Progress is always slow for children with Fragile X, which makes it harder to manually measure the small, incremental progress, if any.

4.2 Results

The child has been successfully providing language samples on her own without formal reinforcement. The language samples are reflective of her real life experiences and her current language abilities. We have been able to use the ASDF software framework to analyze individual posts and to compare posts against historical ones. There has been no significant change in the quality of her language over the last three months indicating that: (1) She continues to require language therapy, and (2) As anticipated, progress for children with Fragile X is very slow.

From a human factors point of view the software is easier to use than legacy systems. It only requires saving the samples as text files in a folder and then executing the program, which automatically scans the files, analyzes the text and outputs the results.

5 Conclusion

Sample Language Analysis is an important tool for Speech-Language Pathologists to assess the language abilities of children and adults with speech and language impairments. While important, its utilization has been limited due to several factors. Manual analysis of samples is not efficient and can only examine 1 or 2 metrics. Computer-aided analysis requires commercial PC-based software that is dated, not readily available and is capped in terms of the metrics it provides. It also requires other devices such as voice recorders and transcription tools.

We offer an open source framework based on the modern open source Natural Language Toolkit that can be used to analyze language samples. In addition to providing new metrics the open source nature of ASDF means that future metrics can be added easily to the software as researchers develop innovative methods to evaluate language samples. At this time, ASDF does not provide a historical data set for comparison. However, it does allow for longitudinal collection of data samples from the same clients, thus allowing SLPs to track change in each client's language abilities and progress over time.

While current approaches to SLA do not inherently limit the analysis to spoken language, that is the only usage mode in clinics and in published research. We propose that, for certain segments of the population that cannot provide spoken language samples for one reason or another, we can utilize modern social media to elicit samples in a written format. A single subject case study informs the ability to successfully collect language samples from social media posts from children otherwise unable to provide speech samples in a guided context.

The current software framework we built provides an easy to use tool for analyzing text; however, data files and result files need to be managed by the user. We are using ASDF as a building block leading to a more comprehensive web application that can act as a blogging platform in lieu of using social media while allowing clinicians, teachers and caregivers to analyze data overtime, perform longitudinal studies and compare results against larger data sets.

Beyond analyzing language samples, the authors are interested in characterizing the natural history of children with Fragile X and more generally on the Autism Spectrum Disorders. As such the ASDF framework can be further enhanced by pluggable modules that examine complex sentence structures and grammar to further study the evolution of the children's language abilities over time.

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Georeferencing in Logistics Transplant

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Abstract It is important to know the receiver's location in organ and tissue transplant procedure in order to optimize logistics of the transplant, allowing the preparation of the surgical procedure and the calculation of cold ischemia of the organ to be transplanted. This study refers to the first stage of this project that analyzes the usability of the geolocation system for the transplant system, allowing the sending of the location of the receptors for the medical staff; monitoring the location with the use of a map; offering multiple means of communication between the team and receiver. The methodology used was a survey, held in São Paulo/Brazil with 33 collaborators who used the tool for 90 days and evaluated the usability using the Usability Scale System. The partial results tests show that the usability meets the needs of collaborators.

Keywords Geolocation receiver · Logistics transplant · Usability · Organ transplant

1 Introduction

The transplantation is the only therapeutic option for patients with vital organ condemned, its procedure is consolidated worldwide and the demand for it follows an increasing trend due to this consolidation treatment throughout history transplants [1]. Transplantation involves the wrapping process, storage and transport of organs within a lead-time (execution time of a task) predetermined by ischemia time of each organ (time in which the organ is no vascularization), the ischemia leads to the obstruction of blood flow to peripheral tissues, which is known as the no-reflow

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phenomenon. This obstruction is progressive, with the formation of thrombi in the microcirculation, platelet aggregation, cell and tissue edema [2].

Data of Transplants Brazilian Registry about organ donation and transplants performed from January/September 2015 shows that São Paulo, Brazil, is one of the states that performs transplants with potential donors (2053), effective donors (635) and transplants in the country (57 %), there are 9234 subscribers of 18,948 potential recipients on the waiting list [3].

Receptors that are active in the list and are not hospitalized are waiting to be contacted for surgical procedure, and this is done by phone call, which cannot be completed. Another problem is to measure the viability of in a timely manner transplant taking into consideration the origin of receptor at the time of contact, because the patient who cannot supply precisely describes these coordinates. The need to shift the receptors-res to the hospital should be as soon as possible to ensure the quality of the organ to be transplanted. The Central of São Paulo transplant can trigger patient transport service if the patient has trouble shifting between the source and the destination or hospital that does the transplant.

