Advances in Intelligent Systems and Computing 957

Nancy J. Lightner
Jay Kalra *Editors*

Advances in Human Factors and Ergonomics in Healthcare and Medical Devices

Proceedings of the AHFE 2019 International Conference on Human Factors and Ergonomics in Healthcare and Medical Devices, July 24–28, 2019, Washington D.C., USA

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Advances in Human Factors and Ergonomics 2019

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10th International Conference on Applied Human Factors and Ergonomics and the Affiliated Conferences

Proceedings of the AHFE 2019 International Conference on Human Factors and Ergonomics in Healthcare and Medical Devices, held on July 24–28, 2019, in Washington D.C., USA

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Preface

This book is concerned with human factors and ergonomics in healthcare and medical devices. 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 allow practitioners to gain a great deal of knowledge overall from this book.

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

Section 1 Patient Safety
Section 2 Healthcare Information Systems
Section 3 Healthcare Worker Risk
Section 4 Diagnosis Systems
Section 5 Medical Device Development
Section 6 Aging and Gerontology

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.

July 2019

Nancy J. Lightner
Jay Kalra

The original version of the book was revised: For detailed information see correction chapter. The correction to the book is available at https://doi.org/10.1007/978-3-030-20451-8_34

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Patient Safety

Towards a Deeper Understanding of Conceptual Models that Incorporate Patient Safety

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Abstract. Over the past decades, researchers, clinicians, and engineers have introduced many different conceptual models that incorporate patient safety. These models share similarities in some dimensions but may differ in others. A hermeneutic and natural language processing approach was utilized to interpret relevant literature on this subject. This descriptive account provides philosophical considerations that help to frame understanding of these models. The aim is to facilitate greater understanding of safety in health care.

Keywords: Patient safety · Conceptual models · Human factors · Language · Natural language processing · Hermeneutics · Philosophy of patient safety

1 Background

There are numerous models and frameworks developed to describe features and relationships within the domains of health care and patient safety. These models often integrate concepts, features, and relationships from multiple domains, including systems engineering and patient safety [1], information science and health information technology [2], communication science and patient safety [3], and cognitive sciences and diagnostic decision making and error [4]. The present work focuses on models and frameworks with the goal of facilitating further interpretation and understanding of the landscape of patient safety modeling.

Nilsen describes models as descriptive in nature and a simplification of a phenomenon and a framework as a structure or outline that describes concepts and relationships of empirical phenomena [5]. We recognize that there are differences and overlap in the contextual use of the words "model" and "framework" within the scientific literature. Our objective is not to attempt to clarify or dissect these contextual uses, but instead use them as a starting point in searching the literature towards collectively conceptualizing current thoughts in patient safety.

Tapping into our existing library and knowledge of models and frameworks that relate to patient safety, we meditate on our current understanding of the landscape. Then we identify and collect models and frameworks from the literature, extract features, and explore concepts, relationships and reflect on potential themes. By applying hermeneutic and text analytic approaches, similar to those described, respectively, by

The original version of this chapter was revised: a few typographical errors were corrected. The correction to this chapter is available at https://doi.org/10.1007/978-3-030-20451-8_34

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Boell and Cecez-Kecmanovic [6] and previously by the authors [7] in exploring the literature, we hope to facilitate a deeper understanding of this landscape.

We turn to Nersessian [8] to locate a path towards conceptualization by designing and exploring visual representations and analogies in the spirit of thought experimentation. We expand upon this pathway by exploring language models and visualizations.

With this approach, we aim to add to the conversation and facilitate understanding of the value, the constraints, and the trade-offs that are described by these models and frameworks related to safety. This process may provide insight into ergonomics features and relationships and greater understanding into thoughts surrounding human factors principles applied to the health care domain. In addition, Rokach's [9] work with ensemble methods in pattern classification may provide a parallel in the exploration of ensemble and nested analogical models that may share characteristics with the study of patient safety.

The focus of this work is to unite these models into a common discussion of abstraction and patient safety rather than attempt to draw particular conclusions regarding the models. Our hope is that sharing these reflections and this journey will provide an environment of discovery for exploring and discussing models, frameworks, and opportunities related to the discipline of patient safety.

2 Approach

2.1 Walk Through the Literature

A hermeneutic approach was utilized to walk through the literature. Hermeneutics has been described as the philosophy of the interpretation of text. Sherratt [10, p. 91] interpreted Gadamer's view, discussing how access to the hermeneutic circle is necessary for understanding to occur through "admittance to tracking back and forth between the parts and the whole, constantly projecting and revising our understanding." Boell & Cecez-Kecmanovic [6] described a hermeneutic framework as a substitute or supplement for the systematic review of literature. The authors discussed how all relevant texts need not be identified, but reading relevant texts "will facilitate the quest for further relevant literature" [6, p. 133].

A natural language processing (NLP) approach with exploration of subsequent interactive visualizations was paired with a hermeneutic approach for guiding reflection. The purpose of incorporating an NLP approach was to facilitate the identification and interpretation of relevant texts through the examination and exploration of interactive language models.

Our primary objectives are to attempt to capture steps as we proceed, although this account fails to describe all conceptualizations, conversations, and backtrackings. Throughout, we attempt to interpret and reinterpret conversations regarding conceptual models and frameworks that incorporate safety and formulate broader questions.

First, a quick sample of publications as a starting point was extracted from PubMed. We searched and extracted titles and abstracts that included "patient safety" and ("model" or "framework"). Other forms of the same lexeme, such as "models" or "frameworks" or other forms of the word "model" when used as a verb, such as "modeled", "modeling", and so on were excluded from this initial search. Titles with "patient safety" and ("model" or "framework") were extracted as a subset.

Probabilistic latent semantic analysis (pLSA) was performed on this subset to assemble sets of words into text clusters to assist in visualizing themes. The resultant text cluster word co-occurrence network is shown (Fig. 1). This visualization facilitated, or seeded, the beginning of this thought experiment. System, model, level, study, research, culture, climate, social, personal, report, review, incident, concept, classification, ontology, and insurance are a few words that we picked up on that appeared to be central in this representation. This was in line with our initial preconceptions of this topic. In our analysis, this representation is interactive (word context can be explored and reflected upon); the static form provided here is a limitation of publishing.

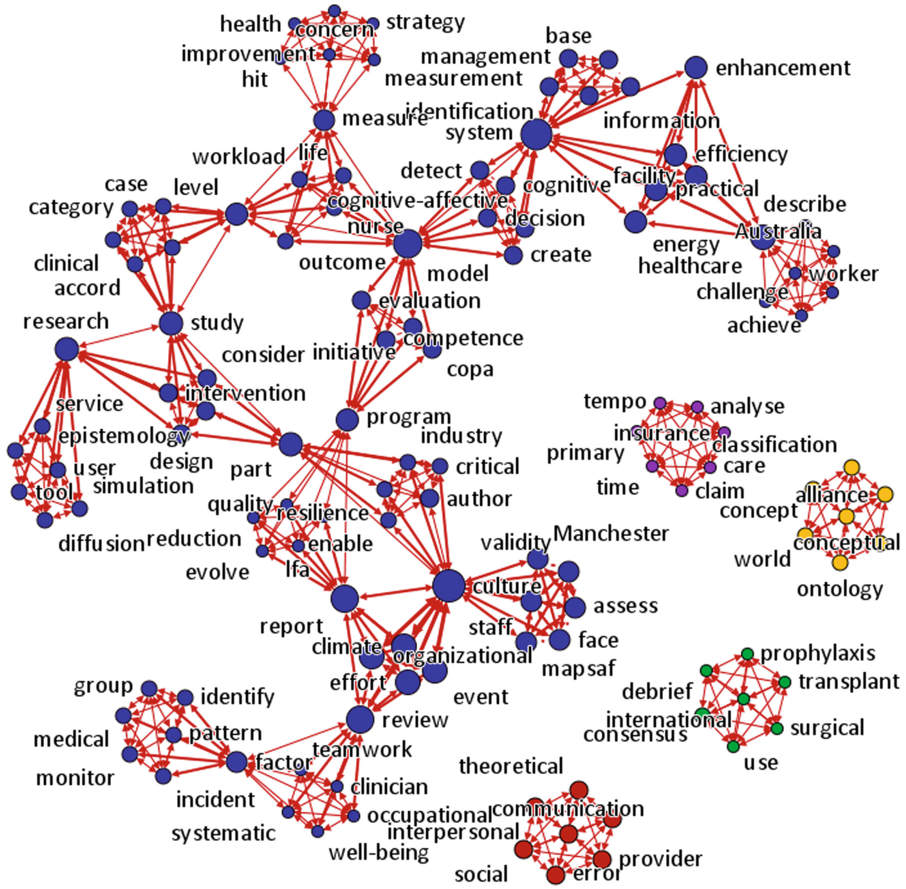

Fig. 1. Example text cluster word co-occurrence network for exploring titles from PubMed that included "patient safety" and ("model" or "framework"). This network visualization was created using PolyAnalyst™ (Version 6.5.2030; Megaputer Intelligence) [11].

An expanded extraction of the literature was performed in PubMed and Google Scholar, with the search terms in themselves constraining the text returned. The study of safety science has historically been an interprofessional endeavor; therefore, there are relevant publications in the fields of ergonomics, engineering, computer science, and cognitive science that are not indexed in PubMed. Extracting abstracts and titles from PubMed is a simpler task. We recognize limitations to both techniques [12]. Also, we recognize that the presence of the search terms provided did not guarantee that the publication discussed conceptual models or frameworks that incorporate safety. Conversely, papers may not use these search words in the title or abstract, but they may appear later in the full text or the authors may present these concepts using a synonym or similar notions. Through manual interpretation and multiple interactive visualizations that focus on context, we hoped to filter out publications outside the scope of this review.

The PubMed extraction was expanded to include the following combinations of terms within the title or abstract: “patient safety” and (“model” or “models” or “framework” or “frameworks”). A total of 3,918 articles were extracted utilizing this search strategy. Total publications were aggregated by year of publication. Annual aggregations were represented as a percentage of total annual publication (Fig. 2) using annual Medline trends (http://dan.corlan.net/medline-trend.html).

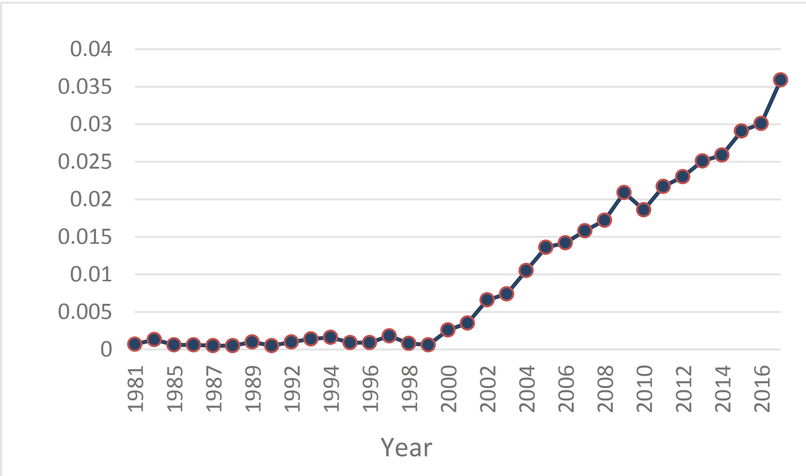

Fig. 2. Titles/abstracts in PubMed that contained patient safety and (model/s or framework/s) as a percentage of the total number of annual publications as a function of year.

Acronyms and initialisms were extracted as a strategy to begin to identify individual models and frameworks named in the title/abstract collection. This task was performed in parallel with text clustering to bring forth themes and provide context. Text clustering was performed utilizing pLSA.

In correlation with these tasks, full publications were retrieved subjectively for review. Retrieval of full publications was not restricted to the 3,918 extracted from PubMed.

Full publications were retrieved and reviewed based on subjective assessment. Reviewed publications could include publications within the PubMed extract, citations included within those previously reviewed, subsequently published articles that cite those retrieved, and any other relevant publications the authors identified.

Multiple approaches utilizing text analytics were explored. Sentiment analysis, semi-supervised classification, and text clustering techniques were used to explore the text of the PubMed extract. As titles/abstracts and full publications were reviewed, we subjectively and iteratively conceptualized ideas and captured thoughts while curating a list of words and phrases associated with the publications. Thoughts, models, and concepts were collected in a journal over a two-month period (e.g., Fig. 3).

System, model, level, study, research, culture, climate, social, personal, report, review, incident, concept, classification, ontology, learning, curriculum, education, location, clinical sub-domain, clinical role, descriptive, prescriptive, veteran, layer of abstraction, framework

Fig. 3. Words and phrases collected from the reviews of the models.

Numerous approaches to NLP and interactive visualization of language models were applied; examples of processing tasks and resultant artifacts are shown in Tables 1 and 2. Initialisms and/or acronyms were extracted using sequential regular expressions and were subsequently reviewed in context. Initialisms are provided in an example list of models and frameworks proposed in health care and patient safety (Table 1). From the titles/abstracts, descriptors and relationships surrounding the word "model" in the form of verbs and adjectives were extracted along with different word-forms of the lexeme "model." Text clusters were then extracted from this subset and clusters were subsequently reviewed in context. Text clusters are provided in Table 2.

2.2 Interpretation

Through further exploration and interpretation of the literature, we observed the following features that were repeated in multiple articles.

1. The questions of "What can go wrong?" (also described as an epidemiological accident model or Patient Safety I) vs. "What can go right?" (also described as a resiliency-based model or Patient Safety II)
2. Nomothetic (universalism) vs. idiographic (relativism)
3. Natural sciences vs. humanities as a means for inquiry
4. Descriptive vs. prescriptive. Models in the context of the PubMed extract tend to be descriptive, whereas frameworks tend to be prescriptive
5. Interprofessional nature of the study and application of patient safety operations.

This walk through the literature brings us to Rasmussen's article "Risk Management in a Dynamic Society: A Modelling Problem," [13] which was identified external to PubMed. Rasmussen's visualization of the merging of science models and relation to

Table 1. Examples of acronyms and/or initialisms that refer to models or frameworks extracted from the large PubMed text corpus of titles/abstracts.

Model or Framework Name	Initialism
Model repository framework	(MRF)
Circle of Care Modeling	(CCM)
Model linking workplace bullying	(WPB)
Outcomes and Performance Assessment Model	(COPA)
Business Process Model and Notation	(BPMN)
European Excellence Model	(EFQM)
Prevention, appraisal and failure model	(PAF)
Model predictive controller	(MPC)
Common-Sense Model of Self-Regulation	(CSM)
Ottawa Model of Research Use	(OMRU)
Model of Communicative Proficiency	(MCP)
Effort Reward Imbalance model	(ERI)
Logical framework approach	(LFA)
Theoretical Domains Framework	(TDF)
Consolidated Framework for Implementation Research	(CFIR)
Human Factors Classification Framework	(HFCF)
National Patient Safety Education Framework	(NPSF)
Emergency nursing assessment framework	(ENAF)
Team Strategies and Tools to Enhance Performance and Patient Safety	(TeamSTEPPS)
Yorkshire Contributory Factors Framework	(YCFF)
Quality and Outcomes Framework	(QOF)
Unified Ontological Framework	(UOF)
Framework of design thinking	(DT)
Framework of a computer-aided diagnosis	(CAD)
Theoretical Domains Framework Implementation	(TDFI)
Common Training Framework	(CTF)
Systems Engineering Initiative for Patient Safety	(SEIPS)

safety features provided fundamental concepts in facilitating the trajectory of this discussion. It is of no surprise that multiple features share similarity with observations already described. There are multiple possible explanations for similarities between our observations and features described by Rasmussen. Two additional lines of questioning are drawn from Rasmussen's article. (1) What is missing from the study and application

Table 2. Text clusters extracted from the large PubMed text corpus of titles/abstracts that contained the word stem "model." Text clusters were created using PolyAnalyst™ (Version 6.5.2030; Megaputer Intelligence) [11].

Cluster #	Cluster name
#1	new, base, provide, describe, include, patient, establish
#2	use, modeling
#3	logistic, develop, adjust
#4	conceptual, explore
#5	linear, examine
#6	identify, predictive, transformational
#7	hierarchical, evaluate, multilevel, modelling
#8	mixed, generalize, linear
#9	good, demonstrate, exist
#10	model, simulate, enable
#11	mental, share, consider
#12	theoretical, present
#13	show, allow, acceptable
#14	clinical, serve, promote
#15	predict, high, several, provide
#16	propose, dynamic
#17	multivariable, fit, use
#18	random, perform, work
#19	educational, utilize, combine

of patient safety or in other words where do future opportunities lie? Are there disciplines underrepresented in this work and could they provide insight in the form of concepts and analogies? (2) Which references might facilitate a deeper understanding of these questions? We address the latter question now by retrieving and reviewing two publications, one referenced by and one that references Rasmussen [13]: "The Hermeneutics of Accidents and Safety" [14] and "Reflecting on Jens Rasmussen's Legacy. A strong program for a hard problem" [15].

Taylor [14] provides a philosophical discussion and explanation of hermeneutical inquiry into the study of safety, particularly road safety. He describes the limitations of the doctrine of mechanism as applied to the study of accidents and safety pointing to the humanities as an alternative or supplement in our path towards understanding. Taylor suggests accidents are meaningless events and thus, "It is difficult to link the antecedents of accidents with their consequences, because exactly similar events can lead to widely different consequences (the property of 'divergence' noted in catastrophe theory)" [14, p. 491]. His discussion suggests that the study of accidents from an epidemiological perspective will always be necessary but should not overshadow or supplant other approaches of inquiry into safe operations.

Dekker [16] discusses the constraints to an epidemiological accident model and describes the solution space as framed in such a way that it incrementally increases system complexity and fragility. He describes Reason's Swiss Cheese Model as a barrier accident model, with discussion of its value and limitations [17]. The model's high visual impact aids understanding, but it may be embraced too liberally and suggest overly simplistic solutions. Looking at safe operations through an epidemiological lens promotes the layering of barriers, likely at the risk of increasing system complexity and introducing new vulnerabilities. Morel and colleagues [18] offer a compelling argument that introducing constraints, such as barriers, to facilitate safe operations comes with considerable cost to self-managed safety or system resiliency.

From the perspective of value, does the barrier model foster a collective understanding and facilitate a step in the collective evolution of safety thinking in a move past our initial response in blaming a person? This brings us to Rogers [19] and his thoughts on the diffusion of innovation, including the collective complexity-simplicity continuum and trialability. Does the evolution of accident models represent a step in the evolution of patient safety, in which we migrate incrementally and collectively from blaming the human to blaming the system? Is it possible that a next step in this evolution will be a move collectively from an epidemiological accident model, in which we blame some aspect of the system, to some hybrid and in flux with what Hollnagel [20] and Dekker [17] describe as the resiliency-based patient safety II model?

Is the act of assigning blame rooted in the emotion of doubt in some system component? How do doubt and hope in the system frame our understanding of system design and dynamics? Can we hold doubt in one hand and hope in the other? Both emotions can be strong motivators, both can be experienced semi-simultaneously. For example, we may have doubt about some micro-component of the system, but hope in the macro-level entity prevails. How might temporary emotional states and views through a longitudinal lens frame system understanding and subsequent solutions or redesign, individually and collectively?

We go back to this idea of the cultural evolution of safety and system thinking. Collins and colleagues [21] discuss the benefits and limitations of blame and self-blame in medical culture. Suggested benefits of blame in medical culture are incentivization to learn, the facilitation of empathy and sympathetic behavior between colleagues, and the fashioning of beliefs that human intervention has some influence over natural processes. If blame and self-blame are beneficial and interwoven into the fabric of medical culture, perhaps this is an antecedent to a preponderant view of patient safety through the lens of an epidemiological accident model.

3 Discussion

We have grouped this discussion section into sections of broader questions, with the understanding that associations exist between sections. This approach was for purposes of working through this back-and-forth feature of hermeneutic inquiry and making some sense of all of this.

3.1 Learning

A subjective account of characteristics associated with the study of patient safety has been provided throughout this conversation. Many of the models and frameworks extracted from PubMed share concepts discussed by Rasmussen, Reason, Hollnagel, Wood, Dekker, Cook, and many others.

How do we monitor for unintended consequences of change and the introduction of vulnerabilities even with the good intention of promoting safety? Do we assume safety? Before a drug is introduced to the market, the US Food and Drug Administration requires rigorous studies into safety and efficacy; after introduction, manufacturers must conduct post market surveillance.

Are there other approaches and analogous models that may expand the collective understanding of patient safety? What might new ensembles or nesting of approaches in science and the humanities look like? What can the study of patient safety learn from history and the study of safety? What opportunities still lie in wait, and what can we still learn from the humanities and natural sciences, including biology, philosophy, ethics, linguistics, history, religion, law, anthropology, and the arts?

3.2 Biological Models

Throughout the historical study of safety, few biological models have been tapped into for purposes of analogical reasoning. Rasmussen uses the model of Brownian motion (applicable to cellular biology) to describe how, "Under the presence of strong gradients behaviour will very likely migrate toward the boundary of acceptable performance" [13, p. 190]. Gibson's work on the "Ecological Approach to Visual Perception" [22] has been instrumental in fashioning the world of safety science.

Which biological models are being used to facilitate analogical thinking in the domain of patient safety? Biological models may provide important considerations that are helpful in modeling life and systems with the primary purpose of sustaining life. Micro to macro models of biological systems from the cellular to the ecosystem level may provide new lenses through which to view the problem space of patient safety. Can and how can the discipline of patient safety learn from the eusocial behavior of hymenopterans, biosemiotics, or other biological models?

Two examples of models that may transfer across domains were identified. Lyons and colleagues [23] provide a framework for a virtual environment for collaborative learning of scientific phenomena of complex adaptive systems. This shares similarities with collaborative clinical simulation training environments but with a primary focus of emphasizing learning of multilayered phenomena and the influence of slight changes to and adaptation of the system. Simulated environments of this sort could be designed with the intention of facilitating understanding of complex adaptive interactions and interdisciplinary problems at the management and organizational level. Interaction with environments of this type could promote health systems learning about collaborative behaviors and insight into distributed cognition.