The studied problem is highly relevant because 24 % of transplants are not performed for logistics [4]. Not hospitalized receivers waiting for telephone contact who go to the hospital transplant, the contact, however, cannot be established due to the weakness of this medium. Another problem is to decide on the viability of the transplant given the receiver's location, as it may be reported inaccurately and still be necessary to transport drive to the receiver.

Research in Design Science (DS) cites unresolved problems in a unique way, innovative or making the most efficient and effective solutions way, expanding scientific knowledge and contributing to new methodologies and Design Science Research (DSR) involves the creation of knowledge through innovative design or artifacts, as well as the analysis of the use [5].

Artifacts have been built to improve the Transplant System of the State of São Paulo [6, 7] with the transmission of the data donor to medical staff [8] to speed up the transplantation procedure.

2 Artifact

This artifact, software is to collect, process and present data of receiver's geolocation to the medical teams to support decision making on the time of use features such as the operating room, bed allocation care unit intensive, receiver transport service and the most important, cold ischemia time in order to succeed in organ transplantation. It was designed to be used on Android smartphone since version 2.3.3.

The software is designed to contact the receivers, by multiple means, alternatively the phone call and to determine the geolocation of these patients with regard to hospital transplant with greater accuracy in the collection and presentation of data and information to support logistics decision to transplant unfeasibility due to

insufficient travel time to drive means of transport to the patient or to support the shift feasibility inference by their own means. The following features have been built:

- Contact and geolocation receivers that have smartphone with Android operating system.
- Send and receive contact notification via application by (app) (Push Notification).
- Make phone call contact by app.
- Capture geolocation by app using selectively the best means available, such as GPS and Network.
- Present geolocation one or more patients in the form of map, as well as having numerically this representing an estimate of the patient's travel time to your hospital transplant and a numerical and graphical representation of the distance between the source and destination path, desirably with the best driveable way.

This device should be used by organ transplant recipients in Brazil, a country where the organ waiting list is only a state of the Federation, and whose priority order is determined by the degree of clinical severity, by as much as more severe the condition of the patient, the higher its priority in the queue. It is not considered the purchasing power of the patient to pay their treatment costs are financed by the National Health System, allowing access to treatment to patients from different social classes. Another feature that should be taken into consideration is that there is no age restriction for the registration on the waiting list, which must be taken into consideration for the treatment of human-computer interaction because the user experience and interface design should be as simple as possible.

3 Geolocation

Geolocation consists of associating a geocoding with the content of an item, thus this content may be traceable on the globe. The precision of the geolocation is desired, so it is preferable to know that a determined product is found in a street and specific number, only know that the product is in a city [9].

Currently, geolocation can be established with the use of a Global Position System (GPS) device that indicates its location based on satellite signals, or via WiFi Positioning System (WPS) which is to understand the distances between the devices and systems WiFi next to calculate your Positioning, more accurately [10]. Moreover, WPS system can identify the position of an element in areas where GPS does not have reach.

The user position identifying the GPS system occurs through the latitude and longitude coordinates, this information is forwarded via Web Service Representational State Transfer (REST) to the Central System, which shows the locations on the map through Google Maps the Application Programming Interface (API).

4 Usability

Conceived in 1990, the term User Experience (UX) has as objective encompass all elements that involve the user experience with a product or a company, its operating area, called User Experience Design (UX Design) studies how the creation and synchronization of these elements can affect the user experience in order to influence their perceptions and behavior. Given that competition, the high level of demand from users in the search for extreme quality and satisfaction that the products should provide you; and the complexity of the process and methodologies should be taken into account in UX steps [11].

The User Centered Design is the practice of considering the users' needs and desires at all stages of development of a product. Your goal is to understand all the possibilities to which the user is likely in the interaction with the product and understand your expectations during this process. An interface can be useful, but cannot too complex for a nonprofessional user [12]. Figure 1 depicts the steps of the User-Centered Design.