Chandrasekaharan and Nersessian [24, 25] describe a video game called "Foldit" that is designed to harness collective human ingenuity in the exploration and discovery of novel protein-folds. This strategy taps into the distributive cognition of experts and novices. In this example, a young novice's designs were described as superior to experts in the field. Similarly, collectively harnessing the power of novel and expert minds for exploring a problem space could be beneficial to the discipline of patient safety. Quinn & Bederson [24, 25] go on to describe a similar approach as "distributed human computation"; this harnesses a network of human computational power in collaboration with computers. Virtual environments designed to model organizational features, processes, and relationships and adaptation of these systems may provide learning environments for individuals and organizations in capturing the collective power of imagination.

3.3 Linguistics and Computational Linguistics

How have linguistic models, frameworks, and NLP been incorporated in the conversation on safety or explored in analogical fashion? NLP has been frequently described in facilitating the classification of patient safety reports [26, 27]. There are numerous publications that describe ontological or taxonomic frameworks regarding information science that incorporate patient safety. Many ontologies described in the large PubMed extract attempt to represent features of an epidemiological approach to patient safety; others describe the design of clinical ontologies with safety in mind. De Bie [28] described the development of meta-models for dynamic clinical checklists as well as an approach for automating technological adaptation.

In our preliminary reflections and interpretations, NLP approaches tended to be descriptive in nature but may inform the design of ontologies and taxonomies. Ontological and taxonomic frameworks tended to be normative or prescriptive.

The authors previously [29] described an approach for facilitating learning and local language awareness amongst design teams during co-production efforts within the level of Rasmussen's [13] socio-technical model. The authors also described an approach for recycling local language use for use in local design [29]. Has linguistic inquiry been utilized to describe the distributive language features of the literature of safety and patient safety as a discipline and compared to other disciplines such as philosophy? Have we described the collective language of patient safety and changes in this language over time? Have we compared these features with the languages of other disciplines and cultures? Can they be mapped? Can different sublanguages and languages provide a new angle in which to inquire into and visualize the study and application of patient safety?

3.4 Philosophy

Through our review and interpretation of the PubMed extract, there was limited discussion of the intersection of philosophy and patient safety. Of those articles reflected upon internal and external to the PubMed extract, when philosophy was discussed it was often viewed through the lens of the philosophy of science. Taylor [14], Ilgen [30], and Bryan [31] all look at patient safety through an expanded view of philosophy. Taylor [14] highlights the limitations of a "mechanistic model of man" and provides a philosophical discussion on the relevance of hermeneutical inquiry into the meaning of background features associated with accidents. Gadamer [32, p. 39] discusses ideas of "mechane" and technology, writing, "Among all the sciences concerned with nature the science of medicine is the one which can never be understood entirely as a technology, precisely because it invariably experiences its own abilities and skills simply as restoration of what belongs to nature." In "Truth and Method", Gadamer [33, p. 49] discusses the doctrine of aesthetic ideas and interprets Kant on the harmony between imagination and understanding: "Genius is ultimately a manifestation of this vivifying spirit for, as opposed to the pedant's rigid adherence to rules, genius exhibits a free sweep of invention and thus the originality that creates new models." Finally, it seems notable that missing from the PubMed extract of 3,918 titles/abstracts and subsequent query of full texts is the word "imagination."

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An Interactive Device for Reducing Risk of Infusion Therapy and Blood Transfusions

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Abstract. Administration of high-risk medications and transfusion of blood components are routinary medical procedures that can be potentially harmful to patients due to a set of multifaceted factors, such as, conservation of the medical product, poor asset tracking, and human errors. Although they represent a very small percentage of adverse events, errors and complications associated with transfusion and infusion therapy can cause major morbidity and death.

In the recent years, several reporting initiatives and intervention measures led to the adoption of dedicated processes and tools designed for preventing errors, reducing the associated potential damage, and increasing patient safety. Nevertheless, statistics and reports of incidents demonstrate that infusion and transfusion therapies still demand more effective solutions. In this paper, we introduce an innovative interactive system that aims at reducing risk by taking into consideration human factors that are involved at bedside, such as, fatigue, stress, attention, and cognitive load. Specifically, the proposed solution consists in an attachment that locks a medical container in the prescription phase and prevents access to its content and administration unless all the safety conditions as met. In addition to enforcing safety with a physical barrier, it operates as a visual management tool throughout the process and, specifically, at bedside, where most incidents occur.

Keywords: Risk prevention · Hemovigilance · Pharmacovigilance · Patient safety

1 Introduction

Blood transfusion and infusion therapy are common medical procedures that contribute to saving millions of lives every year; also, they increase life expectancy and improve the quality of life of patients suffering from medical conditions or undergoing surgical interventions. Specifically, over 2 billion blood transfusions and high-risk drug infusions are realized in Europe and United States yearly [1]. Although they involve several risk factors, most of them result in little to no harmful consequences on patients. Nevertheless, despite adverse events happen in a very limited number of cases, blood transfusion and infusion therapy result in 7 million adverse events every year. Primarily, incidents are caused by the conditions of preservation of the medical product and its handling (e.g., labeling, integrity of the container, expiration date, and conservation

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temperature). Moreover, risk factors are determined by processes realized over a long supply chain involving multiple stakeholders, steps, and procedures [2], which complicates incident reporting and root cause analysis. Furthermore, equipment accounts for a variety of risk factors [3]. However, for the most part, common incidents are the result of administering the medical component to a different patient, at a wrong time, and with an incorrect dosage [4]. Typically, these types of adverse events are caused by human errors related to distraction, excessive cognitive load, and stress, and mainly occur at the so-called last mile, that is, in the Intensive Care Unit or at bedside [5, 6].

Although consequences vary depending on the cause and type of the event, incidents result in prolonged hospitalization and temporary or permanent conditions, which include several types of disability. Many studies have reported incidences between 0.02 to 0.05 percent, though risk is substantial even if the proportion of patients who experience adverse events is negligible. Moreover, errors, such as, overdosage or transfusion of incompatible blood type, directly or indirectly account for 7000 deaths every year, in the US alone [1].

In addition to consequences affecting patients, adverse events related to blood transfer and administration of drugs cost 600000 US dollars in compensation on average, and they collectively lead to a yearly expenditure of more than 40 billion US dollars [7]. Furthermore, incidents have an impact on the perceived quality of service of the specific hospital involved in a case as well as the entire Health System. Consequently, the World Health Organization and major organizations focusing on Patient Safety started encouraging private and public hospitals to adopt and comply with adverse events policies to reduce the number of incidents, their damage, and their consequent financial and reputation burden [8]. Also, the US Food and Drug Administration, as well as other agencies worldwide, started hemovigilance programs aimed at standardizing definitions, collecting data, and developing prevention measures to ultimately reduce deaths and adverse events [9]. Nevertheless, several studies in the context of blood transfusion [10, 11] unveiled major under-reporting concerns especially in case of reactive incident monitoring. Therefore, many stakeholders advocate for systems that address risk proactively through the whole supply chain and especially in the phases where adverse events are most likely to occur.

Specifically, as root cause analyses established the crucial role of bedside care, research focused on developing prevention measures for last-mile transfusion and infusion practices, as they heavily rely on human attention [12]. To this end, several technical solutions have been developed over the last decade to detect and mitigate errors. Pre-administration controls using standard checklists or electronic tools have been tested in transfusion therapy [13] and they are transferable to infusion therapy as well. However, they do not prevent errors caused by forgetfulness: accidentally skipping the required control does not stop the clinical staff from accessing and administering the medical component. Other solutions, based on safety containers equipped with locks that aim at restricting access to medications or blood components [14] introduce additional tasks that might increase risk, or complicate operations.

In this paper, we describe an innovative hardware/software system that takes into consideration human factors occurring at bedside. By doing so, the proposed system aims at helping hospitals reduce adverse events and their associated costs, increasing the overall quality of treatment, and improve compliance by enforcing safety and error reporting. We discuss the hardware architecture of the system, that consists in an Internet of Things device that can be attached to a medical container to prevent access to its content. Moreover, we detail its workflow and user interface, which are especially designed for simplifying integration with clinical procedures and, simultaneously, for reducing distraction and other risk factors related to cognitive load. Finally, we discuss the benefits of the proposed system in terms of risk reduction and improvement of staff work.

2 Related Work

In the last decade, several research groups studied transfusion and infusion errors and obtained a taxonomy of adverse events and their causes [15]. This, in turn, enabled root cause analyses that led to the development of guidelines and prevention programs (e.g., the Serious Hazards of Transfusion initiative [16]) aimed at enforcing patient safety throughout the entire process. The adoption of end-to-end electronic transfusion management systems is among the most fundamental practices implemented by hospitals [10], and it supports establishing controls and restrictions that enforce safety of blood and high-risk medication [17]. Also, closing the loop between reactive incident reporting and proactive safety measures [18] has a critical importance in infusion and transfusion therapy [19], as it helps make sense of the data that are being collected.

In addition to studying how to increase quality in the management banks of medical components, the authors of [20] investigated the use of formal methods for automatically analyzing Standard Operating Procedures and predicting the potential occurrence of mode confusion (i.e., misinterpretation of information in the system, execution of inappropriate actions while realizing an activity, and omission of crucial steps of a task), which, in turn, are known to increase the risk of adverse events. Although ensuring the formal correctness of clinical processes improves clinical outcomes and reduces ambiguity, does not prevent risks that are especially related to human factors.

Indeed, the last mile, that is, the bedside or the Intensive Care Unit, is the phase in which errors are most likely to occur and, simultaneously, the last line of defense. Thus, the implementation of several intervention measures especially focused on requiring additional controls at the very endpoint of the process. Several measures aim at ensuring that the administration of the medical component occurs only after verification and confirmation of conditions, such as, the correctness of the component, dose, patient, time, and place [21], as a minimum set of required controls. Paper-based and electronic systems for realizing pre-transfusion and pre-infusion checks have been tested in numerous hospitals and result in significant improvement. The authors of [13, 22] developed an electronic identification system based on Radio Frequency Identification (RFID) that enables verifying the correspondence between the identity of the patient and the blood component before administering a transfusion, and they devised recommendations and guidelines for electronic controls at the bedside.

Unfortunately, patient identification systems alone are not sufficient for reducing risk related to the condition and integrity of the medical product and for preventing other causes of adverse events (e.g., overdosage). Moreover, as they do not prevent physical access to the blood or medical component, they might fail in enforcing safety controls before the therapy is administered to the patient. Conversely, pervasive solutions consisting of attachable devices that can track assets or individuals along clinical processes [18, 23] seem to be more effective. Specifically, the authors of [24] presents a system for equipping blood bags with sensors locking and tracking the medical component, whereas [25] introduces a smart system that uses patient wristbands to verify that the prescription matches the recipient of an infusion or transfusion therapy before unlocking the container of the medical component.

3 System Design and Architecture

In this Section, we describe the hardware and software architecture of the proposed solution, and we detail the design of its main components. The system consists of a device that can be attached to different types of containers for blood and medications to lock their content and prevent access to the medical component, so that it cannot be administered until the necessary safety conditions have been verified. Completing the required controls unlocks the device, which enables removing the attachment from the container and accessing the medical content. As a result, the system acts as a smart barrier that has the purpose of enforcing safety checklists currently utilized in the Intensive Care Unit or at bedside.

The hardware component of the system consists of an electromechanical device that can be applied to different types of containers (e.g., blood bags, medication packages, drug dispensers, and blister packaging) to follow them throughout the different steps of the process, from the prescription phase to administration. Its design was structured according to a modular architecture similar to the device described in [26]. To this end, it is structured in two parts, as shown in Fig. 1: a central unit and an accessory. The former controls the operation of the system and, specifically, activates and deactivates a lock depending on whether all the safety checks are positive. The accessory has the purpose of preventing the staff from the medical component by creating a physical barrier that blocks the opening of the container.

The central unit contains all the intelligent components of the system. Specifically, it includes a microcontroller for operating the device, an internal memory storage, a rechargeable battery, a set of LED lights that have the purpose of providing visual information about the type and status of the required security controls, a set of switches for confirming safety checks, an actuator that opens or closes the locking mechanism. The latter can consist in a small motor or in an electromagnetic clamp that secures both endpoints of the accessory and prevents their removal from the central unit.

The electromechanical components are designed to be enclosed in a water-resistant plastic container so that the central unit be reused after appropriate cleaning procedures. Each LED indicates a necessary safety check (e.g., patient identification) that must be realized before the container can be unlocked, and a corresponding switch enables marking the condition as verified. When all the switches and LEDs indicate that the checklist is complete, the central unit releases the lock, so that the accessory can be removed from the central unit and it can be opened and removed.

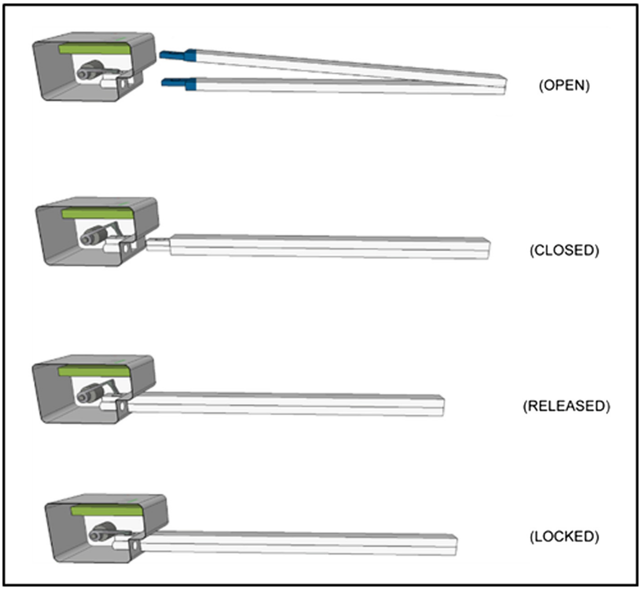

Fig. 1. Overview of the proposed system in different configurations: a standard attachment enables connecting the central unit (on the left) to the accessory (on the right) and preventing access to the medical content. Accessories can be customized to be utilized with diverse medical containers in in different shapes and materials.

Additionally, the central unit can incorporate communication systems for interconnecting the system with external devices and exchanging information with them. As a result, the system can be integrated with end-to-end blood and medication management systems, as well as with asset-tracking software. Furthermore, the system supports adding sensors for monitoring variables (e.g., temperature) that can impact the quality and integrity of the medical component in the different phases of the process.

The attachment has the sole purpose of preventing physical access to the component. By doing this, the system enforces patient safety checks and prevents human factors, such as, fatigue and stress, from causing events that could lead to errors (e.g., checking the wrong bag or skipping some checks). The device was initially designed for securing blood bags. As shown in Fig. 1, the attachment consists in two rigid arms that create light compression on the bag and stops the blood from accessing the intravenous lines. However, the shape and material of the accessory can vary depending on the type of container (as described in Fig. 2), so that they can be utilized with different medical components, such as, injection syringes, various types of pill and medication dispensers, and even larger containers (e.g., organ transport coolers). Also, different types of custom locking accessories can be realized to match the size and shape of specific containers. For instance, an elastic rubber band can be utilized for capsule containers and other types of dispensers. Regardless of the type of accessory, the standard attachment located at the endpoints provides a universal adapter, so that the central unit can be utilized with multiple containers. Accessories can consist of reusable or disposable medical grade material. The system supports manual overriding if standard procedures for unlocking the device fails or in case of malfunction. Overriding events can be tracked by the central unit, to report any failure or attempt of tampering with the system.

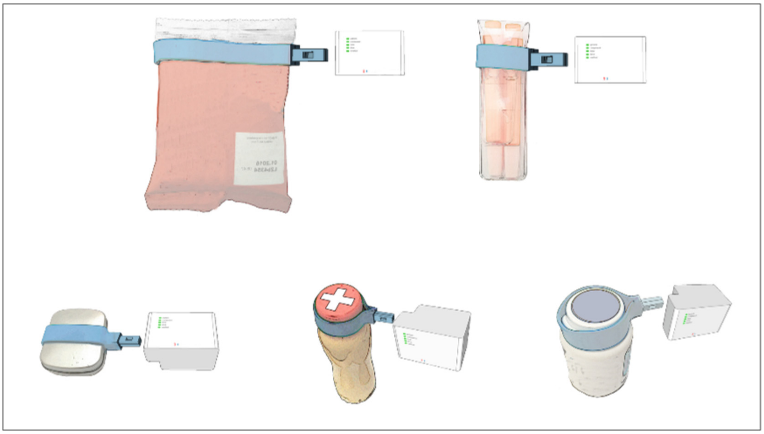

Fig. 2. The proposed system applied to different types of containers, such as, injection syringes and blood bags (on the top), and various types of pill and medication dispensers (on the bottom).

The system intervenes at the beginning of transfusion and infusion procedures: when a new request for medical component is received, the specialist responsible for dispensing it (e.g., hematologist) applies the appropriate accessory that matches the medical container and activates the locking mechanism by inserting it in the slot of the central unit. As a result, the LEDs indicating the safety checks show a red light to signal that the container will be locked until all the items are cleared. When the container arrives at the ward, some items can be pre-checked and ticked off (e.g., integrity of the medical product, or correct dose) by activating the corresponding switches. Finally, the personnel administering the infusion or transfusion can realize the last controls (e.g., correct patient), which releases the accessory.

4 System and Human Factors Evaluation

In order to evaluate the applicability of the system, we involved members of the clinical staff to join the design since the initial phase. Specifically, we analyzed current Standard Operating Procedures for infusion and transfusion therapy and we mapped the entire process from request to administration. Our analysis focused on understanding the human factors occurring in each step of the infusion and transfusion supply chain with the objective of identifying the items that contribute the most to increasing the occurrence of human errors.

The first step is the prescription phase, in which a medical component for a specific patient is requested to the dispensing unit (e.g., the internal blood bank of a hospital). Nowadays, management systems enable to automatically verify the correspondence between patient information (e.g., blood type) and the type of blood or medication that is being requested, and they help prevent most of the errors that are caused by distraction, interpretation of handwriting. As a result, the proposed system would not apply to this step. Nevertheless, the device can be effective in addressing other factors, such as, preservation of the medical component, that involve hazard for the patient: by attaching the system to the container when the medical product is packaged, the propose device can collect information that would otherwise be difficult to track (e.g., temperature).

Subsequently, the request is received by the internal blood or medication storage ward and the medical component is retrieved, checked, labeled, and dispensed. In this step, the staff experiences some degree of cognitive load that is directly proportional to the type and complexity of the procedure, which may vary depending on the organization. Moreover, in general, cognitive load is directly proportional to the number and rate of requests in a given time frame. Errors in this step are caused by simultaneously processing multiple medical products: when two prescriptions are served in parallel, the operator can swap containers and dispense the wrong one. In this context, the proposed system alleviates the issue: applying the device to a container and locking it helps the staff identify the medical components that have already been processed. By doing this, the proposed solution acts as a visual management tool that labels requests that are ready to be dispensed and helps the staff separate them from medical components that are in the queue.

The same type of issue impacts the next phase of the process, when the medical component reaches the destination ward and the clinical staff realizes preliminary controls: as multiple blood bags for different patients can simultaneously be transported on the same cart, some containers could be accidentally checked twice, whereas others could be skipped. By activating the switches on the central unit of the device, the staff can change the status of a container; the presence of LEDs and the implementation of a traffic-light system helps easily identify the items that have been processed. In addition to helping distinguish the components that have been verified, the central unit acts as a visual tag that enables the staff in the next phase to detect if a step was missed.

Finally, when the container reaches the last mile, preventing physical access to the medical component before all the necessary safety checks are successfully realized has a three-fold purpose: (1) enforcing the checklist and its importance, (2) creating a sequential check-unlock-administer pipeline that prevents process parallelization (main cause of incidents occurring due to accidentally swapping container), and (3) recognizing the status of the container in the pipeline, so that the medical component that has been checked can be identified as ready to be administered.

As a result, the system simultaneously acts as a physical barrier and as a visual management tool. In this regard, the device is designed to address two key principles that underpin every stage of the administration process, that is, positive patient and component identification and support to communication. Moreover, instead of changing the process and requiring the adoption of a specific technology for verifying patient safety requirements as detailed in [13], the proposed solution is agnostic about the specific procedure and checklist utilized for infusion and transfusion therapy. Consequently, it can seamlessly integrate with current clinical processes and achieve higher level of acceptance from the clinical staff. Although the system focuses on reducing risk of erroneous administration of blood and high-risk medications by specifically taking into consideration several adverse events caused by human factors involved in the last mile, it addresses patient safety from the initial steps. Furthermore, by visually tagging a medical container and changing its status along the process, the device can help recognize errors and prevent them from propagating further.

5 Conclusion

In this paper, we discussed a solution that is especially designed to reduce errors due to human factors during the last mile of the administration of an infusion or transfusion therapy, that is, at bedside or in the Intensive Care Unit, where most of adverse events that can be prevented occur.

To this end, the proposed system consists of an interactive hardware device can be attached to any blood bag or pharmaceutical container to lock it and prevent access to its medical content unless verification of necessary safety conditions succeeds (e.g., correspondence of patient, time, and dosage). Before administering the medical component, the system requires the staff to execute a multi-factor safety check that can unlock the container and enable access to its content.

Specifically, the purpose of system is to target the most critical phase and prevent adverse events in the last mile, with specific regard to human errors. Nevertheless, as blood and high-risk medication have a long supply-chain, the system is designed to integrate with end-to-end infusion and transfusion management processes and systems used by hospitals and blood centers [10]; moreover, it can incorporate additional sensors and data transmission devices that can enable connecting and communicating with external devices and software systems, track the entire process, and provide the clinical staff with asset management features that simultaneously enable doctors and nurses to assess and report about the quality and integrity of the medical component.

The system has several advantages from a human factors standpoint: it was designed to be extremely simple to operate and to seamlessly integrate with current procedures; it does not introduce any complexity other than attaching and removing the accessory from the medical container. Moreover, the modular attachment architecture supports using a single interface with many different types of medical products and containers, whereas other systems are specifically targeted for a single purpose and their adoption requires the staff to learn and use multiple different products.

Indeed, the proposed solution is potentially subject to the same limitations of other technology, that is, the introduction of an additional step, which might result in unexpected risk elements that ultimately affect patient safety. Therefore, in our follow-up work, we will study applications of the proposed system in different scenarios, in hospital settings and at home, to evaluate its effectiveness in actually preventing adverse events.

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Medical Error Disclosure - A Canadian Perspective in Improving Quality of Health Care

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Abstract. Disclosure of an adverse event is an important element in managing the consequences of a medical error. The objectives of this study was to review and compare the disclosure policies implemented by individual health care authorities and hospitals in western Canada. The evaluation of the policies of individual health authorities was carried out based on the inclusion of various guidelines including avoidance of blame; support to the staff; an apology or expression of regret; avoidance of speculation; some form of patient support; and education/training to health care workers. The complexities of medical error disclosure to patients present ideal opportunities for medical educators to probe how learners are balancing the ethical complexities involved in error disclosure with other related fields. We suggest that the disclosure policies can provide framework and guidelines for appropriate disclosure that can lead to practices that are more transparent.

Keywords: Medical error · Adverse event · Disclosure · Quality · Patient safety

1 Introduction

1.1 Medical Error

The quality of health care is an emerging concern worldwide [1]. Problems surrounding the delivery of quality health care persist and require careful attention and resolution. Several studies, including "Defining Patient Safety and Quality Care" [2] and "Why quality in healthcare" [3] suggest that medical error is bound to occur if quality is mismanaged. Medical error has received substantial attention in recent years [4–6]. Disclosure of an adverse event is an important element in managing the consequences of a medical error. Bates *et al.* define an adverse event as "injuries that result from medical management rather than the underlying disease" [7]. In any health care process, exposure to an adverse event is inevitable [8, 9]. When a situation requiring

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disclosure arises, physicians realize that disclosure should take place. However, they face overwhelming hurdles and/or are unsure about if and how to disclose errors. It is estimated that between 98,000 and 440,000 deaths in the United States of America are caused by medical error each year, making it the third leading cause of death [10]. Baker *et al.* estimated that hospitalized Canadians have a 7.4% chance of experiencing an adverse event and that 38% of adverse events are preventable [11]. Disclosure policy is therefore a crucial component in creating a health care culture that revolves around safety.

1.2 Barriers for Disclosure

Reluctance to admit medical errors and to disclose errors to patients and their families is prevalent in the current health care system. Past research has shown that approximately three out of four physicians who have failed to disclose error to a patient [12]. This lack of disclosure may be due to various barriers faced by physicians when attempting to disclose an incident of medical error. Barriers include fear of litigation, broken patient-physician relationships, and degraded professional reputation [13]. It is common practice for hospital lawyers to advise physicians against timely admissions of errors to avoid legal ramifications. Broken patient-physician relationships create additional challenges to the process of disclosing medical errors. Perceived consequences of disclosing errors include loss of respect and trust from patients and reduced patient compliance in future encounters [14]. Modern health care culture has allowed the threat of malpractice litigation to become common practice. While these barriers may be well founded, they add difficulty and complexity to the task of disclosing adverse events in medical practice.

1.3 Benefits of Disclosure

Despite various challenges and implications, disclosing medical errors to patients and their families an essential component of quality health care on both ethical and pragmatic grounds [15, 16]. Failure to appropriately disclose medical errors is of ethical concern as it compromises the autonomy of the patient [17]. Failure to provide information to patients hinders their ability to provide informed consent and to make informed medical decisions. The fact that part of the physician-patient process involves medical consent implies that being denied information will severely impede the patient’s ability to act within his/her best interests. Policies directing appropriate disclosure of a medical error limit breaches of trust and safeguard the therapeutic relationship [18].

Although concern of litigation following the disclosure of medical error is a major concern, lack of disclosure may further increase risk. Studies have reported that failing to properly explain and communicate medical errors increases the risk of malpractice litigation [19]. O’Connor et *al.* demonstrated that honesty and openness with the patient can help improve the relationship between the two parties [20] reducing the legal strain to follow. From a practical standpoint, it has been suggested that patients expect full disclosure of harmful errors, but are concerned that health care workers will not provide this information [21]. Consequently, studies have shown that disclosing the medical error in a prompt and open manner enhanced patient trust in the physician by fulfilling a need that the patient did not expect to be fulfilled [22].

1.4 International Disclosure Policies

Various countries around the globe have developed policies surrounding disclosure of medical error [23–25]. Canada is lagging behind in comparison to other nations when it comes to setting national disclosure policies and procedures. The United States (US) Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has mandated open disclosure of any critical event during care to either the patient or their family [26]. This has become a critical component for accreditation at medical institutions. The Australian policy integrates the disclosure process with a risk management analysis toward investigating critical events [27]. In 2003, the National Health Services (NHS) in the United Kingdom directed physicians to inform a patient of an act of negligence or error that causes harm following their "duty of a candour" declaration [28]. In New Zealand, the patients suffering a medical error are rehabilitated and reimbursed through a no-fault, state-funded compensation scheme. Patients' rights and the providers' duties are set out in a code of consumers' rights, which applies to all providers of health [29].

1.5 Canadian Disclosure Policies

In Canada, through the Colleges of Physician and Surgeons, various provinces have adopted some form of a disclosure policy while others are in the process of developing such policies. Many provinces have failed to enact legislation that enforces the disclosure of adverse events, and even fewer offer protection against malpractice lawsuits after a medical error. The Royal College of Physicians and Surgeons has endorsed the disclosure of adverse events, including medical errors, to all partners including patients [30], but no uniform Canadian guidelines are yet in place. Provinces of western Canada have adopted various forms of a disclosure policy and though these initiatives are similar in content, they remain isolated because of their non-mandatory nature and absence of federal or provincial laws on disclosure. The College of Physicians and Surgeons of Saskatchewan requires the physician to disclose any medical error to the patient or his or her family as soon as possible during care [31]. Manitoba's provincial government has complemented the province's medical policy by legislating that physicians have a duty to notify patients or their families of critical incidents resulting from medical errors [32]. British Columbia is the only province that has adopted laws that prevent apologies for medical errors from being referenced in courts for proving liability, although doctors are not obligated to disclose adverse events [33]. The purpose of this study was to examine and compare the medical error disclosure policies implemented by the individual health authorities and hospitals in the western Canadian provinces; Saskatchewan, Manitoba, Alberta, British Columbia, and to identify trends and possible areas of quality improvement.

2 Methodology

Disclosure policies for adverse events in the health authorities and hospitals in western Canada were collected and compared. Contact information was obtained from the health authority websites. A standard email was sent to every health authority in western Canada requesting a copy of their disclosure policy or a reply stating there was no policy in place. Various authorities responding indicated that there would be changes to their policies in accordance with the Canadian Patient Safety Institute (CPSI) upcoming release of revised guidelines. Of the authorities that replied, only one did not have any policy in place.

The aspects we chose to compare within medical error disclosure policies were: who should disclose, when disclosure should take place, whether an apology was included in the policy, mention of provider support, mention of provider training, mention of avoidance of blame, avoidance of speculation, support for the patient, as well as any unique characteristics of individual policies. Six components were identified that are critical for any medical error disclosure policy. Although these are all important features, we have taken the liberty to rank them in order of importance as summarized in Table 1. This is done in the hopes of providing the best guidelines for the development current and future medical error disclosure policies.

Table 1. Critical components of disclosure policies in order of importance

Feature	Order of importance
Expression of regret or apology	1
Patient support	2
Avoidance of blame	3
Support for health care provider	4
Training	5
Avoidance of speculation	6

3 Results

In reviewing and comparing the medical error disclosure policies across the western Canadian provinces, most policies did not differ regarding who should disclose and when the disclosure should be done.

In the province of Saskatchewan there are 13 health authorities. We received policies from 92% (12/13) of the health authorities. Of the policies we received, 82% mention the absence of blaming statements, 45% state that health care providers and staff involved in the disclosure process should have support available to them, 73% include an apology or expression of regret in the disclosure process, 100% mention some form of training or education for the staff, and 77% of the policies included patient support. Only 18% of policies made mention of training or education for the members involved in the disclosure discussion. During the study period in 2012–2016, there were 13 health authorities in the province of Saskatchewan. Currently, the 13 authorities have amalgamated into a single unified Saskatchewan Health Authority.

In Alberta, there is only one health authority that governs all hospitals in the province. We found this policy described regret as a critical component of the disclosure discussion. Overall, the policy was found to be quite complete, including mention of support for providers and training, the avoidance of blame, training or education for the staff, avoidance of speculation, and patient support (Fig. 1).

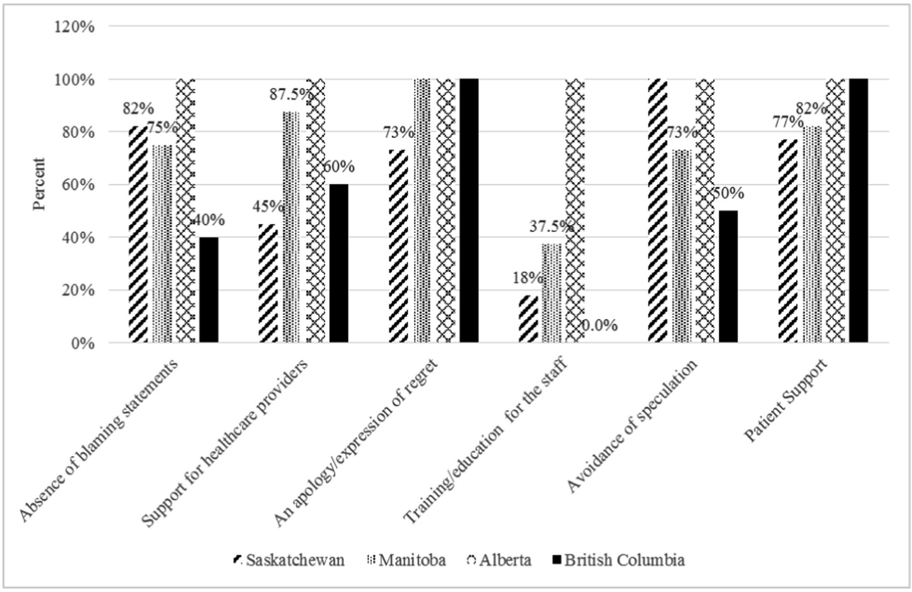

Fig. 1. Percentage of each component found in the disclosure policies of each of the western Canadian provinces.

For the province of Manitoba, there are 11 health authorities. We received 81.8% (9/11) of the health authorities' policies. Of these policies, 87.5% included support for providers, 100% included an apology or expression of regret, 75% included avoidance of blame, 73% included the avoidance of speculation, and 82% included patient support in the policy. Only 37.5% of the received policies include training for those involved in disclosure. In one of the policies in Manitoba, it listed to address the clinical and emotional needs of the client and staff involved as priority on the procedure process, making it the only policy in all of western Canada to do so.

British Columbia has six health authorities. We received 83% (5/6) of the policies from these health authorities. All (100%) of the health authorities responded to our email and have a policy in place. However, one policy was under revision and was not sent to us. All of the policies included the need to apologize or express regret, 60% included provider support, 40% included avoidance of blame, 50% included the need to avoid speculation, and 100% included some form of patient support. None of the policies in British Columbia included providing some form of training or education for the staff.

4 Discussion

We have previously reported various Canadian provincial initiatives in medical error disclosure and have suggested that adequate policies be an integral part of the institutional accreditation process [31, 34–36]. The results of the present study have allowed us to identify six components that are critical for any medical error disclosure policy. Although we believe that they are all important features, we have taken the liberty to rank them in order of importance to establish the best guidelines for current and future medical error disclosure.

The expression of regret or an apology to the patient and their family is the most important component of medical error disclosure policies. The CPSI guidelines indicate that when a patient receives a statement of apology, it often leads to a restoration of the patient-physician trust [37]. It is important to begin the disclosure of a medical error with an apology or expression of regret as it allows for a better relation to be established serving as a gateway to open and honest discussion.

The second most important component of a medical error disclosure policy is support for the patient. This is particularly important following the occurrence of a medical error as patients are in their most vulnerable state. Provision of support for a patient offers a chance to strengthen the patient-physician relation.

The avoidance of blame and support for the provider go hand in hand and have been grouped together as the next most important components of a medical disclosure policy. Health care providers receive little support after an adverse event [38]. The CPSI advises support to anyone involved in an adverse event and/or disclosure discussion [37]. Lack of support for health care providers can potentially have similar negative consequences as the lack of support for patients [39]. The avoidance of blame is another way in which to provide support for those involved. By providing support for those involved, we can foster a culture that is non-punitive and adheres to a no-fault model of care.

The inclusion of training for those involved is critical to medical error disclosure policy. We encourage facilities to develop disclosure discussion and training workshops for new and current staff to attend. Many policies in western Canada do not currently include the provision of training for their staff. Provision of training is necessary to avoid the re-occurrence of a medical error. Currently, the inclusion of training for those involved in disclosure is the feature most often omitted in disclosure policies of the health authorities in western Canada.

Lastly, the avoidance of speculation is crucial to disclosure policy. Physicians and patients should both avoid speculation as it might create unwanted and avoidable strain. Only sufficient and correct knowledge should be used to speculate the cause and factors leading to a medical error. In this way, no individuals will be wrongfully blamed for an error which adheres to a non-punitive and no-fault model.

The inclusion of these critical components in medical error disclosure policies will allow for more uniform policy creation and the avoidance of medical error ramifications. These consequences include the possibility of malpractice litigation, broken patient physician relationships, and ethical implications on the health care team [40, 41].

5 Conclusion

Malpractice continues to be a growing issue for those practicing in health care [42]. Legal action being taken against these individuals is usually ill intended and relies solely on the gains of monetary compensation creating an inappropriate use of the tort system. Although justice for an error is required, the method through which it is carried out must promote honesty and full disclosure. This makes the disclosure to patients an ideal opportunity for medical educators to probe how learners are balancing the ethical complexities involved in error disclosure. The designing of an error disclosure policy requires integration of various aspects including bioethics, physician-patient communication, quality of care, and team-based care delivery. It is important to provide support to health care workers and emphasize an expression of regret within disclosure policies. Moreover, the training for proper disclosure is crucial and staff members must be made aware of the resources and training available to them. We suggest a greater inclusion of the Canadian provincial initiatives in the hopes of implementing a uniform policy that is directed towards disclosure of error through an honest and non-punitive approach. Making disclosure of error a pillar in the health care industry, will raise the quality of care being given which will in turn protect the health and autonomy of patients. The other challenge lies in achieving a balance between a non-punitive approach to error and the need for a process that includes accountability and suitable compensation for patients. We suggest that this balance can be achieved by a system-based error disclosure programme which would better allow us to serve as the protectors of the health and autonomy of patients. We believe that the disclosure policies can provide framework and guidelines for appropriate disclosure that can lead to practices that are more transparent. We suggest the improvement of disclosure practice by creating a uniform policy, centered on addressing errors in a non-punitive manner and respecting the patients' right to an honest disclosure and as part of the standard of care.

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Pattern of Postural Sway of Diabetic Peripheral Neuropathy People

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Abstract. Diabetic peripheral neuropathy can cause a loss of sensation in the feet, leading to impaired stability of body balance, and resulting in a risk of falls or slips. In the literature, a considerable number of studies have reported that people with diabetic peripheral neuropathy tend to have trouble keeping posture stable when the equilibrium of body balance is disturbed, even when standing quietly. In general, many studies found differences of postural stability between people with diabetic peripheral neuropathy and without neuropathy. However, little research has been done to find a difference of sway patterns between them. The objective of this study was to characterize the pattern of body sway for finding an effect of peripheral neuropathy on postural control when the stability of posture was disturbed. Pattern of body sway was investigated in terms of placement of center of pressure over the four quadrants during several time intervals such as quiet standing before a perturbation, during the perturbation, and after the perturbation. No significant difference of patterns of body sway was found between diabetic people with and without peripheral neuropathy during quiet standing and for most of considered perturbation directions at low velocity of perturbation. However, when the velocity of perturbation increased, a significant difference of placement of center of pressure was found from the third and fourth quadrants.

Keywords: Diabetic neuropathy · Postural sway · Perturbation

1 Introduction

It is fundamental to keep the center of gravity of the body within the base of posture during gait to avoid a stumble caused by losing balance of posture. When posture stability is disrupted by an unexpected external perturbation, it is necessary to detect its instability by coordinating visual, vestibular, and somatosensory functions and then to regain posture stability. Sensory function of the feet is one of primary components for controlling posture. Diabetic peripheral neuropathy has been known as one of causes of degenerative foot sensation [1]. Damages on large and small fibers of the lower extremity can degrade its ability of proprioception and result in declined postural control [2]. Thus, people with diabetic peripheral neuropathy tend to be at higher risk of falls or slips [3].

Relationship between capability of postural control and diabetic peripheral neuropathy has been investigated in the literature. Postural control is evaluated in terms of

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body sway under a speculation that the better postural control, the less body sway. Body sway is assessed by observing floor reaction force under the feet on a platform, called center of pressure (COP). One of the following metrics has been used to analyze center of pressure: range of COP, area of COP, velocity of COP, and virtual time to contact boundary of stability. Two posture standing conditions are considered: quiet standing and disturbed standing. A disturbed standing is simulated by moving a platform. In general, diabetic people with peripheral neuropathy tend to have a larger range of COP, area of COP, and velocity of COP in quiet standing condition [4–8] and disturbed standing condition [7–11], and lower time-to-contact stability boundary [12–16]. When applying a range of COP to find a difference between diabetic groups with/without peripheral neuropathy, no significant result compared to previous studies has also been reported [17]. However, when the range of COP is considered separately by a perturbation period and a recovery period, it is possible to find a similar result like previous studies [18].

In the literature, difference of postural control between diabetic people with and without peripheral neuropathy has been investigated from the perspective of longitudinal and/or accelerated center of pressure during body sway, but not from placement of center of pressure over quadrants of base of support for posture. In this study, pattern of placement of center of pressure was explored to find a difference of body sway characteristics between diabetic people with/without peripheral neuropathy during quiet standing and disturbed standing.

2 Methods

2.1 Participants

Upon an approval of IRB informed consent two participant groups were recruited, that is, diabetic with peripheral neuropathy (DPN) and diabetic without peripheral neuropathy (DNN). A set of questionnaires was used to determine whether the recruited volunteers were eligible for this study before further participations. Questionnaires included history of cardiovascular or neurological disease, orthopedic surgeries or constraints, any degenerative eye condition such as glaucoma, cataracts, blood pressure greater than 160/90 mmHg, and BMI greater than 37.5 kg/m^2.

2.2 Peripheral Neuropathy Testing

Each participant went through two sensory threshold tests to measure the grade of diabetic peripheral neuropathy. The sensation of five separate points on the plantar surface of each foot, that is, the first distal phalanx, the first, third, and fifth metatarsal heads, and the calcaneus was evaluated using the Semmes-Weinstein monofilaments (North Coast Medical, Inc. Morgan Hill, CA) and Biothesiometer (Bio-Medical Instrument Co., Newbury, OH). The Semmes-Weinstein monofilaments tested the sensation threshold by increasing the size of the monofilament until participants felt the monofilament applied to the testing point. When participants felt the monofilament at below 5.07 g of pressure, participants were considered non-neuropathy [19].

The Biothesiometer testing applied a tip of electrode to the testing site and increased the voltage slowly until participants felt the vibration. The sensory threshold for Biothesiometer testing was 25 V for participants to be considered non-neuropathy [20]. When at least one of the five testing sites on the plantar surface of each foot did not meet the sensation threshold from the two administered tests, participant was classified into peripheral neuropathy group.

2.3 Instruments and Protocol

The placement of center of pressure (COP) during body sway was collected using a force platform that was controlled by NeuroCom Research Module (Natus Medical Inc., Clackamas, OR). Stability of posture was disturbed by applying an external perturbation for participants to sway more than in quiet standing. Four directions and two velocities were considered to make a perturbation. Four directions were anterior, posterior, right lateral, and left lateral, and two velocities were 10 cm/s and 20 cm/s. For preventing participants from any incident of falling during perturbations, upper body of participant was harnessed to an overhead bar of the platform. Two trials were administered for each direction and velocity of perturbation using random orders. The time window for collecting data from each trial was five seconds and divided into three phases, such as (1) quiet standing on the force platform for a half second, (2) a half second long perturbation, and (3) four seconds of recovery. After filtering raw data using a low-pass filer at 20 Hz, placement of COP over the four quadrants was found according to x and y coordinates of COP using MATLAB (MathWorks, Natick, Massachusetts).

2.4 Data Analysis

Two hundred points of COP placements were collected for one second and proportion of placement of COP in each quadrant was calculated for the considered time phases above. Results of two trials for each perturbation were combined to estimate COP placement's proportion for each quadrant. Figure 1 showed the four quadrants over the base of posture support. The duration of experiment time (5 s) was divided into six periods as follows: (1) period 1: quiet standing (0.5 s), (2) period 2: perturbation (0.5 s), (3) period 3: recovery period from 1 s to 2 s, (4) period 4: recovery period from 2 s to 3 s, (5) period 5: recovery from 3 s to 4 s, and (6) period 6: recovery from 4 s to 5 s. Difference of proportions between the two groups for each period was compared

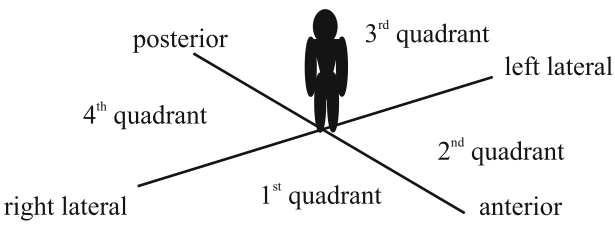

Fig. 1. Four quadrants over the base of posture support

with two-sample t test (two-tailed) at the significance level of $\alpha = 0.05$ from the perspective of perturbation direction and velocity of platform for the perturbation.