There are ways to measure both the usability and effectiveness of the system, a common scale is System Usability Scale (SUS), and been possible to ensure the usability of a more effective way system [14]. It was developed in order to provide an overview of the usability in user perception, subjectively with the application

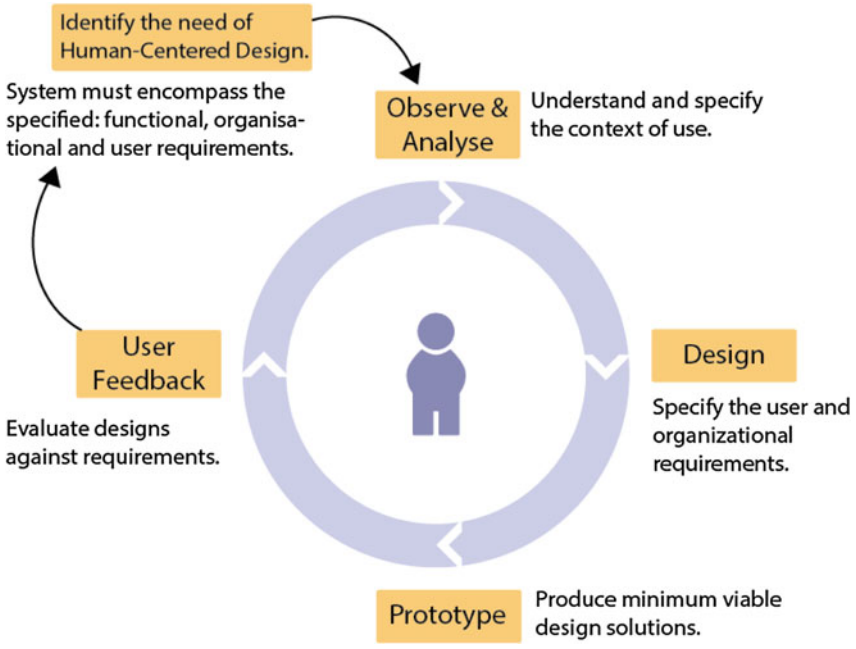

Fig. 1 User-centered design [13]

operation [15, 16]. The scale with 10 items was developed by Digital Equipment Corporation in 1986, and is based on three usability criteria, they are:

(a) user's ability to complete tasks using the system, and the quality of output of these tasks;
(b) level of resources required in performing the tasks;
(c) user satisfaction, measured by the subjective reactions when using the system.

The questions used in the SUS questionnaire are in Portuguese and are weighted with number of pairs answers, so that the respondent has half of the favorable responses alternatives and half opposed. The answers follow the Likert scale with five alternatives: strongly agree; I agree; indifferent; I disagree and strongly disagree.

5 Design Science Research

Design Science Research (DSR) produces four types of products: constructs, models, methods and instantiations, consisting of two basic activities such as construction and evaluation and the first is the artifact of the construction process for a specific purpose and the second is the process determination of how the device performs its function [17].

To use of the DSR is necessary formally the adoption these seven guidelines proposed by Hevner and Chatterjee [5]. The guideline is the definition of the artifact itself, with the first guideline defined in artifact item and the seventh guideline, research communication, is this article.

Guideline 2—Relevance of the Problem: In Brazil, spending on health care that represents 9 % of GDP [18] and transplants are financed with public funds. The failure rate in transplantations is around 30 % due to the refusal of authorization of the donor family. The remaining 70 % are due to logistical nature of problems [4].

Guideline 3—Artifact: The evaluation of the results of the DSR is based on accuracy requirements, performance, usability and artifact response time. This evaluation involves the integration of the artifact with the environment [12] with the evaluation of artifact usability by collaborators, students and professionals Information Technology (IT) as well as others who are not IT professionals. This article presents the results of usability tests that were conducted with the initial prototype, according to standard procedures described in usability testing literature. The artifact is not available in the Play Store. After registering with the project site, collaborators receive a login, password and the address to perform the download of the application for subsequent installation of the artifact. Once installed the artifact the participant should carry out the sign in geolocation system and remain with the application connected to the realization of location throughout the day. It was used for three months, being carried out monitoring of collaborators using historical location, in order to measure the accuracy of georeferencing. After this time, a

survey of cross-section was performed without considering the evolution in time with numerical nature of information in order to assess the artifact.

The data analysis was performed using Microsoft® Excel®, which were extrapolated according to weighted average SUS, the minimum and maximum of the answers.

Guideline 4—Contribution Search: The DSR should be able to provide three contributions: innovation, expansion of knowledge and importance of the artifact. This artifact undertakes to provide a breakthrough in transplant system with the transmission of geolocation receivers allowing improved logistics of transplantation.

Guideline 5—Rigor Search: The DSR requires the application of rigorous methods in the construction and evaluation. Data for Software Engineering is being adopts the like application of rigorous methods in construction and especially in the evaluation of the artifact. This is a project with user-centered design (DCU), with medical staff participating in the development of the location requirements. Initially not interviewed patients for issues related to anxiety in the transplant process and time in the development of the artifact. Usability is assessed with the System Usability Scale (System Usability Scale—SUS) [14]. After the evolution of the application of these tests, the step with the receivers will start.