3 Results

3.1 Physical Characteristics and Peripheral Neuropathy

Fourteen participants (7 DPN and 7 DNN) were recruited and analyzed for this study. Basic physical characteristics were summarized and compared between the two groups. No significant differences of physical conditions were found with p-values as summarized in Table 1. But, when comparing sensory thresholds from the two administered tests, the diabetic group with peripheral neuropathy showed significantly higher threshold values for the both foot than did the group without peripheral neuropathy for both tests as shown in Table 2.

Table 1. Physical characteristics of participants.

Measures	DPN	DNN	p-value*
Age (years)	51.86±12.8	49.57±7.2	0.69
Height (cm)	176.00±13.8	164.23±5.9	0.06
Weight (Kg)	98.67±14.8	82.81±10.3	0.03
BMI (kg/m^2)	32.00±4.9	30.69±3.3	0.57

*: $\alpha = 0.05$

Table 2. Results of peripheral neuropathy tests.

Sensory test	Foot	DPN	DNN	p-value*
Semmes-Weinstein Monofilaments (g)	Right	5.23±0.7	4.17±0.2	***0.002***
	Left	5.23±0.8	4.09±0.1	***0.004***
Biothesiometer (V)	Right	26.49±12.4	5.30±2.1	***0.001***
	Left	18.28±13.0	5.95±2.2	***0.03***

*: $\alpha = 0.05$

3.2 Placement of Center of Pressure

Placement of COP over the four quadrants was investigated for three phases such as (1) quiet standing on the force platform for a half second, (2) a half second long perturbation, and (3) five seconds of recovery.

Period 1: Quiet Standing. Two groups did not show any significant difference of proportion of COP placement over the four quadrants. The proportions during quiet standing before a perturbation was applied in different directions and velocities were summarized in Table 3. In general, the natural sway of body during quiet standing tended to lean to backward (posterior) more than forward (anterior).

Table 3. Difference of COP placement rates (%) between two groups for period 1.

Direction	Velocity	10 cm/sec				20 cm/sec			
	Quadrant	1st	2nd	3rd	4th	1st	2nd	3rd	4th
Anterior	DPN	0	5.5	61.6	32.9	6.1	3.1	33.1	57.7
	DNN	0	1.5	48.5	50	0	0.4	66.3	33.3
	p-value	n/a	0.49	0.48	0.36	0.36	0.41	0.13	0.27
Posterior	DPN	0	0	58.2	41.8	0	0	31.4	68.6
	DNN	0	0	63.1	36.9	0	11.4	52.2	36.4
	p-value	n/a	n/a	0.78	0.78	n/a	0.16	0.24	0.07
Right-lateral	DPN	1.4	5.7	44.4	48.5	0	0	52.8	47.2
	DNN	0	7.1	43.5	49.4	0	0.8	63.5	35.7
	p-value	0.33	0.88	0.96	0.97	n/a	0.33	0.55	0.53
Left-lateral	DPN	6.1	0	51.3	42.6	0	0	46.1	53.9
	DNN	0	4.1	45.9	50	0	7.1	28.6	64.3
	p-value	0.33	0.33	0.77	0.69	n/a	0.33	0.32	0.56

*: $\alpha = 0.05$

Period 2: Perturbation. No significant difference of COP placement rates between diabetics with neuropathy and without neuropathy groups was found in all directions at the low perturbation (10 cm/s). It was interesting to note that COP placement rates were almost equal among the four quadrants for both groups only when the perturbation was applied in backward. In other directions, more placement rates were observed in the quadrants that were reactive directions to perturbation directions, e.g., more placement rate on the third quadrant that other quadrants for rightward perturbation. DPN showed higher placement rates on the third quadrant than DNN when the perturbation was given in the rightward at high velocity (20 cm/s) only (Table 4).

Table 4. Difference of COP placement rates (%) between two groups for period 2.

Direction	Velocity	10 cm/sec				20 cm/sec			
	Quadrant	1st	2nd	3rd	4th	1st	2nd	3rd	4th
Anterior	DPN	0	1.1	55.9	43.0	1.9	0	47.3	50.8
	DNN	0	0.3	49.4	50.3	0	1.0	64.1	34.9
	p-value	n/a	0.49	0.66	0.64	0.36	0.31	0.34	0.37
Posterior	DPN	28.3	25.5	24.3	21.9	36.0	29.2	14.7	20.1
	DNN	13.2	23.6	40.7	22.5	16.1	32.8	34.2	16.9
	p-value	0.09	0.86	0.15	0.97	0.07	0.75	0.08	0.69
Right-lateral	DPN	0	7.1	86.2	6.7	0	0	96.4	3.6
	DNN	0.3	11.6	81.3	6.8	0	4.9	88.5	6.6
	p-value	0.33	0.68	0.66	0.97	n/a	0.16	***0.05***	0.32
Left-lateral	DPN	0.5	0	9.1	90.4	0	0	5.0	95.0
	DNN	3.0	1.1	11.1	84.8	6.3	0.7	1.9	91.1
	p-value	0.42	0.33	0.67	0.42	0.11	0.33	0.16	0.47

*: $\alpha = 0.05$

Period 3: Recovery from 1 s to 2 s. During the recovery period right after a perturbation, DNN swayed toward the fourth and third quadrant more than did DPN when the perturbation was applied in anterior and posterior direction, respectively, at high velocity. No significant difference of placement between two groups was found in other conditions (Table 5).

Table 5. Difference of COP placement rates (%) between two groups for period 3.

Direction	Velocity	10 cm/sec				20 cm/sec			
	Quadrant	1st	2nd	3rd	4th	1st	2nd	3rd	4th
Anterior	DPN	7.2	27.0	39.7	26.1	9.2	14.4	44.8	31.6
	DNN	6.3	10.6	38.8	44.3	3.7	0.8	27.1	68.4
	p-value	0.86	0.12	0.94	0.17	0.47	0.15	0.29	***0.03***
Posterior	DPN	3.1	11.1	51.7	34.1	23.4	23.1	27.1	26.4
	DNN	2.5	5.4	63.2	28.9	8.0	15.1	54.0	22.9
	p-value	0.79	0.23	0.40	0.72	0.06	0.34	***0.04***	0.76
Right-lateral	DPN	1.7	5.3	25.8	67.2	11.2	8.6	43.2	37.0
	DNN	15.0	4.8	25.1	55.1	6.2	4.4	31.5	57.9
	p-value	0.11	0.91	0.94	0.34	0.45	0.46	0.22	***0.03***
Left-lateral	DPN	12.4	3.3	63.1	21.2	2.9	2.6	54.4	40.1
	DNN	0	3.9	70.6	25.5	2.6	9.1	60.5	27.8
	p-value	0.11	0.87	0.42	0.52	0.93	0.24	0.55	0.21

*: $\alpha = 0.05$

Period 4: Recovery from 2 s to 3 s. In the middle of recovery period after a perturbation, no significant difference of placement of COP in all four quadrants between two groups was found under the considered conditions (Table 6).

Table 6. Difference of COP placement rates (%) between two groups for period 4.

Direction	Velocity	10 cm/sec				20 cm/sec			
	Quadrant	1st	2nd	3rd	4th	1st	2nd	3rd	4th
Anterior	DPN	4.6	8.3	55.5	31.6	1.7	1.1	49.4	47.8
	DNN	0	0.9	41.0	58.1	0	0	53.1	46.9
	p-value	0.33	0.31	0.42	0.13	0.36	0.36	0.86	0.96
Posterior	DPN	1.9	2.8	43.8	51.5	5.8	10.4	33.2	50.6
	DNN	0	5.0	67.6	27.4	1.4	1.8	63.8	33.0
	p-value	0.33	0.55	0.13	0.13	0.21	0.23	0.07	0.29
Right-lateral	DPN	0	7.1	26.2	66.7	0	0.6	55.4	44.0
	DNN	0	10.1	56.0	33.9	0	14.3	39.3	46.4
	p-value	n/a	0.78	0.07	0.06	n/a	0.17	0.37	0.89
Left-lateral	DPN	4.7	3.2	39.3	52.8	5.8	2.4	36.9	54.9
	DNN	0	2.9	49.8	47.3	0	0	44.8	55.2
	p-value	0.08	0.93	0.53	0.74	0.29	0.32	0.63	0.98

*: $\alpha = 0.05$

Period 5: Recovery from 3 s to 4 s. As the recovery period approached to a status of stabilized posture, two groups showed a significant difference of COP placement. Particularly, when the perturbation was applied in anterior direction at low velocity, diabetic group with peripheral neuropathy swayed less toward the fourth quadrant than did diabetic group without peripheral neuropathy. It was interesting to note that two groups showed opposite likelihood of COP placements between the third and fourth quadrant when the perturbation was applied in right and left lateral directions at high velocity, that is, more placement in the third quadrant for DPN in right-lateral perturbation direction, but more placement in the fourth quadrant for DNN in left-lateral perturbation direction (Table 7).

Table 7. Difference of COP placement rates (%) between two groups for period 5.

Direction	Velocity	10 cm/sec				20 cm/sec			
	Quadrant	1st	2nd	3rd	4th	1st	2nd	3rd	4th
Anterior	DPN	4.4	8.1	61.2	26.3	4.2	3.1	41.6	51.1
	DNN	0	0	35.6	64.4	0	0.3	68.6	31.1
	p-value	0.26	0.17	0.15	***0.02***	0.36	0.31	0.18	0.31
Posterior	DPN	2.7	0.7	43.8	52.8	0	0.5	44.6	54.9
	DNN	0	5.6	51.0	43.4	1.5	4.4	61.6	32.5
	p-value	0.33	0.39	0.69	0.61	0.31	0.37	0.32	0.19
Right-lateral	DPN	0	7.1	42.8	50.1	0	0.7	69.2	30.1
	DNN	0	7.8	40.9	51.3	0	14.3	32.2	53.5
	p-value	n/a	0.94	0.91	0.95	n/a	0.17	***0.04***	0.21
Left-lateral	DPN	0	0.3	63.1	36.6	0.5	0	56.4	43.1
	DNN	0	4.7	49.1	46.2	0	0	27.0	73.0
	p-value	n/a	0.35	0.45	0.61	0.33	n/a	0.06	***0.05***

*: $\alpha = 0.05$

Table 8. Difference of COP placement rates (%) between two groups for period 6.

Direction	Velocity	10 cm/sec				20 cm/sec			
	Quadrant	1st	2nd	3rd	4th	1st	2nd	3rd	4th
Anterior	DPN	6.1	0.3	62.1	31.5	0	0	44.2	55.8
	DNN	0	0	38.9	61.1	0	2.7	68.7	28.6
	p-value	0.18	0.33	0.19	0.10	n/a	0.31	0.22	0.16
Posterior	DPN	0	0	45.2	54.8	0	0.3	46.5	53.2
	DNN	0	5.4	59.0	35.6	0	7.7	61.0	31.3
	p-value	n/a	0.33	0.45	0.29	n/a	0.33	0.42	0.21
Right-lateral	DPN	1.6	1.6	46.4	50.4	0	0	68.4	31.6
	DNN	0	13.2	49.0	37.8	0	11.8	38.2	50.0
	p-value	0.33	0.16	0.88	0.47	n/a	0.16	0.10	0.33
Left-lateral	DPN	0.4	0.3	49.9	49.4	7.1	0	62.9	30
	DNN	0	7.1	40.2	52.7	0	0	24.6	75.4
	p-value	0.33	0.34	0.58	0.85	0.33	n/a	***0.03***	***0.01***

*: $\alpha = 0.05$

Period 6: Recovery from 4 s to 5 s. At the end of recovery period, both groups had most of COP be placed in the third and fourth quadrant under the considered conditions, except under the perturbation of left-lateral at high velocity. When the posture was stabilized after a perturbation in the left-lateral direction at high velocity, DPN showed more placement of COP in the third quadrant, but DNN in the fourth quadrant (Table 8).

4 Conclusions

In this study, difference of pattern of body sway between diabetic people with and without peripheral neuropathy was investigated. Displacement rates of center of pressure over the four quadrants for the base of posture support were evaluated to compare body sway patterns. During a quiet standing period, two groups did not show a significant difference of body sway patterns. The posture swayed mainly in lateral and posterior direction. Right after a perturbation was applied, two groups showed quite similar patterns of body sway for each perturbation direction. For instance, when the perturbation was given in anterior direction, the posture leaned to posterior direction as a reaction so that the center of pressure placed in either the third quadrant or the fourth quadrant. For the right or left lateral perturbation, its postural reaction was observed accordingly, i.e., placement of COP in the third quadrant for the right lateral perturbation and the fourth quadrant for the left lateral perturbation. However, when the perturbation was applied in posterior direction, the center of pressure dispersed over the four quadrants. At the low velocity of perturbation, two groups did not show any significant difference of sway patterns during the recovery period for all different directions of perturbation except anterior direction. For the anterior direction of perturbation, diabetic people with peripheral neuropathy tended to lean more toward the third quadrant than the fourth quadrant compared to people without neuropathy during the recovery period. Similar reactions were observed for the right and left lateral directions at the high velocity of perturbation.

One of the peripheral neuropathy tests indicated that diabetic people with peripheral neuropathy showed less severity of neuropathy on the left foot than the right foot with Biothesiometer testing. The difference of severity of neuropathy between the feet may be related to the difference of sway tendency. However, it is not verified yet at this point because people without neuropathy tended to sway more to the fourth quadrant that the third quadrant even though they had both foot almost same level of sensitivity. It may be necessary to consider an effect of dominant foot on postural control. It should be noted that this study has some limitations such as small sample sizes and small number of trials.

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Quality Assessment and Management: An Overview of Concordance and Discordance Rates Between Clinical and Autopsy Diagnoses

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Abstract. Autopsy diagnoses have traditionally been used as the "Gold Standard" for determining the cause of death. The purpose of this study was to use autopsy to determine the rate of concordance and discordance between clinical diagnoses and post-mortem findings in patients admitted to the hospitals of the Saskatoon Health Region. A retrospective record review of the medical and autopsy charts was carried out by three independent observers for all the deceased adult in-patients admitted during 2006 to 2008. In accordance with selection criteria, 102 (59 males; 43 females) cases were assessed. The concordance rate between clinical and autopsy diagnosis was found to be 86.3%. The discordance rate was 12.7% and in 1.0% was inconclusive. We encourage residents and physicians to continue using autopsy as an important tool to extend our understanding of disease processes.

Keywords: Concordance · Discordance · Medical error · Autopsy · Clinical diagnosis · Post-mortem diagnosis

1 Introduction

The detailed measurement of the rate of diagnostic error has been described as both an essential first step [1, 2] and an unavoidable obstacle [3] in the progress of the medicine. This 'next frontier in patient safety' [4] has received relatively little attention [5] and requires focused research to inform future intervention strategies [6]. The diagnostic process is a vital component of medical care as it determines the appropriate course of treatment and prognosis [7]. Therefore, diagnostic inaccuracies have considerable consequences including patient injury, suffering, and death [8, 9]. Recently, the World Health Organization has included diagnostic errors as a high-priority issue [10].

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The autopsy has been used as a diagnostic tool for more than 3000 years [11] and today remains the gold standard in identifying pathologies and cause of death [12]. Furthermore, it allows physicians to calibrate diagnostic skills and processes through feedback [13]. However, the rate of autopsies being performed has declined considerably [14]. Peaking at about 50%–60% around the 1960's, rates of autopsies have since steadily declined and begun to stabilize at 10% or less in recent years [15, 16]. Reasons for this decline include fear of legal ramifications for incorrect diagnoses, limited resources, lack of minimum autopsy rate requirement for hospital accreditation, limited exposure to autopsies for medical trainees, and advances in imaging modalities [16–18].

The precise prevalence of overall diagnostic error remains unknown as different studies have reported widely different rates of error. Illustrative examples of rates discordance that have been reported around the world include 9.3% in India [19], 17.2% in USA [17], 19% in Greece [20], 19.8% in USA [18], 21% in Belgium [21], 31.7% in France [22], and 48.4% in Jamaica [23]. Among the highest quality of evidence available, systematic reviews and meta-analyses have reported various ranges for rates of diagnostic error including 4.1–49.8% [24], 5–15% [25], 10–15% [26], and 10–20% [1]. Although discrepancies between studies may be partly due to different characteristics of the study population and the context in which each study took place, a general trend of greater sample sizes yielding higher rates of discordance exists [15]. The purpose of this study was to investigate rates of discordance between clinical diagnoses and post-mortem findings among university and community hospitals in Saskatoon, Saskatchewan, Canada, and to assess the role of imaging modalities and the effects of potential determinants on the discrepancy rate including age, organ system involved, and length of stay in hospital on the rate of discordance.

2 Methods

To determine rates of concordance and discordance among clinical diagnoses and post-mortem findings, a retrospective chart review was carried out, by three independent observers on 102 patients that passed away between January 1, 2006 and December 31, 2008 while admitted at one of three hospitals in Saskatoon Health Region (SHR) including Royal University Hospital (RUH), St. Paul's Hospital (SPH) and Saskatoon City Hospital (SCH). Inclusion criteria included being over the age of 16 at time of death and having a clinician- or family -requested autopsy performed. Exclusion criteria included medico-legal autopsies, pediatric autopsies and coroner's autopsies as well as incomplete charts and autopsy data. Data including admission records, discharge summaries, autopsy reports and imaging reports were manually extracted from patient's charts and included in analyses. Diagnostic discordance was operationally defined as non-agreement between the clinical diagnosis given premortem and the autopsy findings discovered post-mortem. Diagnostic concordance was operationally defined as agreement between pre- and post-mortem diagnoses of cause of death in which a major diagnosis that lead to or contributed to death was not missed.

To gain a more in depth understanding of diagnostic inaccuracies, it is important to measure and classify the types of errors that are being observed. This endeavor was most notably initiated by Goldman [27]. Class 1 are discrepancies of the major diagnosis in which knowledge of the diagnosis premortem would have changed treatment to prolong survival or cure the disease [27]. Class 2 are discrepancies of the major diagnosis in which knowledge premortem would not have changed survival even with the correct treatment [27]. Class 3 are discrepancies of the minor diagnosis that did not directly relate to cause of death but were related to the terminal disease [27]. Class 4 are discrepancies of the minor diagnosis that may have had the potential to influence prognosis or eventually contribute to the cause death and may have epidemiological importance [27]. Since the original Goldman classification system was developed, a 5th classification has been added [11, 28]. Class 5 is defined as non-discrepant diagnoses in which there was complete agreement between the clinical diagnosis and autopsy findings [11, 28].

The distribution of organ systems involved in the cause of death was assessed in all cases included in the analysis and compared to discordant cases. The influence of various determinants on the discordance rate was examined including length of stay in hospital, age of patient, organ system involved, as well as the impact of diagnostic modalities, such as X-ray, Computerized Tomographic Scanning (CT), and Magnetic Resonance Imaging (MRI). Imaging tests that were incomplete or had failed were excluded from analyses. In regard to classifying the impact of imaging modalities, instances in which the imaging modality confirmed a previously suspected diagnosis or confirmed the absence of competing diagnoses were classified as confirmatory. Instances in which the imaging modality provided a previously unsuspected diagnosis were classified as diagnostic. If imaging studies provided vague diagnoses, misleading diagnoses or were unable to detect pathologies that was later revealed on autopsy, then the instance was classified as inconclusive.

3 Results

Assessing patient records from the three hospitals in the SHR, 102 cases were found to be eligible for analysis (Fig. 1).

184069 Hospital Admissions	→	3770 In-patient deaths	→	233 Autopsies performed	→	102 Eligible cases

Fig. 1. Number of hospital admissions, deaths, total autopsies and eligible cases in Saskatoon Health Region between 2006 and 2008.

Of the 3770 patient-deaths that occurred in the SHR between 2006 and 2008, 1706 (45.3%) occurred at SPH, 1227 (32.5%) took place at the RUH and 837 (22.2%) occurred at the SCH. A total of 233 autopsies were performed on the 3770 patients-deaths – resulting in an autopsy rate of 6.2%. The autopsy rate was remained consistent over time, ranging from 6.0% in 2007 to 6.4% in 2006.

Of the 102 autopsy cases included in the analysis, 49 occurred at the RUH, 38 occurred at SPH, and 15 occurred at the SCH. Approximately 58.2% (59/102) of cases were male and the average age of patients was 65 years old ± 14 years. The average length of stay in hospital was 12.7 days. The place of death in hospital for 44.1% (45/102) patients was the Intensive Care Unit or the Critical Care Unit. Similarly, 44.1% (45/102) died on the wards.

The overall concordance rate between 2006 and 2008 was 86.3% (88/102) while the discordance rate was 12.7% (13/102). In one case, concordance or discordance could not be determined due a limited autopsy – this one case, 1.0% (1/102), was classified as inconclusive. The rate of concordance in the SHR was similar across the three years of the study – 82.5% in 2006, 90.3% in 2007, and 87.1% in 2008 (Fig. 2).

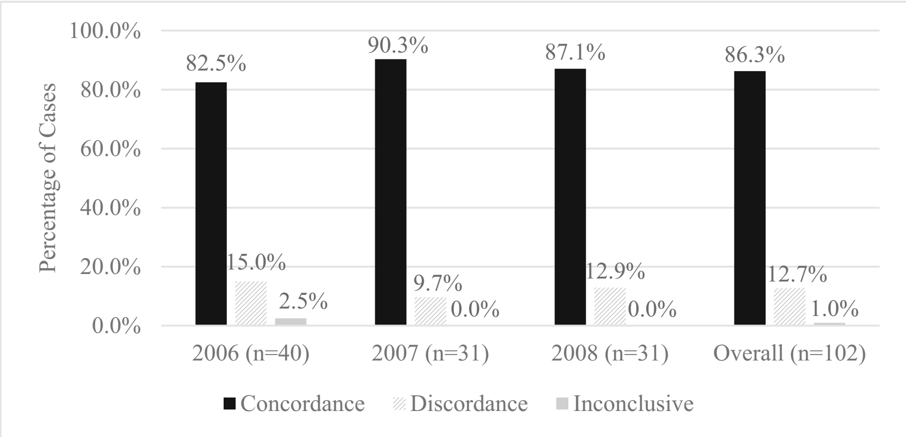

Fig. 2. Concordance and discordance rates between clinical and autopsy diagnoses for all hospitals in the Saskatoon Health Region from 2006 to 2008.

Rates of concordance ranged from 84.2% in SPH to 93.3% in SCH. Rates of discordance ranged from 6.7% in SCH to 15.8% in SPH. The 1 inconclusive case (2.0%) occurred at RUH (Fig. 3).

Class 1 discrepancies ranged from 4.1% in RUH to 13.2% in SPH. Class 2 discrepancies ranged from 0.0% in SCH to 8.2% in RUH. Class 3 ranged from 6.7% at SCH to 15.8% at SPH. Class 4 ranged from 13.3% at SCH to 28.9% at SPH. Lastly, rates of class 5 ranged from 39.5% at SPH to 73.3% at SCH. Overall, the rate of discrepancies involving minor diagnoses (class 3 and class 4) were more than twice as common as discrepancies involving the major diagnoses (class 1 and class 2), 12.7% and 35.3% respectively. The proportion of cases that have been classified as each type of concordance or discordance is shown in Table 1.

Class 1 rates ranged from 3.2% in 2007 to 12.5% in 2006. Class 2 rates ranged from 2.5% in 2006 to 6.5% in 2007 and 2008. Class 3 rates ranged from 9.7% in 2008 to 12.9% in 2007. Class 4 rates ranged from 19.4% in 2007 to 32.3% in 2008. In each year, class 5 represented the most cases (ranging from 45.2% in 2008 to 58.1% in 2007) (Fig. 4).

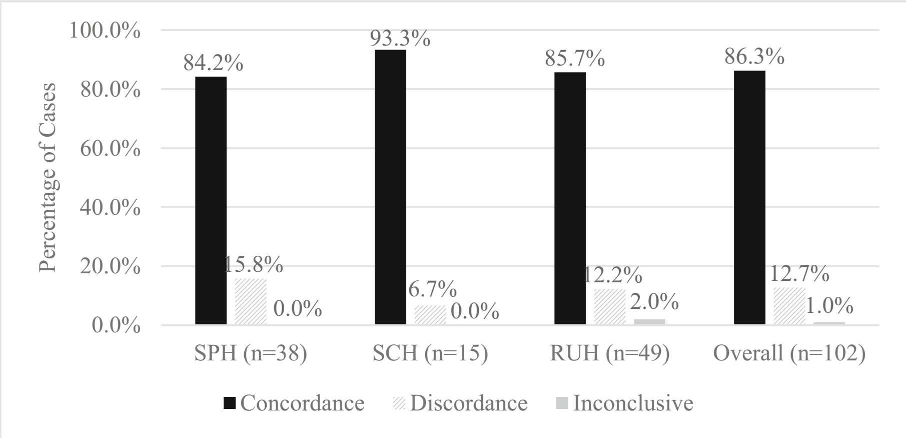

Fig. 3. Overall concordance and discordance rates between clinical and autopsy diagnoses for the Saskatoon Health Region hospitals for the years 2006 to 2008.

Table 1. Classification of the types of discrepancies between clinical and autopsy diagnoses of hospitals in the Saskatoon Health Region.

Classification	SPH (n = 38)	SCH (n = 15)	RUH (n = 49)	Overall (n = 102)
C1	13.2%	6.7%	4.1%	7.8%
C2	2.6%	0.0%	8.2%	4.9%
C3	15.8%	6.7%	8.2%	10.8%
C4	28.9%	13.3%	24.5%	24.5%
C5	39.5%	73.3%	55.1%	52.0%

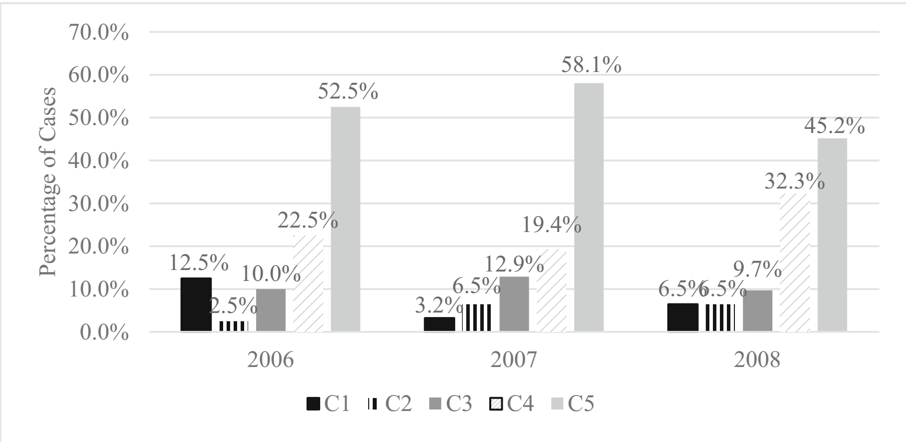

Fig. 4. Classification of the types of discrepancies between clinical and autopsy diagnoses of hospitals in the Saskatoon Health Region between 2006 and 2008.

Cardiovascular and respiratory systems are most commonly involved in the cause of death when including all 102 cases. The gastrointestinal system and the genitourinary system were the most common systems involved in the cause of death in discordant cases. The distribution of organ systems involved in the cause of death in all patient deaths included in the analysis is shown next to the distribution of organ systems involved in the cause of death in discordant cases in Table 2.

Table 2. Distribution of organ system involved in cause of death among 102 cases in the Saskatoon Health Region between 2006 and 2008.

	All cases		Discordant cases		Relative discordance
Organ system	n	%	n	%	%
Cardiovascular	35	34.3	3	23.1	8.6
Respiratory	22	21.6	2	15.4	9.1
Gastrointestinal	9	8.8	3	23.1	33.3
Genitourinary	5	4.9	2	15.4	40.0
Neurologic	6	5.9	1	7.7	16.7
Other	25	24.5	2	15.4	19.1

The confirmatory rate of X-rays was consistent between the three hospitals ranging from 52.7% in SPH to 57.8% in the SCH. Similarly, the diagnostic rate of X-rays between the three hospitals fell within a narrow range from 42.2% in the SCH to 46.9% in SPH. Of the 744 X-rays that were performed, 686 were chest X-rays (54.1% confirmatory and 45.9% diagnostic) and 62 were abdominal X-rays (58.1% confirmatory and 38.7% diagnostic). Of the 744 X-rays that were performed, 473 occurred at RUH, 207 at SPH and 64 at SCH. Of the two inconclusive X-rays, both were abdominal X-rays – one occurred at SPH and one occurred at the RUH (Fig. 5).

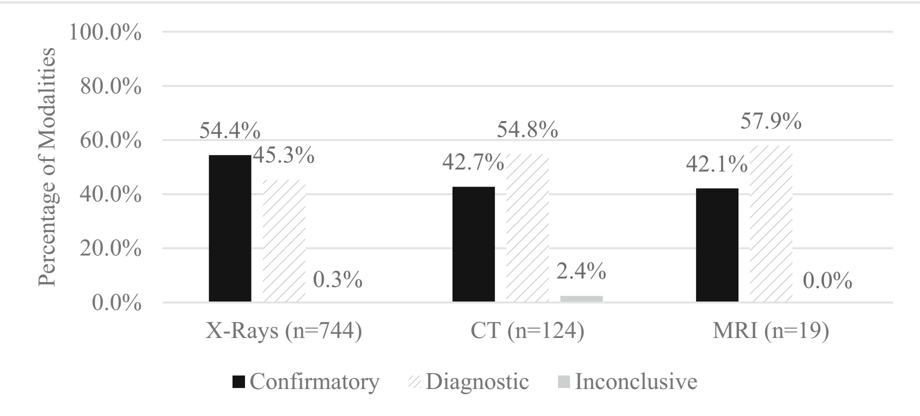

Fig. 5. Comparison of confirmatory, diagnostic and inconclusive rates among imaging modalities (X-rays, CT, MRI) in Saskatoon Health Region from 2006 to 2008.

Of the 124 CT that were performed, 59 were of the head (55.9% confirmatory and 44.1% diagnostic), 30 of the chest (23.3% confirmatory and 70.0% diagnostic), and 35 of the abdomen/pelvis (37.1% confirmatory and 60.0% diagnostic). Of the 124 CTs that were performed, 90 took place at RUH, 27 at SPH and only 7 at SCH. Due to the limited number of CTs performed at some hospitals, hospital-specific confirmatory and diagnostic rates of CTs are not shown. There was a total of three inconclusive CTs – one abdominal/pelvis CT at RUH, and two chest CTs also at RUH.

Of the 19 MRIs that were performed, 15 took place at RUH, 4 took place at SPH, and 0 took place at SCH – therefore hospital-specific confirmatory and diagnostic rates are not shown. There were no inconclusive MRIs.

4 Discussion

The concordance rate between clinical and autopsy diagnoses in the SHR between 2006 and 2008 was 86.3% (88/102), while the discordance rate was 12.7% (13/102). Our findings fall into the ranges of discordance reported by meta-analyses and reviews on the topic including for rates of diagnostic error including 4.1–49.8% [24], 5–15% [25], 10–15% [26], and 10–20% [1]. These findings suggest that overall rates of concordance and discordance between clinical diagnoses and autopsy reports in the Saskatoon Health Region are generally consistent with previously reported in North America and around the world.

The classification of discrepancies between clinical and autopsy diagnoses allows a better understanding of the implications of diagnostic inaccuracies. Class 1 discrepancies comprised 7.8% of cases in this study. These cases have important implications as if they had been prevented would have changed treatment to prolong survival or cure the disease [27]. This finding is aligned with previous reports of rates of Class 1 errors including 5% [24], 8% [29], 9.1% [30], 9.9% [12]. Class 2 discrepancies represented 4.9% of cases. These cases also involve major diagnosis, however, even with the correct treatment would not have changed survival. Previous studies have found Class 2 rates of 6.1% [31], 10.8% [32], and 15% [29]. Class 3 discrepancies represent 10.8% of cases in this study and although not related to the cause of death, caused symptoms that would have eventually contributed to the prognosis or could have been treated [27]. In previous studies rates of Class 3 discrepancies that have been reported include 3.6% [12], 7.5% [11], 10.3% [32], and 15% [29]. Class 4 discrepancies represented 24.5% of cases. Although these discrepancies involve only minor occult diseases they are of epidemiological importance and have been found to be 16.1% [11], 21% [29], 28.5% [32] and 32.9% [12]. Class 5 instances represent complete concordance between clinical and autopsy diagnoses – in this study Class 5 represented 52.0% of cases. This is in line with previous studies that have included same definition of Class 5, including 29% [20], 30.6% [31], 39.2% [32], 44% [12], and 57% [33]. Overall, the results of classification of concordant and discordant cases of this study are strongly aligned with previous research.

When assessing both concordant and discordant cases together, cardiovascular and respiratory systems are most commonly involved in the cause of death, representing 34.3% and 21.6% of cases respectively. These systems were found to have relatively low relative discordance rates. Of the 35 cases that died of cardiovascular causes, 3 (8.6%) were found to be discordant. Of the 22 cases that died of respiratory causes, 2 (15.4%) were found to be discordant. The gastrointestinal system and the genitourinary system were the most common systems involved in the cause of death in discordant cases, each representing 23.1% of discordant cases. These two systems represented the highest rates of relative discordance – 33.5% (3/9) for the gastrointestinal system and 40.0% (2/5) for the genitourinary system. Note that data on these systems is limited by small sample sizes.

Regarding diagnostic rates, our data show MRI to be the superior modality (57.9% diagnostic), followed my CT scan (54.8% diagnostic) and lastly X-ray (54.4% diagnostic). These findings are consistent with the level of detail of the imaging produced by each modality. The results of this study suggest that despite the technical advances in diagnostic modalities, diagnostic discrepancies remain prevalent in the present-day health care system.

Barriers exist to determining the accuracy of clinical diagnoses. In the context of this study, limited sample sizes are the primary restriction to the depth and breadth of analysis and interpretation that can be made. Low rates of autopsy limit the availability of data that can be investigated [14]. Despite having begun with 184, 069 hospital admissions and 3770 in-patient deaths, only 233 autopsy reports were available and only 102 were eligible for analysis based on the inclusion criteria resulting in an autopsy rate of 6.2%. Lower autopsy rates are associated with higher rates of diagnostic errors [24]. More specifically, it has been found that for every 10% increase in autopsy rates there is a 12.4% decrease in major medical errors [24]. This illustrates the important educational value of autopsy examinations in established quality assurance tool in progressing medical diagnostics [34].

It may be argued that selection bias may influence these findings as cases of diagnostic uncertainty have been shown to be more likely to involve autopsy investigation [24] and autopsy investigations tend to be ordered for clinically challenging cases [34]. However, clinician certainty in the diagnosis has been shown to have little influence on the rate of discrepancies [35]. The discrepancy rate among cases where the clinician felt certain of the diagnosis was 12%, compared to the rate of 15% for all levels of certainty [35]. Similarly, among cases where the clinician would normally have ordered an autopsy the discrepancy rate was 15% whereas among cases where the clinician would normally not have ordered an autopsy the discrepancy rate was 14% [35].

5 Conclusion

Autopsy is an established quality assurance tool that will bring to light discrepancies and will play an important role in contributing to clinical knowledge, medical education and quality assurance programs. This area of work contributes to the field of diagnostic medicine by enhancing accuracy and knowledge of disease [15, 34] and providing more accurate epidemiological mortality data. [36]. Furthermore, it allows physicians to calibrate diagnostic skills and processes through feedback [13].

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Comparative Assessment of the Risk of Manual Patient Handling Between Standard Methods and Job Analysis

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Abstract. Some tasks performed by healthcare workers, such as the manual patient handling, may lead to musculoskeletal disorders. Exposure to biomechanical overload includes patient handling operations, the pulling and pushing of beds/stretchers (considering the extra weight of the patient. Theese actions could be evaluate thanks to the Snook Ciriello method (ISO 11228). The Center for Ergonomics of the University of Michigan has developed a software able to evaluate the biomechanical overload, which takes into consideration postures or the manual lifting of loads for each task, i.e. the 3DSSPP (Static Strength Prediction Program). The occupational specialist can apply the Job Analysis to determine which tasks should be performed by the worker without being overloaded. Therefore guaranteeing the correct positioning of staff even those affected by musculoskeletal disorders.

Keywords: Healthcare worker · Musculoskeletal disorders · Manual patient handling · Job analysis · 3DSSPP software

1 Introduction

The aging of health care providers and patients is an inevitable phenomena that is to be faced by the SSN (Servizio Sanitario Nazionale) [1]. However, this involves overcoming multiple challenges, some of which currently available strategies are not always able to do. Indeed, the advancing age of the health care providers is destined to have important consequences on the functioning of Health Care Structure (HCS) and requires that the current policies and personnel management systems be re-orientated to meet needs [2]. Managing senior personnel involves a series of problems, including the fact that they have a lower physical tolerance to tasks that necessitate significant physical effort and are more subject to the negative consequences of stress associated with frequent changes in the sleep-wake rhythm typical of shift work. All of which is to be carried out in such a way that the HCS is able to guarantee them an environment (physical and organizational) that can benefit from of their long-term acquired

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professional skills. This boils down to management and professionally guided dedicated age management strategies being a must so as to contrast the negative effects of the current general framework, whilst enhancing the abilities acquired by skilled personnel during the course of their professional activities, i.e. placing them I the category of valuable resources within the system.

One of the most common musculoskeletal disorders is what Anglo-Saxon authors call "Low Back Pain" (LBP) [3]. This is a painful symptomatology located in the lumbosacral spine with consequent functional limitation and difficulty or even impossibility to perform some tasks. The most common causes are incorrect patient handling techniques, a bad choice of furnishings and/or equipment dedicated to patient handling/movement, torsion, flexion, etc…., heavy loads (weight) and high physical effort due to poorly distributed weight of patients with poor or no collaboration.

From a biomechanical point of view, tasks such as the lifting and manual transfer of patients are overloading operations, especially for the lumbar spine, as patients should be considered a significant weight load, that not only have an unevenly distributed mass but may make sudden changes in movement. Indeed, handling strategies should be tailored to a series of elements, including how collaborative the patient is able/willing to be and the level of training and experience of the health care provider. Even in the presence of handling aids, the work organization and the characteristics of the environments these operations are carried out in may have a significant influence on the handling methods and the consequent risks.

Therefore, the question of how to combine efficiency to a good cost/benefit ratio in an increasingly aging working population no longer able to carry out their duties arises.

2 Materials and Methods

The first step in the preparation of optimal strategies, in terms of prevention and protection of the safety and well-being of the HCS staff, is the identification of the departments most subject to the risks involved in manual patient handling. This is followed by the assessment of the biomechanical overload risk through the application of standard evaluation tools, such as the Italian MAPO method[1].

Our attention was focused on the nursing staff as they are the exposed category to handling risks and have the highest prevalence of not fit to work declarations and/or limitations (prevalence of 24.1%).

Table 1 reports the type of unsuitability and limitation expressed in percentages. As can be observed, over 50% of these declarations were due to the manual handling of loads and patients. Moreover, the type of unsuitability plays a pivotal role in the choice of preventive strategies, including structural reorganization, which are to prevail over equipment and/or training.

As the study continued, the MAPO method [4] was used for the assessment of the risk of moving patients from some departments to others in hospitals that make up The City of Health and Science of Turin. The coordinators of each department were

[1] MAPO: Handling and assistance for hospital patients.

Table 1. Types unsuitability associated to the percentage in the SSN in 2015

Type of unsuitability	Percentage of unfitness and limitations
Manual handling	49.50%
Incongruous postures	12.60%
Stress/burn out	4.10%
Night-work shifts	12.00%
Chemical risk and allergies	5.40%
Other	16.40%

interviewed with the aim of obtaining organizational and structural information. The objective of the organizational analysis was to evaluate the assistance load, in terms of manual patient handling and to estimate how often an operator performed handling operations [5]. The method is based on the principle of the evaluation of the risk factors that characterize the work exposure:

– the care load determined by the ratio between non self-sufficient patients present on average in the ward and the number of operators involved in their handling during the three shifts. The non-self-sufficient patients were divided into two categories: partially collaborating patients or those who have residual capacities and partially collaborate in the movement and non-collaborating patients or those who do not perform any movement, either with their upper or lower limbs.
– the equipment, where the analysis of this factor leads to the identification of the ergonomic requirements of wheelchairs, lifts, minor aids, hospital beds and stretchers (quantity, type of electrical or manual regulation, maintenance status).
– the structure, where the purpose of the evaluation is to determine the adequacy of the rooms in the wards and the toilet facilities. This was followed by an analysis of the routes and accesses (corridors, lifts), which, although do not influence the risk index, they do describe the critical aspects of pulling and pushing operations.
– the training, where the type and duration were recorded during the interview. The interview was documented with a specific as proof that it had been done.

The MAPO method uses an index expressed by a simple correlation with the sum and the multiplication of the analyzed risk factors. This allows for a classification of the work situation by exposure entity and the identification of three levels of action, according to the typical green yellow and red colorimetric model.

Healthcare providers' exposure to biomechanical overload, in this case nurses, included not only patient handling operations on the wards, but also the pulling and pushing of beds/stretchers. In this case the loads were aggravated by the patient's additional weight and had to be analyzed applying a different evaluation method, i.e. the Snook Ciriello method, as referred to in the ISO 11228-2 [6]. The study start by breaking down the overall movement into elementary actions, such as pushing and maintenance. The pulling or pushing index or that which applies to flat transport also summarizes a risk indicator and is evaluated by comparing the recommended limit effort with the one actually moved by measuring it with the electronic dynamometer (connected to a metal handle equipped with special hooks so as to be able to pull or push the instrumentation - in this case the PCE dynamometer, model FG2 k was used), which is able to verify the applied force and the peak: as the ratio increases, so does the risk factor.

Lastly, the NIOSH method was used to evaluate the load lifting actions usually performed: handling, lifting, moving, such as with packs of sheets, hospital garments, dirty and clean linen, etc. The method is able to determine the so-called recommended limit weight for each lifting action through an equation that, starting from a maximum lifting weight under ideal conditions (constant weight of 25 kg for men and 15 kg for women), considers the existence of unfavorable elements and applies the appropriate reduction factors to them.

3 Results

The application of standardized methods has led to the recognition of particularly critical issues. A MAPO assessment of a ward provides an approximate estimation of its risk index, as some field values are not included in the final calculation of the risk index. It also does not take into account the gender of the worker, the weight of the mobilized patients, or the other anthropometric variables, e.g. there is a very important difference between a newborn and an adult, even more so for an obese patient. Without taking into consideration an obese patient [7].

It is not always an easy task to identify even the average daily number of non-collaborating and partially collaborating patients. Another risk determinant is operator training, where the concept of training adequacy is defined according to the type and duration of the training (theoretical/practical course of at least 6 h). Other relevant aspects are the minimum number of operators involved, or at least 75% of the operators involved in the manual patient handling. That is to say, not all the personnel involved in the handling must necessarily undergo continuous training courses. The sufficiency or numerical insufficiency of the auxiliary equipment, does not mean that they are used and if they are, that they are used correctly. Moreover, this method does not provide a personalized assessment for every worker nor does it take into account either gender or its anthropometric variability. It does not even evaluate the worker's posture during a task [8].