Guideline 6—Design and Process: A survey requires knowledge of the application domain and the domain of the solution, and the artifact or his creative process, the best solution in a given space and time. The body of this article describes artifact geolocation solution to the receivers, which aims to reduce the lead-time in transplant service, and especially, the evaluation of the usability.

6 Outcome

Evaluation included 33 collaborators, 25 students of Technology Systems Analysis and 8 friends or family. In the group of friends or family members show different areas of school education. The student group presents the undergraduate course and all are digital natives. The group of friends does not have this feature. Among the respondents, 27 % are female representatives and 73 % are male.

The average was 66.43 on a scale of 0–100, with 27.5 the minimum score and maximum score 95, the higher the score, the better the usability of the application. Figure 2 shows a curve of the values of answered scores. Only four collaborators total score lower than 51, and 3 collaborators are not people connected directly to the IT field. This score is equal to F on a scale from A to F, A being the largest value.

Sixteen collaborators had their answers in the total score between 62 and 67, representing 42 % respondents, seventeen collaborators had their answers in the total score between 68 and 80 four respondents pointed responses totaling over 80.

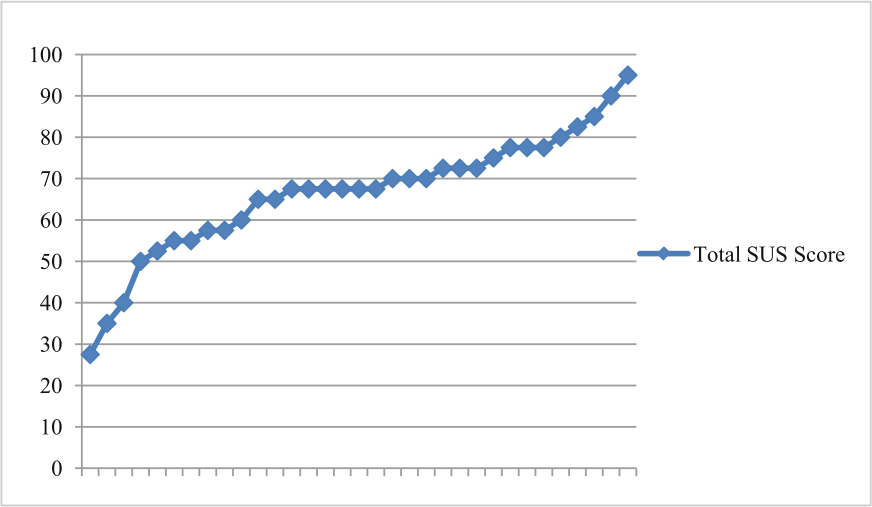

Fig. 2 Total SUS score

7 Conclusion

The artifact is not yet available in the Play Store, because it is in the testing phase. Collaborators should register on the project website to receive an email with instructions to download the application, which has represented a problem for some of them.

It was found that a difficulty for respondents was related to the operating system Android settings, such as turning on or off GPS, activity that required more user interaction with the application. Another difficulty reported by respondents was related to application installation permission that are not in the Play Store, hindering the installation process because many are not used to this type of installation.

The first analysis indicate that the artifact, although the score is 66.43, needs little improvements in the interface, improved installation because several collaborators reported difficulties in installation. Many collaborators requested that the tool warn them about the need for GPS status change, although the tool does not just use the GPS for location because, first will be performed research on the network and then use the GPS.

The results of the usability tests showed that the device was well accepted, but needs improvement in the login interface as a reminder of the password or request password change; improvement in the visualization of location data such as size and color of the characters. Collaborators positively reported the accuracy of geolocation them, for the artifact shows the smartphone screen location with address, neighborhood, city and state.

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Erratum to: Examination of the Validity of Anatomical Knowledge Associated with Daily Lifestyle Issues: A Comparison Between Perspectives of Anatomy and Nursing Researchers

Masaaki Takayanagi, Manami Nozaki, Reiko Mitsuya, Teruko Takayanagi and Fumi Sato

Erratum to:
"Examination of the Validity of Anatomical Knowledge Associated with Daily Lifestyle Issues: A Comparison Between Perspectives of Anatomy and Nursing Researchers" in: V.G. Duffy and N. Lightner (eds.), ***Advances in Human Factors and Ergonomics in Healthcare*****, Advances in Intelligent Systems and Computing 482, DOI 10.1007/978-3-319-41652-6_9**

The spelling of the author's family name was inadvertently published as "Takayanagil" instead of "Takayanagi" in the book. The erratum chapter and the book has been updated with the change.

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