The Snook & Ciriello method, as does the NIOSH method, was born for industrial realities and, therefore, is characterized by the repetitiveness of movements. Indeed, the first method involves restrictive frequencies: one passes from an action every 8 h to an action every 30 min. According to NIOSH, the ideal lifting weight for male workers is 25 kg and 15 kg for female workers, which is well below the weight of an adult patient. Furthermore, it is difficult to define the frequency of movements, as they vary widely.

4 Discussion

Starting from the critical points in the Snook Ciriello method, the Center for Ergonomics of the University of Michigan developed a software called 3DSSPP (Static Strength Prediction Program), based on Job Analysis, for the assessment of biomechanical overload, supported, above all, at a rachis level in the lumbar spine, when taking certain postures or manually lifting a load for each task performed by the worker [9].

The analysis, based on the inclusion of complex anthropometric items, including that of the hand, is supported by an automatic posture generation function and by three dimensional graphic illustrations that can make an approximate simulation of the task performed by a male or female.

The calculated forces are shown as percentiles for the male and female working population expected to have sufficient strength to withstand the type of load handling. NIOSH recommends the strength limits that can be tolerated by 99% of the male population and 75% of the female population; for safety reasons it also recommends a maximum spinal compression force of 3,400 N[2] (about 350 kg).

As aforementioned, the 3DSSPP software is based on Job Analysis, i.e. the breaking down of the job into activities and then the activities into tasks. This analysis allows for the identification of how much force is necessary for the required effort and the related biomechanical overload for each body district, differ greatly for the head, trunk, lower and upper limbs. A simple, but less precise way is to click on the corners of the districts of the stylized subject to modify the subject's posture: in this way the postural changes are mirrored in biomechanical overload changes, enabling the identification of any non-ergonomic workstations. Moreover, variations can be observed from three different angles: top, front, side (Fig. 1).

Red arrows are positioned to indicate the various forces applied to determine the overload, especially at the level of the lumbar spine.

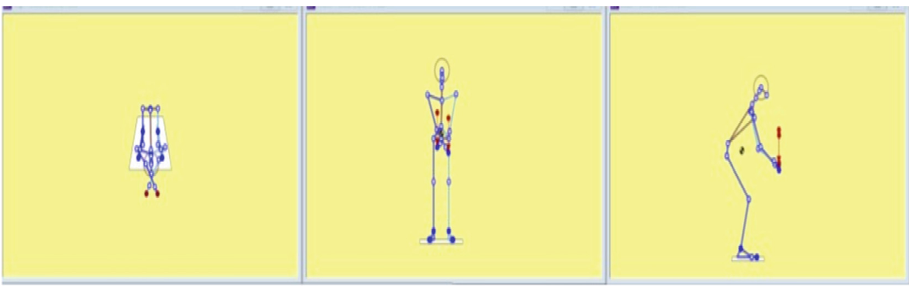

Fig. 1. 3DSSPP software: the worker's posture, seen from three different angles: top, front, side.

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[2] This limit has been assessed on the basis of epidemiological and biomechanical evidence and is one of the criteria used for the development of the NIOSH lifting equation (NIOSH 1981; Waters et al. 1993).

These images depict (Figs. 2 and 3.) a simulation of a female repositioning a patient into a wheelchair. The software output provides green, red, yellow results, depending

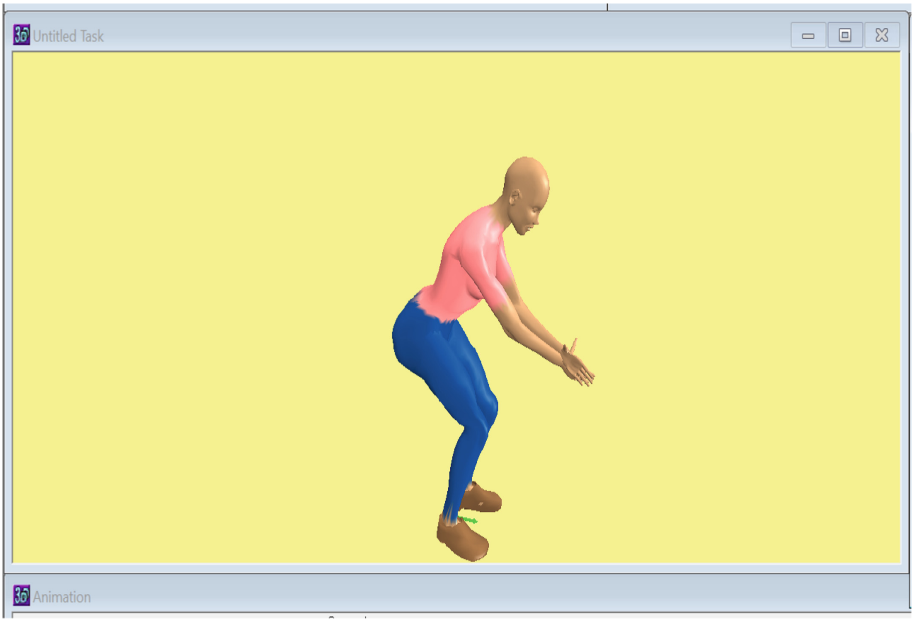

Fig. 2. 3DSSPP Software: three-dimensional image of the simulation of a task performed by a female worker.

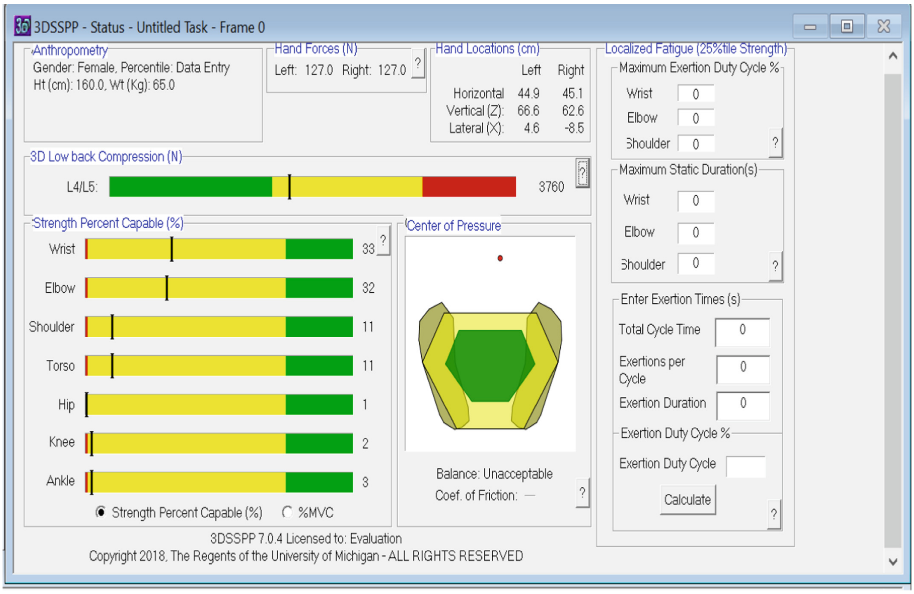

Fig. 3. 3DSSPP Software: software output expressed in terms of biomechanical overload at the level of the different districts, especially at the level of the lumbar spine.

on the gravity of the biomechanical overload for each detected district. In the case analyzed, the value is related to the overload on the lumbar spine and can be seen to fall within the yellow range, meaning that this operation (and/or the condition it is performed under) is a criticality.

5 Conclusions

As this type of assessment allows for the identification of most of the overloading operations, it might well be a predicative tool of the development future musculoskeletal related diseases later on. Although the application to different realities does necessitate longer timings, the results are immediately visible, cutting technical assessment times. This innovative type of analysis allows the physician encharged with the evaluation to determine what a worker with limitations or that has been declared unfit can or cannot actually do (e.g. due to musculoskeletal disorders strongly connected to the type of job, that are destined to worsen with progressive aging), thus formulating a judgment of unfitness related to the tasks rather than the job [10]. A judgment of unfitness is not intended to discriminate a worker in difficulty from a healthier one, but rather to allow this person to be assigned to a context where the tasks to be performed do not compromise their state of health, whilst, at the same time, ensuring the professionalism of the worker is protected. The effective management of human resources involved in the movement of patients, with a declaration of unfitness or with prescriptions mainly due to musculoskeletal disorders, such as LBP, is a key element in the healthcare sector. Indeed, chronic diseases, especially ones related to the musculoskeletal system, are a typical condition in an ageing population and are, therefore, unavoidable. However, prevention strategies against the worsening of these conditions or to slow down the process of these pathologies, may be enacted to promote health. These include: postural gymnastics (included in the work shift) to strengthen the musculoskeletal system, where team work or working in pairs is preferred, especially when it comes to moving patients. This enhances professional skills, which fall partly into the so-called life skills (skills for life); which include the skills and competences acquired over time through quality training aimed at enhancing the healthcare providers' awareness of their potential, skills, abilities, as well as the critical issues related to their daily activities, promoting correct handling techniques and the correct use of equipment and aids provided by the company. All of which is carried out under the guidance of an ergo-coach in each shift, i.e. a professional figure that provides positive or negative feedback on the activity/ies to be performed. The sum of which leads to an increase in well-being or work and well-being within the hospital, which also has a positive effect on the patient-health relationship, which on the one hand is perceived by the patient in terms of greater reliability and on the other, gratifies the activity performed by the staff. Age management can be handled by further strategies, such as job rotation, providing suitable training courses, favouring horizontal career paths on the one hand and, on the other, reducing the risk of potential alienation by workers. Therefore, an archive containing the Job Analysis can be set- up thanks to the expertise of Occupational Medicine, Health Departments, Nursing Areas, the Prevention and Protection Service and through an accurate analysis of the tasks constituting the activities of each job of the health personnel.

This will mark the starting point for the formulation of the assessment of suitability/inability to tasks for each worker by the physician entrusted with the task of evaluation, making the occupational specialist a pivotal figure in the aforementioned cooperation system. This will make it possible not only to identify the measures and interventions required to allow for an effective management of the phenomenon of unsuitability or limitations, but also to ensure the reintegration of any persons affected by musculoskeletal disorders and their assignment to the most suitable tasks for their abilities and capabilities.

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Healthcare Information Systems

Electronic Health Records in Hospitals: Preventing Dosing Errors in the Medication Administration Context

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Abstract. Medication errors are among the highest contributors to complications during a hospital stay. Dosing errors have an impact on the detrimental effects of a medication error. While clinical decision support systems have targeted prescribing errors, the system design challenges associated with dosing error prevention in the medication administration context is not well understood. This paper presents an overview of the effectiveness of current systems used in the medication delivery process. The system enhancement strategies to improve dosing error detection and prevention in the medication administration context should consider the medication safety loopholes in the electronic health record (EHR).

Keywords: Electronic health record · Patient safety · Dosing errors · Medication administration errors · Decision support

1 Introduction

According to the National Coordinating Council for Medical Error Reporting and Prevention, "A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer" [1]. Even though medication errors may occur in any healthcare setting, admitted patients are three times more likely to experience an adverse drug event [2]. In 2001, Phillips and colleagues analyzed a five year long data set on fatal medication errors from the Food and Drug Administration (FDA) Adverse Event Reporting System, and found improper dosing constituted 40.9% of the reported fatalities, followed by wrong drug and wrong route (16% and 4.9%, respectively) [3]. The occurrence of medication errors in the inpatient setting is among the highest contributors to hospital-related complications [4], and contribute to a significant increase in healthcare costs even though the error may not have led to harm [5]. Even though the healthcare team members have a shared responsibility in preventing medication errors, the nurses bear the primary responsibility in preventing them from reaching the patient. With technology rapidly advancing in healthcare, many clinicians depend on computers to complete the medication delivery process. This paper provides an overview of the safety loopholes associated with dosing errors in the hospital setting.

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2 Medication Delivery Process

A medication administration error is when the pharmacological intervention does not match the patient's medical condition (e.g., diagnosis, allergy) or the medication order in the patient's record [6, 7]. When investigating a medication error, the prescribing, transcribing, dispensing, and administration events must be analyzed to determine error-prone activities in the medication delivery process. While medication errors may occur at any stage of the medication delivery process [8–11], they are more likely to occur in the prescribing and the administration phases [12–19].

Frequent dose changes have been linked to medication errors [20, 21], dosage calculation errors are not easy to detect in clinical practice [8, 22]. Donaldson et al. [23] completed an analysis of the Collaborative Alliance for Nursing Outcomes' (CALNOC) registry dataset with 33,425 medication administration events from 157 adult hospitals. While the overall medication administration error rates were low (less than 1%), missing dose and dosing errors were among the most frequently reported medication errors [23]. The nurses are required to verify the five medication administration rights, which are right patient, drug, dose, route, and time, with every medication administration event [24]. Dosing errors may occur even with accurate medication calculations prior to administration because the prescribed dose may not be appropriate for a given patient. This may lead to unintended adverse events for patients and may have legal ramifications.

3 Impact of Dosing Errors

While the scientific work in improving the strategies of verifying pharmacological interventions is improving, medication errors pose a risk in patient safety [25, 26]. According to the Agency for Healthcare Research and Quality (AHRQ) (2018), adverse events can be categorized as preventable or non-preventable, and they typically result from an erroneous action (commission) or failure to prevent the error from occurring (omission) [27]. When the wrong action is prevented from occurring that is called a near miss event [28, 29]. An adverse drug event (ADE) occurs when a patient experiences an undesirable response to medication therapy [30]. ADEs may not be reported if the health care team does not identify them. Also, other reasons for underreporting are underestimating the seriousness of the error, preventing a negative reaction from administrators, or a lack of time to report the event [31–35]. To better understand the contributing factors that lead to unsafe acts and adverse drug events, the science of early detection of ADEs with computer-mediated tools is on the rise [36, 37].

ADEs constitute approximately one-third of adverse events in the hospital setting [38]. In 2011, an analysis of ADEs from 32 states showed 129 out of 1,000 patients experienced an ADE that originated during the hospital stay [2]. A comparison of ADEs between hospital-based versus present on admission showed that ADEs with CNS depressants and anesthetics have the highest likelihood to originate in the hospital setting, and antibiotic and anti-infectives have a comparable risk of occurring in either setting [2]. Iatrogenic overdosing [39–41] or underdosing [41–43] may occur due to the oversight of relevant patient and drug-specific criteria. Medications that are prescribed outside the recommended dose range limits have a higher risk of causing harm to the patient [6, 39, 44–47].

4 Electronic Health Record

More than 80% of the non-federal government hospitals reported using an electronic health record (EHR) in 2015 [48]. There is a growing interest in understanding the usability of information systems in the healthcare setting and their impact on patient care [49, 50]. Most EHRs have integrated role-specific workflows to complete their respective medication management tasks [51]. The medication delivery process in the EHR starts with a licensed independent practitioner (LIP) (e.g., physician, nurse practitioner, physician assistant) initiating the medication order in the order entry module in the EHR. After the LIP saves the medication order, it is automatically sent to the pharmacy module in the EHR for verification. Once the pharmacist reviews the medication order, the medication order is then converted to a verified status to notify the nurse that it is safe to administer. The pharmacist will add the medication to the patient's profile to allow the nurse to obtain it from an automated medication dispensing cabinet. Some clinical settings may not require pharmacy verification for certain medication orders (e.g., immediate doses or STAT medications), as the medication order may display on the electronic medication administration record (eMAR) as soon as the medication order is electronically signed by the LIP. The pharmacy may dispense the medication to the patient's location if it is not stocked in the automated medication dispensing cabinet. Finally, the nurse acknowledges the new medication order and administers it as per instructions on the electronic medication administration record (eMAR). The nurse is required to sign off on the doses that were given to the patient on the eMAR. If the pharmacist or the nurse suspects that a prescribing error occurred, then they contact the ordering LIP or discuss findings with the healthcare team to ensure that the necessary corrections are made in the patient's record. A detailed description of the decision support tools in preventing dosing errors is provided below.

4.1 Prescribing Errors

Computerized provider order entry (CPOE) and clinical decision support systems (CDSS) together have shown to reduce medication errors, but they have not decreased the ADE rates [52]. A recent study on the cost of preventable ADEs from prescribing alert overrides at one academic hospital was estimated between $871 million and $1.8 billion based on an analysis of a year-long dataset from a random sample of nearly 41,000 adult patients [53]. The dosing alerts in CPOE with scheduled frequencies may be more accurate than one-time doses [54]. Providers may ignore dose alerts on high-risk medications if the clinicians prefer to use other internal workflows to establish patient-specific dosing parameters [55]. Some hospitals have embedded Infobuttons, which are context-specific links to relevant online resources into some contexts of the EHR to offer a less intrusive approach to access online resources [56, 57]. Their effectiveness in preventing medication errors is unknown. Prescribing medications is more complicated when the patient's status exceeds the standard dosing guidelines, such as obese children [58]. Koppel et al. [79] analyzed 114 medication orders that were rapidly discontinued by residents and found two-thirds of the medications contained dosing errors. When decision support features in CPOE push out alerts with outdated or confusing information, the providers may become desensitized and ignore them. A high number of safety notifications on prescribing actions that have a low or no risk of causing harm to the patient may lead to alert fatigue. Dosing alerts that are slightly over the high and low parameters are more likely to be ignored than massive overdose alerts [52, 55, 59]. Even though EHR components are integrated to maximize information flow [60], its effectiveness in preventing medication errors vary by design [61, 62]. User interface challenges in CPOE typically stem from design flaws [63, 64]. For instance, system design may be inadequate for a clinical setting with highly specialized treatment plans and patient care workflows [65, 66]. Also, some providers may fear medical-legal disputes from non-adherence to the preset CDSS recommendations [63].

CPOE may reduce pharmacy order processing times by 90% [67], but a backlog of medication orders in the pharmacist's queue may also lead to pharmacy verification errors [68]. The eMAR is a computerized version of a paper medication administration record, and it is generally integrated with CPOE and the pharmacy components in the EHR. It also contains a list of scheduled or as needed medications as well as time columns that display when medications are due [69]. Some EHRs have medication calculation tools for nurses to use in contexts outside of the eMAR (e.g., documentation contexts) [70]. When nurses work across different EHR contexts to complete the medication administration task, this increases the nurses' workload and creates additional opportunities to make verification errors. The advanced dose checking features designed to detect prescribing errors are not available in the eMAR [71], therefore dosing errors may be missed in the medication administration context.

4.2 Medication Administration Errors

Technology-aided medication verification has become the norm by integrating the eMAR with external with barcode scanning features [72, 73]. Barcode technology has emerged to assist the pharmacy technicians, ancillary staff, and nurses with required medication verification steps. In the pharmacy, barcode scanners are used by technicians to check dispensing errors [74]. At the point of care, barcode scanners may be used by ancillary staff (e.g., radiology technicians) to verify the patient and the procedural medication for a given test [75]. Also, barcode scanners may be used by nurses at the bedside to check the patient and the medication on hand against the medication order [76, 77]. The workflow requires the nurse to scan the medication label and the patient's armband using a handheld barcode scanner [72]. The Bar-coded Medication Administration System (BCMA) system alerts the nurse if the scanned information does not match the information on the electronic medication order [72, 78–80]. While it is not technically possible to verify the medication route via scanning (e.g., unable to scan the patient's mouth, intravenous (IV) site, etc.), BCMA does not entirely prevent the nurse from making wrong route errors (e.g., administer by mouth instead of IV or give via a feeding tube instead of orally and vice versa) [81, 82]. In the BCMA workflow, the drug form (e.g., tablet, injectable) is used to determine whether the medication should be given orally or parenterally. This has limitations because some medications may be administered both orally and intravenously [83]. Dosing errors may still reach the patient due to a calculation error that originated during CPOE.

Other complementary clinical information systems are designed to deliver medications. The infusion pumps with an embedded drug library software are called "smart pumps" [84]. The drug library software in the pump contains hard (enforced) and soft (recommended) limits that are designed to prevent dose and infusion errors. Also, the drug library database can be configured to display institutionally accepted drugs that are appropriate for specific clinical settings (e.g., critical care, emergency department, labor & delivery, etc.). Incomplete drug libraries and medication errors that fall between the preset low and high dosing or infusion parameters are some of the safety loopholes pertaining to smart pump use [85–88]. Also, programming options that allow using a weight-band to compute the dose and infusion rates using estimated rather than actual measurements undermine their effectiveness in detecting drug calculation errors [89]. Push-button errors [86], or circumventing the drug library programming steps in smart pumps [85, 87] are other sources of error. Establishing standard dosing concentrations to prevent 10-fold dosing errors during pump setting [90] and increasing the number of drug libraries to boost usage rates [91] are strategies to decrease intravenous medication administration errors. EHR and smart pump integration is a high-tech strategy to reduce programming errors by establishing the information flow between the two systems. Some hospitals are beta testing computer-based workflows to transmit infusion rates from the infusion pumps to the relevant contexts in the EHR [92–94]. Establishing and maintaining bi-directional connectivity between smart pumps and the EHR is dependent on the hospital's ability to sustain continuous support from functional champions and technical staff to work on break fixes, optimization requests, and train end users. The EHR-smart pump interoperability resulted in an 86% decrease in keystrokes, reduced programming errors, and improved IV therapy charge capture [95]. While the researchers were not able to quantify the financial benefits of reducing the burden of IV therapy documentation, a 3% reduction in lost charges in the ambulatory setting resulted in a $370,000 increase in hospital revenue [95].

In addition to the EHR-based systems and medication delivery devices, approximately 300 hospitals in the United States have implemented Technology Assisted Double Check™ (TADC) tools to allow nurses to quickly verify the ordered dose against an external drug knowledge base [96]. The TADC workflow requires the nurse to enter the information on the medication label either by hand or through a camera phone enabled drug barcode reader to retrieve a web-based drug resource to check for dosing errors and review preparation and administration instructions. To facilitate the secure transmission of patient data from the EHR to external smart applications like TADC, the Substitutable Medical Applications and Reusable Technologies (SMART) project was formed to establish the standards for data exchange [97, 98]. Leading EHR vendors (e.g., Epic Systems Corporation, Cerner Corporation) have formed partnerships with smart app vendors to expand the decision support capabilities of the EHR through the implementation of SMART standards [99, 100]. While there is a growing number of smart app developers who are looking for system design alternatives to prevent medication errors from reaching the patient, the eMAR cannot detect medication calculation errors that originate in CPOE or through pharmacy verification.

5 Future Considerations

With the widespread use of technology in the medication delivery process, hospital administrators should continuously monitor noncompliant behavior that leads to deviations from safe practices [101]. For instance, the BCMA system contains scanning and alert management activity reports that show the occurrence of workarounds [72]. The misuse of technology [73, 79, 102] and system workarounds [79] could be a symptom of system design flaws. Hospital-based process improvement initiatives rely on incident reporting systems to identify usability issues that lead to dosing errors [81]. Usability-error ontology is needed to track and monitor the unintended events, and ultimately, gain a better understanding of the technology-induced error landscape in the healthcare setting [103].

In the overview provided above, the researchers identified that medication safety considerations must be embedded in every stage of the medication delivery process. Dosing errors are one of the leading determinants of ADEs. Information technology plays an important role in preventing dosing errors. The dosing error detection features in the EHR are not evenly distributed in the medication delivery workflow. Most of the sophisticated medication safety warnings and dosage calculation tools that are designed to prevent such errors are front-loaded in the order entry phase of the medication delivery process. Overall, the user interface considerations such as accessibility, structure, functions, cognitive burden, and information quality also impact whether the technology will be successful in addressing the targeted medication safety issue in the medication delivery process. A high number of safety notifications may lead to alert fatigue. System developers should pursue practical approaches to embed dosage calculation tools into the medication verification steps in the eMAR. The embedded decision support feature must be robust enough to compare the prescribed dose against a drug knowledge database. There is an opportunity to learn from the system design challenges in other EHR contexts when developing nurse-friendly tools that target dosing errors in the last stage of the medication delivery process.

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Satisfying Product Features of a Dementia Care Support Smartphone App and Potential Users' Willingness to Pay: Web-Based Survey Among Older Adults

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Abstract. Dementia is a large economic, social and health concern with the aging population. One of the best ways to care for people living with dementia is to keep them at home in a familiar environment. Smartphone applications may provide assistance to patients and caregivers. An open web-based survey was answered by 104 individuals older than 50 years. Participants rated eight features of a potential dementia care support app according to the Kano technique. Out of the eight product features investigated, six were positively associated with an application (wandering detection, weather and other threat detection, notifications and voice prompts, location sharing, emergency services contact, and medical records). The median for the amount people were willing to pay per month was 25$ (CanD) with a third quartile of 50$ (CanD). The results show which features should be included in an application to have maximum acceptance and usability and how much potential users are willing to pay on a monthly basis a dementia care support smartphone app.

Keywords: Health · Dementia · Kano technique · Willingness to pay · Older adults

1 Introduction

Dementia is a rapidly growing problem with senior citizens. It has been found that 1 in 3 individuals over the age of 65 will die having some symptoms of chronic mental decline that interfere with their daily lives (i.e. Dementia). Once dementia is present, one major concern is wandering. This is when patients will aimlessly walk or move around which leads to them getting lost or confused. Strategies for managing this vary from providing reminders and directions to head home, to contacting a caregiver or emergency services [1].

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Improvements in smartphone technology and a growing accessibility to smartphone devices has led to a possible aid for individuals with diagnosed or developing dementia. A smartphone application that supports caregivers as well as prolong the time seniors with dementia could live comfortably in their homes makes sense both financially and socially. As of now there are two main branches of apps available, ones that are preventative, aimed at people who are at risk of developing chronic mental decline, and others that track and maintain the safety of people already experiencing dementia [2–5].

This research investigates which features a dementia care support smartphone application aiming at wandering patients should have. On top of that, it was also assessed what the cost is that individuals would be willing to pay for this product.

2 Method

2.1 Design

An open, self-selected, Web-based survey was created to provide a potential answer to the research goal. The survey was designed in English and provided for English-speaking older adults within the area of Alberta, Canada. The medium of a Web-based survey was used, as it is a convenient and valid method to obtain individuals with particular characteristics without any limitations on physical space [6].

The goal of the survey was to gather information and data that pertains to the expectations surrounding a dementia support application. This was measured using the Kano technique [7].

2.2 Investigated Product Features of a Dementia Support App

To decide on the features, literature and market research were reviewed to determine the products that are currently on the market and which technologies would be beneficial to dementia patients and their caregivers. Instead of broadening the survey to include memory exercises and dementia prevention, the focus is being spent on reducing caregiver time and easing the experience of dementia patients wandering by offering features addressing this phenomenon (see Table 1).

Table 1. Features investigated in to determine product scope

F1	24/7 Tracking of users location
F2	Navigation services for users
F3	Wandering detection
F4	Weather information and alert
F5	Voice based notifications instead of text based ones
F6	Location sharing with family and/or caregiver
F7	Automated emergency service
F8	Storing medical records within the app

24/7 tracking of the location and daily activities of a person with dementia would be collected to be able to provide other services related to wandering. Project Lifesaver is one of several companies producing wearable tracking devices aimed at people with dementia [8].

Map and navigation services are tools available for a person with dementia to use. The app would provide clear and concise directions to ensure their safe arrival at work, home or other locations. This service is recommended by studies as an important tool to aid in dementia care [1, 9].

Automatic wandering detection would have access to GPS tracking data of the person with dementia. The app would gather information regarding their routine and regular schedule and monitor their displacements for irregularities. If found, these irregularities would be analyzed to determine whether or not they are wandering. Other features of the app could then act accordingly to minimize the associated risks such as getting lost or stranded. This is as feature outlined in the paper by Sporaso and an app named iWander [2].

The weather feature is designed to keep a person with dementia out of immediate danger. The app would access local weather information and remind them to take the necessary articles of clothing when leaving their home. There would be warnings about violent weather and recommendations to stay at home. In extreme weather conditions, the app could respond more quickly to an incident where a person with dementia is lost [2].

In the event that a person with dementia is wandering, simple voice prompts or reminders are proven to minimize the risk of getting lost by notifying the person with dementia of a break from their routine. The app could automatically help them return to a safe and familiar location if they deem it necessary. This feature is the first line of defence against getting lost or stranded [1, 2].

Sharing the location of a person with dementia with their family and/or a caregiver can give everyone peace of mind. If something goes wrong, it is easy to communicate and connect through the app to keep a person with dementia safe [1]. This feature is designed to ensure the safety of a person with dementia if the previous strategies have failed to mitigate the risk of getting lost. If the app continues to detect irregularities in their displacements that indicate they are at risk, emergency services will be contacted automatically. They will then provide the needed support. The products on the market that have 24/7 tracking also have access to emergency services. This includes the line of Project Lifesaver products [8].

Providing access to medical records of a person with dementia, the app can make better decisions regarding how to handle their personal situation. This information would need to be filled out with a certified doctor to be implemented within the app's database. The information provided would be medication being taken as well as ailment history. This information could be passed on to emergency services if needed to accelerate emergency response decisions. Such wearable devices already exist. Medic Alert bracelets are the most popular device that has information regarding medical history [8].

2.3 Kano Technique

Described product features were investigated by the Kano technique [7]. With this technique, potential product features are classified according six different categories: attractive, one-dimensional, must-be, indifferent, reverse and questionable. To classify the potential product features according to Kano, pairs of questions are asked. Each feature is asked with one positively worded question (feature is included in the product) and a negatively worded one (feature is not included in the product). Both questions have the same set of answers available to select. To ease confusion and make the choices more clear, the adapted version of answers for the Kano technique, created by Robert Blauthe [10], were chosen. To ensure valid classification two different decision rules were applied. The first decision rule is called total and category strength [11]. In case this decision rule results in unclear classification Fong Test was applied [12].

Along with the categorical placement of each feature, two-sided customer satisfaction (CS+) and customer dissatisfaction (CS−) coefficients were calculated [10]. If these scores are higher than 0.5 in magnitude, corresponding features are determined to be of significant importance to increase or decrease customer satisfaction in case of implementation [10].

2.4 Willingness to Pay

It has been suggested that to gain the most use and generate revenue apps should be free of charge, but then operate with a subscription fee business plan (Freemium Business Model) [13]. Willingness to pay was measured as a monthly fee that potential users of the app would pay. This topic was addressed after participants rated the eight product features. They were then allowed to enter a value that was limited to four characters in Canadian dollars (CanD) (Lin et al. 2013).

2.5 Demographics

The first section on the questionnaire contained questions regarding the population demographics. Including questions on age, gender, ownership of smartphone, length of time having a smartphone, use of health related apps, health literacy and experience with dementia. Determining the sample of percentage of people most likely to be affected by dementia that own a smartphone is a crucial part of realizing the feasibility of using a smartphone as the aid platform. All of the smartphone related questions were used to gage the technical affinity of the sample tested.

2.6 Health Literacy

Getting an idea of the health literacy of the sample will help gauge the validity of the study, as it shows whether the surveyed individuals are aware and understand what dementia is and how it could affect them. This will be done using the HLS-EU16 questionnaire [14]. This questionnaire includes 16 items that pertain to health awareness and prevention and are evaluated on a 4-point Likert scale (1=not correct and 4=fully correct). Subsequently, a final score was calculated according to Röthlin et al. [14].

The final score ranges between 0 points and 16 points, whereas 13 to 16 points represents a good health literacy, 9 to 12 points a concerning health literacy and 0 to 8 points describe a problematic health literacy [14].

2.7 Questionnaire

The survey began with a short description of the study, followed by a section about demographics. Health literacy was then self-assessed by the participant. Participants then read a short description of a product feature and then answered questions according to the Kano technique. This was the way it was structured for all eight features. Next was a question regarding the participant's willingness to pay. Finally, there was a section where participants could give qualitative feedback for the app and project. In total there were 14 pages with 42 questions.

2.8 Data Collection

Data collection started on June 14, 2018 and ended on June 21, 2018. The questionnaire was created using the Web service Unipark (Questback GmbH).

All participants were informed about the duration of the survey, data storage, and the leading investigator. Each participant decided to take part in this survey voluntarily by following the designated link to the survey. A monetary incentive was not offered for participation.

The survey was pretested properly by a total of eleven people. Feedback and concerns were recorded and taken into consideration before sending out a final version of the survey. The Alzheimer's Society of Alberta reviewed the survey to make the wording more appropriate for the target community. For example, "patients" was changed to "people living with dementia". Technical problems, including the amount of numbers that could be inserted in the questionnaire for your year of birth were solved. The final version was sent out after proper revision.

2.9 Recruitment

The survey was sent via email to a personal network of people in Alberta and was then distributed by word of mouth to other participants. Initially the network included two primary groups of people, from Rotary or from the Alberta Teacher's Association (ATA). By using this method, the goal was to reach a large sample of diverse people. A letter was sent out explaining the goal of the research project as well as the target demographic. By using the IP address of the individuals computer or electronic device, the survey software from Unipark (Questback GmbH, Germany) ensured that all responses were from unique individuals.

In total, 218 followed the link to the survey. Of the 218, 75.69% (165 individuals) started the survey. Only 64.68% (141 individuals) completed the survey. Thus participation rate is 75.69% and a completion rate of 64.68% was achieved. The mean completion time was 12 min 28 s with a median of 10 min 8 s.

2.10 Statistical Analysis

Any individual below the age of 50 that had no experience in being a caregiver was excluded from the data. Also, any individual that missed answering a question (excluding individuals who incorrectly inserted the willing to pay data) or was not from Canada was excluded from the data. Remaining data from the Unipark Web-service (Questback GmbH) was exported to SPSS 23 (IBM, USA) for analysis. Microsoft Excel 2010 (Microsoft, USA) was also used to make analysis more efficient. Data was analyzed according to the Kano technique, including total and category strengths calculations, Fong-Test and customer satisfaction coefficients. After general examination of the results more detailed analysis was performed based on grouped comparison by means of dementia experience, age, and HLS-EU scores.

3 Results

3.1 Participants

In total, 104 participants took part in this study. The mean age of the sample was 63.16 years with a standard deviation of 10.84 years. Female participants numbered 63 (60.58%) while males accounted for 40 individuals (38.46%). One person selected "other" as a gender option (0.96%). 94 individuals (90.38%) reported owning a smartphone, while 10 did not (9.62%). Of those who reported owning a smartphone the mean length of time that they have owned one is 7.97 years with a standard deviation of 4.86 years. The number of people that use a health related app on their smartphone is 37 out of 94 smartphone users (39.36%). The sample contains one person (0.96%) who experiences symptoms of dementia while 56 (53.85%) declare that they have experience with someone who has dementia.

3.2 Health Literacy

For the 104 individual sample, the mean health literacy according to the HLS-EU16 was 11.26 with a standard deviation of 3.97. Health literacy is measured on a scale from 0 to 16, and there are 3 classifications based on the numeric answers [14]. From 0 to 8 is considered inadequate, 9 to 12 is considered problematic and 13 to 16 is good. The mean of the 104 person-sample is within the problematic range. The maximum an individual scored was 16 and the minimum was 2.

3.3 Classified Product Features According to Kano Technique

The Kano classifications are shown in Table 2. The features were all categorized using the full Kano model, including strength and Fong tests. In every case, there is a significant classification with the Fong test only having to be used for one feature.

Table 2. Kano classification of features.

		Classification
F1	24/7 Tracking	Indifferent feature
F2	Navigation services	Indifferent feature
F3	Wandering detection	One-dimensional feature
F4	Weather	Attractive feature
F5	Notifications	One-dimensional feature
F6	Location sharing	One-dimensional feature
F7	Emergency services	One-dimensional feature
F8	Medical records	One-dimensional feature

The customer satisfaction coefficients (CS) values are shown in Fig. 1. Four of the eight features are considered to have relevant values for at least one of the two sides of the value (>0.5).

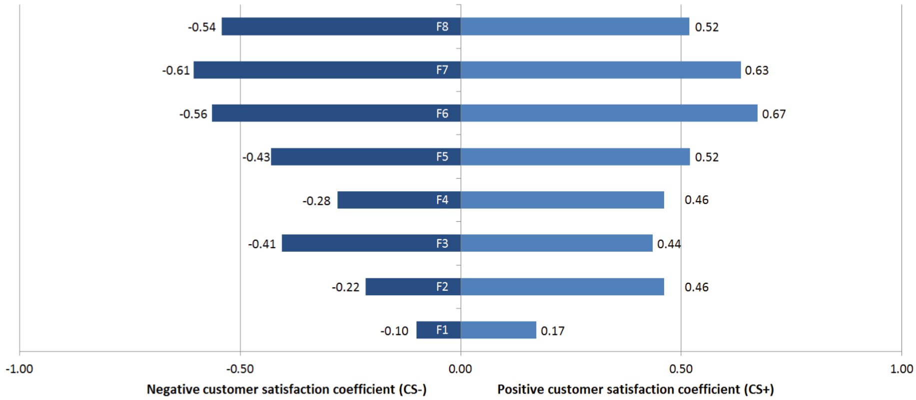

Fig. 1. Customer satisfaction coefficients

3.4 Willingness to Pay

Of the 104 person-sample, 96 individuals inserted a monetary value for the amount they would be willing to pay per month. Values ranged from 0$ to 500$ (CanD) with a mean value of 48.79$ (CanD) and a standard deviation of 8.18$ (CanD). Since there seems to be outliers, the median represents a better resistance to outliers. The median of the sample is 25$ (CanD).

3.5 Qualitative Results of Open-Ended Questions

Of all the participants, 41 responded (39.3%) to the qualitative question section. Most comments were split into three categories: privacy, feasibility and familiarity. There were 16 comments about the feasibility, four each of both privacy and familiarity, two on WTP, six concerns regarding to survey format, five general comments providing support for the project, two about their results of the Kano model, and three that stated that they had no comments. Concerns regarding privacy were that it was imperative to protect both the person living with dementia and their caregiver's data and information. There were numerous people questioning the feasibility of the app. Their main concern was centered around if a person with dementia could use such an app in the designed manner. Anxiety stemmed from interactions with elderly people and technology. Suggestions for having the application programmed individually for each patient were mentioned. Most were ideas for having a loved one be the programmed voice for notifications and voice prompts.

3.6 Kano Feature Groupings

The 104 individual sample was split into different groupings that were investigated for difference. The group having experience with dementia thought that wandering detection was an attractive feature, while the non-dementia group found the feature to be indifferent. Revealed is also that the aged less than 64 years old group and the non-health literate group (less than 13 points on the HLS scale) classified the navigation services as an attractive feature. The health literate group and the less than 64 year old group both categorized medical records as indifferent. The 64+ year old group found wandering detection to be an attractive feature and the less than 64 year old group found weather information and alert as an indifferent feature.

4 Discussion

4.1 Primary Results

In this exploratory study, product features were ranked as to the amount in which they could influence a user's use of a dementia support app. The Kano technique classified eight product features that belonged to two categories: data privacy and remote tracking. Furthermore, the strength and Fong tests revealed that all product features were classified with significance. There were five one-dimensional product features (wandering detection, notifications, location sharing, emergency services and medical records), one attractive feature (weather), and two indifferent features (24/7 tracking and navigation services). Grouping participants by demographic information resulted in little deviation in the Kano classifications.

4.2 Features

For six of the eight features analyzed, the result is that the features are desired in an application regarding dementia. The one-dimensional features that are particularly strong (>0.5) categories if referred to the CS+ values are notifications, location sharing, emergency services and medical records. This shows that these features cause great satisfaction when present. The CS− values are also significant in these categories meaning that the sampled population found these products very important to the application. Wandering detection was still a one-dimensional feature but did not breach the threshold of 0.5 to be overly significant. The one attractive feature was weather. As this is a feature added to the survey as a sort of add on to wandering detection and 24/7 tracking, this classification seems reasonable. 24/7 tracking and navigation services are classified as indifferent and therefore could be put in with no concern to a negative reaction. On the other hand, they cause no satisfaction either. Tracking devices in the market currently are generally accepted and the benefits of tracking outweigh the privacy and other concerns [15]. The 24/7 tracking is used for many of the other features; therefore even if the feature is by itself indifferent, it must be used for other features. The grouping results show that there is little variance between groups, and the small changes have potential explanations for them. Wandering detection became an attractive feature for the dementia experience group while it became an indifferent feature for the group with no dementia experience. This might show that with experience and more knowledge of wandering, you see automatic detection as a real big help and therefore find the feature to be attractive. On the other hand having no dementia experience could cause you to be indifferent about wandering detection. All in all, the groupings overturned no polarizing result which indicates a certain validity to the classifications found.

4.3 User Groups

After splitting the 104 person sample in to groups of dementia experience, age and health literacy, there were no significant differences in the Kano results. The demographics information received had no significant correlation values. This shows a very homogenous sample in which all demographics are distributed evenly. This indicates that the needs and desires for a dementia support app might be universal and therefore the app might be the same for the entire population. This is further supported by the demographics of the sample. Around one half of the sample is experienced with dementia in some form and half are health literate. It shows a balanced sample. Development of an app with the features discussed would potentially not have to be tailored to specific groups.

The technical affinity and number of people that own a smartphone (94/104) potentially indicate that an application is a feasible option for a support medium, although survey participants stated their concerns about dementia patients using technology. It would seem like the smartphone medium would be valid and convenient for caregivers and the older adults sampled, but what is unclear is whether people living with dementia have the technical prowess to benefit from this app. One case study determined that it is possible for individuals with mild cognitive disorders to use smartphones with some teaching [16]. Furthermore, if current trends are maintained, the amount of older adults with smartphones should increase and therefore the feasibility and acceptance of an application would also increase. In Canada, 69% of people aged 55 to 64 year olds and 19% of people aged 75 and over owned a smartphone. This could indicate that in the future, this group of younger people who are at a risk of getting dementia are going to have phones and an application would then have a higher acceptance as a support medium.

4.4 Willingness to Pay

As a producer or developer of a dementia support app, you should not charge more than $25 (CanD) a month. As this is the median value, 50% of the sample is willing to pay this while 50% does not. 75% of respondents would be willing to pay up to $10 (CanD). As this is, to our knowledge, the first research study asking the willingness to pay for a dementia app, there is no real exact comparison to previous works. Compared with other dementia services and studies, the WTP value found is quite low. In France, caregivers are willing to pay 12.1 Euro an hour for informal care [17]. In the USA, they are willing to pay 144 British pounds a month for an hour per day reduction for informal caregivers [18]. As is shown, caregivers are willing to pay a significantly higher amount than what this paper found for informal care, even if they are not quite comparable. For a comparison to an Alzheimer's app that is used to prevent the disease, the WTP value is 155$ (USD) [19]. This provides us with a comparison to another app in the same field, but that is not for continuing care. Thus, a comparison is quite difficult, but if looked at them all as a whole, the WTP is significantly higher in other studies. This could be due to multiple reasons. One of the explanations is that since an app that provides the services of replacing some caregiving time and providing safety to dementia patients is not known that well, the sample population is unsure of how much it should cost. An alternative explanation might be that the sample population felt that this app would not be quite as valuable as an informal caregiver and, therefore, the price point should not be as high. A third consideration is that since health care is government subsidized in Canada, people are not willing to pay as much [20].

4.5 Limitations

There are some limitations of this study. Firstly, the survey distribution method was word of mouth from personal contacts. This might cause the sample to be too similar and possibly not represent the entire population. Since it was passed on by word of mouth, the demographic target of Rotary and the ATA might have been breached and overstepped. Also, since the survey was distributed online, there might be a misrepresentation of the technical affinity of the sample. The questions of smartphone use, health app use, and number of years a smartphone was used, were used to judge technical affinity, but there was no standardized test to measure this. The technical affinity that the survey did measure was very high, with the amount of people owning smartphones found to be large.

5 Conclusion

Dementia care is an ever growing concern. People living with dementia need care from an informal caregiver, which cause major economic and social stress on both patient and caregiver. As technology in smartphones improves, the more a dementia support app can offer. The target of the app is to ease pressure off of caregivers, while keeping a dementia patient independent and living in their own home for a longer period of time. The goal of the study was to determine the acceptability, features needed and willingness to pay for a dementia support application.

A study was conducted with the help of an online survey. Eight product features from reviewed literature were analyzed adhering to the Kano technique. From this technique, six features were found to have a positive correlation with an app while two were found to be indifferent. After completion of the study, the authors believe that an app that includes the eight features would be implemented successfully in the dementia community. Even though the app would probably be accepted, more research into the user-appropriate implementation of each feature needs to be conducted.

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Designing Hospital Wayfinding Systems, Touchscreen Kiosks, Environmental Cues and Mobile Apps: An Evaluation of a Mobile Wayfinding Application

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Abstract. This paper is part of a larger body of work researching wayfinding systems in large, complex, hospital environments. The focus of this second phase of research was to discover usability issues that impact the effectiveness of a mobile wayfinding application used by a large multi-building hospital complex, as well as provide informed recommendations to enhance users' navigation performance. Four researchers conducted a heuristic analysis composed of twenty dimensions across six categories including language, effectiveness of wayfinding instructions, consistency between the environment and application, interface interaction, accessibility and cognitive workload. Primary recommendations consisted of adding a universal search option, orienting navigation cues to user view, and providing assistance to find a help desk. Results from this paper will provide a guideline for the development of mobile wayfinding applications for large hospitals and similar settings.

Keywords: Wayfinding · Healthcare · Usability · Design · Heuristic evaluation · Human factors · Mobile application

1 Introduction

Wayfinding is the process of understanding where you are in the environment, determining where you need to go, identifying the most optimal route to get there, and recognizing when you have arrived [1]. Wayfinding aids in complex environments, such as medical care facilities, are necessary for individuals to find their destinations in a quick and efficient manner. However, even with the assistance of aids, wayfinding has been shown to cause stress for people who are unfamiliar with these complex environments [2]. Studies have since aimed to determine the most effective types of aids. Wayfinding aids have progressed from the use of signs and environmental cues to the use of technology such as interactive touchscreen displays, kiosks and mobile software applications [3]. The purpose of these interactive mobile applications is to simplify the process of wayfinding, allowing the user to access essential information about their location while navigating freely through the environment. Hospitals are now investing in interactive navigation systems, such as mobile applications, to complement traditional

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wayfinding aids. But, if a wayfinding aid does not provide the support expected, users will likely abandon the technology [4]. Wayfinding mobile applications should be easy to use, effective, accessible, and intuitive. If patients and visitors do not find an application effective for their intended purpose, there may be economic loss for the medical care facilities that invest in an ultimately rejected technology [5].

The first phase of this research examined the usability and effectiveness of interactive, touchscreen, wayfinding kiosks in three large hospitals [6]. Participants were recruited onsite from each of these hospitals and asked to complete various tasks using the wayfinding display in their hospital. There were five tasks developed by the researchers that included basic navigation to destinations within the hospital, comprehension of orientation in the environment, accessing help, locating relevant information utilizing the search function, and navigating through the hospital based on the route and directions provided. SUS scores collected and averaged across participants indicated that each interface was perceived by users to be below average in terms of usability. Consistent issues observed were documented and used to draw implications and develop recommendations for future designs. Results from this research indicated that basic heuristics were often overlooked, such as classifying information according to user expectations, including a universal search, minimizing unnecessary on-screen information, adhering to platform standards, presenting visual aids effectively, and orienting navigation information effectively.

In the second phase of research which is the focus of this paper, we have explored several mobile wayfinding applications designed for large multi-building hospital complexes. Evaluating the current apps can help establish guidelines for future wayfinding application designs. Researchers decided to focus on one of these mobile applications for a heuristic analysis. In this type of evaluation, multiple researchers assess whether or not an interface design adheres to certain heuristics, or guidelines, that should be followed for optimal usability [7, 8]. This method provides a simplified benchmark by which to examine interface design and offers varied perspectives to identify usability issues. After prioritizing the criticality of these errors, researchers develop recommendations to be implemented in the next iteration of the design. Given that the standard set of heuristics were established by Nielsen and Molich in the nineties, it has been suggested that they may be too general to evaluate the usability of designs intended for mobile devices and therefore design-specific heuristics are recommended [9]. For this reason, we began by developing our own set of heuristics, influenced by our prior research, to evaluate this specific wayfinding application. Ideally, user-centered design would be incorporated in the development phases, rather than solely using retrospective judgement [5], however we believe evaluating current systems can help establish guidelines for future designs and fill the gap in the current literature about the usability and design of mobile wayfinding applications.

2 Method

Four researchers were selected and briefed on the purpose of this current phase of research surrounding the mobile wayfinding application. A review of the previous research on touchscreen kiosks from phase one was done in order to highlight issues identified with wayfinding systems. Following the review, a set of heuristics (Table 1) were established to measure the usability and effectiveness of the mobile wayfinding system. Twenty heuristics were created comprising six general categories: language, effectiveness of wayfinding instructions, consistency between the environment and application, interface interaction, accessibility and cognitive workload. In order to fully assess these heuristics, the application was examined on site in the hospital. Each researcher used an iOS device to individually conduct a heuristic analysis, taking note of usability issues, documenting impressions of the layout and features of the interface, and capturing screenshots of the application. Additionally, the researchers used the application to navigate to a destination, to evaluate effectiveness and compare the signage, icons, labeling and color coding of the application to the environment. After the evaluations, a debrief was held to discuss the findings, identify usability issues and suggest recommendations for improvement.

3 Results

The first phase of this research examined the usability of interactive, wayfinding, touchscreen kiosks in large complex hospitals. Phase two focused on the use of a mobile application which solved some of the issues found in the initial research. For instance, being able to bring the instructions with you solved the problem of cognitive workload. In phase one, users were required to remember a set of directions given to them by the system. Individuals often missed pages of instructions by leaving the kiosk before realizing that all of the instructions were not visible. An accessibility issue observed in phase one and solved by the mobile app was the difficulty of attempting to use a kiosk from a wheelchair. It is beneficial that this application can be used remotely, making the instructions accessible for anyone, including people with disabilities. Finally, information inside the application complemented other wayfinding aids, such as the colors, landmarks and signage used in the environment. Having the system match the environment is useful because it helps individuals identify other surrounding cues, making the wayfinding process more efficient. Though the mobile app solved some of the issues from phase one, it did not include a universal search feature, provide instructions on how to access help from a human or provide location-based navigation. Following the heuristic evaluation, and categorization of the usability issues, we provided recommendations to improve mobile applications, as detailed below.

Inclusion of a Universal Search. In our previous research on interactive wayfinding kiosks, we found that a search option was often only available within specific categories on the screen. For example, in one task when participants were asked to find the landmark called

Art Gallery, some incorrectly chose the menu option *Food, Shops and Services*. They would then use the search function within that category to obtain the information they sought – in this case the *Art Gallery*. However, because the *Art Gallery* is a landmark, rather than a destination within *Food, Shops and Services*, they were unable to find the information using the search feature. This prompted us to develop a search heuristic for the wayfinding application, since a universal search would enable users to search for diverse data [10], such as doctors, buildings, room numbers, etc., regardless of where you are in the interface. This application contains several comprehensive lists of items (Fig. 1) that require users to scroll extensively through the options. Due to the lack of a universal search option, users are often unable to easily find information they seek, which may lead to frustration. There should be a search feature that allows individuals to search for distinct things particular to each person. It should also be easily discoverable and usable, enabling a more efficient system.

Table 1. Final heuristics for analysis.

Is the terminology for laymen or medical professionals?
Does the interface respond as expected (touch, navigation, familiar elements)
Are the systems accessible for people in wheelchairs?
Is there a universal search?
Can you easily get directions to locations?
Can you correctly use the instructions to navigate?
Are the directions oriented to match their location in the hospital?
Can users tell when they have the full set of directions? Are there timing issues or hidden next button issues?
Is it clear where you are in the system, how to get back, how to proceed?
Is there information overload and confusion of important elements in the directions?
Is there an overload of verbal instructions?
Is there too much information to remember?
Does the color coding match the hospital?
Do the naming conventions match hospital labeling? (rooms, elevators, signs)
Do they use landmarks in the instructions?
Is there good signage in the environment?
Are there multiple helpful signs in the environment?
Is there help?
Is there a culture of helpfulness from the staff?
If there is an error, is it easy to recover from?

Option to Locate a Help Desk. A recommendation from the first phase of this research was to continue to provide a culture of helpfulness in the hospital environments. If participants were unsuccessful at using the interactive system, they generally indicated that they would seek assistance from a hospital employee. In this application, there wasn't an option to search for or guide the user to a help desk nearby, which violated one of the heuristics during evaluation. Providing an option to locate a "Help Desk" would be ideal for patients and visitors who are lost and would like assistance from a human staff member. Ideally patients would never need to ask for help but having an option to identify where help desks are would increase the application's wayfinding effectiveness.

Providing a Map for Visual Aid with Appropriate Orientation. When *Campus Directions* was selected within the application, users were prompted to select a "From" and "To" location (Fig. 2), similar to the mental model of obtaining directions in other common navigation applications. The output provided is a list of instructions with symbols, buttons and icons that match the environment of the hospital. Providing a map of the directions that users are required to travel in order to get to their destination would enhance the effectiveness of the list of instructions. This map should also be oriented appropriately so that users are not confused on which direction they should go. The layout of the maps at each hospital should match the environment in which it is located, giving participants the expected orientation to avoid confusion [11]. This would require allowing different orientations based on physical location of the device in the environment.

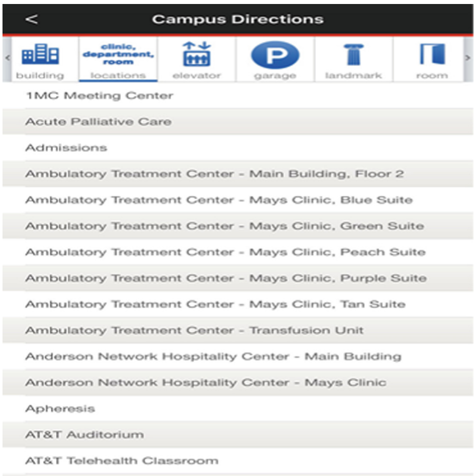

Fig. 1. This is a comprehensive list that individuals are presented whenever they are selecting locations within the hospital. The user must scroll through this list to find their desired location.

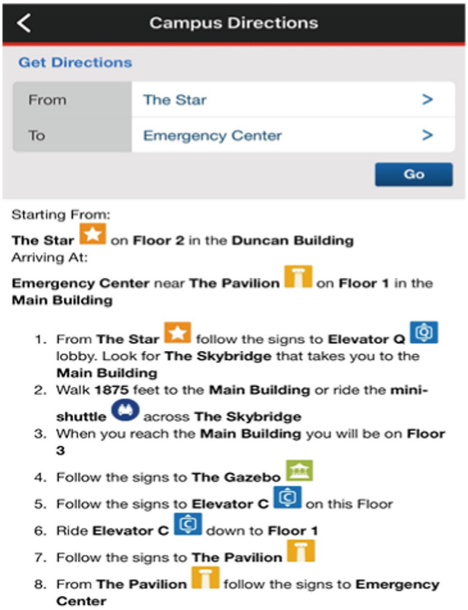

Fig. 2. A list of instructions is provided to the user once they have selected a "From" and "To" location. These directions help the user navigate through the hospital to reach their destination.

4 Discussion

In this paper, we reported issues associated with a mobile wayfinding application designed for one large medical-care facility. Our primary goal was to learn from this application and offer recommendations for the iteration of current and development of future wayfinding applications, to enhance their effectiveness in real-world environments. Creating our own set of heuristics allowed us to identify multiple issues with the wayfinding app that could (Fig. 3) cause individuals frustrations and/or confusion. People visiting hospitals who experience the frustration of a poor interface or receive confusing or incomplete directions from a wayfinding system experience increased stress [12]. Users that experience many obstacles may abandon the technology and search for another source of information. With the amount of money invested in wayfinding systems, the importance of usability should be at the forefront of designers' minds throughout entire process of system design [13].

Interfaces, such as the wayfinding application described, should allow first time users to identify the information needed quickly and effectively. In order to achieve this, wayfinding apps should be designed to reduce cognitive overload, as well as the time it takes to navigate to a specific destination, by implementing intuitive interaction techniques and features consistent with additional wayfinding cues [14]. Wayfinding applications that exist or are currently being developed should consider the environment of the hospital during the design phase. Information inside the application should complement the environmental information such as color coding, landmarks, room and elevator labeling and signage, which this application did well. The key user-centered design principles we recommend to be helpful in wayfinding interfaces are: including a universal search option, including an option to locate help desks in the hospital and providing a map for visual aid with appropriate orientation. These general wayfinding application guidelines should be considered for all types of interface aids including interactive touch displays and static maps.

Fig. 3. Several environmental cues that are consistent with other wayfinding aids help guide users to their intended destinations.

Future work and Limitations. Though we took the approach of developing heuristics specific to the interface design we were evaluating, there is the possibility of missing some heuristics or identifying issues that may only have a minor or negligible impact. Ideally, a heuristic analysis should be part of an iterative design process that includes user testing. We found that the wayfinding application did solve some of the issues found in phase one with the touchscreen kiosk usability testing. As the application is mobile, cognitive overload from a huge set of instructions, overlooking screens of instructions, not being accessible to wheelchair users and the interface elements not responding as expected were solved. However, while the navigation elements of the application responded as expected, it did not provide real time orientation or mapping for navigation. With the advance of GPS technology, expectations have changed [15]. The ideal wayfinding application would provide real time location and direction. Our next step will be identifying an application with this functionality and testing the usability and effectiveness as a wayfinding aid.

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Determining Patient's Interest in Patient Portal Use in a Primary Care Clinic to Improve Portal Adoption

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Abstract. Patients accessing their personal health information has the potential to improve their healthcare decision-making. Despite the potential benefits of patient portals and government reform, adoption has been poor. The objective of this project is to determine patients' awareness of their patient portal and their interest in portal functionalities to assist with increasing patient portal adoption. Forty-two patients completed a 9-item survey at a primary care clinic. Descriptive statistics were used to summarize the data. 83% of patients were interested in having access to their health information. 55% were aware of the patient portal and only 35% were signed up. The main reason for not signing up was unawareness of service (35%). Majority of participants (77%) were most interested in viewing personal health information and 50% were interested in secure messaging. These results provide valuable information about patient's interest in accessing the patient portal and provides information on functionalities of interest.

Keywords: Patients · Personal health record · Needs assessment · Data display · Communication · Primary health care · Information need · Patient-centered care

1 Introduction

There is a growing emphasis on patient-centered care and providing patient with convenient access to their personal health information is necessary to support patients' engagement in their health. The goal of Meaningful Use Stage 3 is to encourage patient engagement by providing patients with protected online access to their personal health information [1]. Patients accessing their personal health information have the potential to improve self-management of their health and healthcare decision-making [2–5]. The purpose of the patient portal is to support patients' access to health information, visit summaries, educational materials, and medication reconciliation [6–8]. Despite the potential benefits of patient portals and government reform, adoption has been poor [9–11].

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Previous studies have shown that patients are interested in accessing their health information [12–15]. An annual survey conducted by the Xerox Corporation on the usage of electronic health records, showed that patients are willing to electronically access their health information if they are shown how [16]. Similarly, a study of US adults' perception, access, and patient portal use by Peacock et al., found that majority of US adults (92%) considered it important to access their personal health information online [17]. Understanding patient portal use and identifying barriers that hinder portal use is essential for increasing patient portal adoption.

1.1 Objective

The objective of this project is to determine patients' awareness of their patient portal and their interest in portal functionalities to assist with increasing patient portal adoption. This project is attempting to solve the problem of the low adoption of the patient portal. The project aims to address five specific research questions:

1. What devices do patients have access to?
2. Are patients interested in having access to their health information?
3. Are patients aware that a patient portal is available to them?
4. What functionalities do patients find useful in a patient portal?
5. Why are patients not signed up to access their patient portal?

2 Methods

2.1 Study Design

To determine current patient portal use, patients completed a brief 9-item survey during their clinic visit. The survey sought to determine their awareness of the clinic's patient portal, their interest in using the portal, and reasons for not signing up for portal access. The survey also inquired about patients comfort using a computer and the different devices they owned.

2.2 Organizational Setting

Nebraska Medicine is an academic health system and its research and education partner is the University of Nebraska Medical Center. Nebraska Medicine has 16 outpatient clinics in Omaha and other locations in Nebraska. The Nebraska Medicine Fontenelle Clinic is a non-profit clinic centered on providing care for adults and children in North Omaha.

The non-profit organization, Healthcare Information and Management Systems Society (HIMSS), examines hospitals' progression toward electronic health record (EHR) adoption, has classified Nebraska Medicine with Stage 7 of the Electronic Medical Record (EMR) Adoption Model [18]. Stage 7 is characterized as hospitals and clinics that have fully integrated EHRs, transfer health information via Continuity of Care Documents (CCD), employ data warehousing to evaluate aggregated clinical data, and demonstrate summary data continuity for all hospital services [19]. Nebraska Medicine offers patients access to their health information through Epic MyChart, a tethered patient portal.

2.3 Participants

Participants in this sample were current patients at the Fontenelle Clinic, 19 years or older, and able to read English.

2.4 Data Collection

Patients were given the survey by the front desk during their clinic visit check-in. The front desk staff explained to patients that the survey was a part of the clinic's quality improvement plan prior to providing the survey. Patients had the entire clinic visit to complete the survey. Patients who completed the survey were able to return the survey to any member of the healthcare team.

2.5 Data Analysis

Survey data was transcribed and analyzed using Microsoft Excel 2016. Descriptive statistics which included counts and percentages were used to summarize the data.

3 Results

3.1 Demographics

Table 1 shows the demographics of the forty-two primary care patients that completed the 9-item survey. Patients' age ranged from 20–84. Seventy-five percent (30/40) of patients were female. Sixty-eight percent (25/37) of patients identified as Black, 27% (10/37) identified as White, 3% (1/37) identified as Hispanic, and 3% (1/37) identified as Black and White.

Thirty-four percent (13/38) of patients' highest level of education was a high school diploma or General Education Development (GED), 26% (10/38) of patients were college graduates, 21% (8/38) of patients completed some college or trade school, 16% (6/38) did not graduate high school, and 3% (1/38) completed a post graduate degree.

3.2 What Devices Do Patients Have Access To?

Smartphones were owned by 82% of patients, 58% of patients owned a desktop/laptop, and 45% of patients owned a tablet or iPad (Fig. 1).

Majority (76%, 29/38) of participants felt either somewhat comfortable or very comfortable using a computer (Fig. 2).

Table 1. Demographics of 42 primary care patients that completed the 9-item survey presented as frequency and percentages. Examined demographics include age, gender, race/ethnicity, and education. Five respondents did not include their date of birth. Two respondents did not include their gender. Six respondents did not include their race/ethnicity. Four patients did not include highest level of education.

Demographics	n	%
Age range	20–84	
Gender		
Female	30	75%
Male	10	25%
Race/Ethnicity		
Black	25	68%
White	10	27%
Hispanic	1	3%
Black/White	1	3%
Education		
Did not graduate high school	6	16%
High school graduate/GED	13	34%
Trade school/some college	8	21%
College graduate	10	26%
Post graduate degree	1	3%

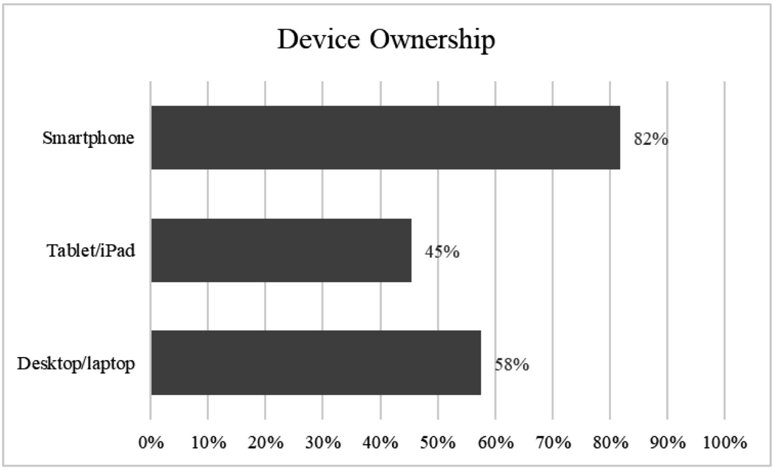

Fig. 1. Patients' device ownership displayed as percentages.

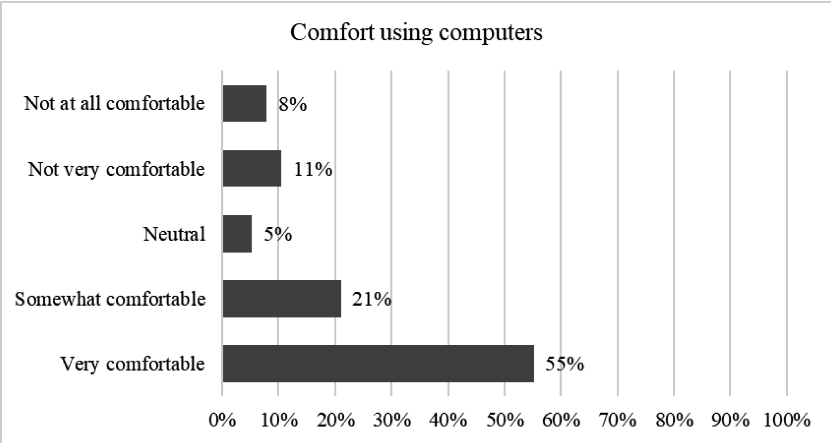

Fig. 2. Shows patients' level of comfort using a computer displayed as percentages.

3.3 Are Patients Interested in Having Access to Their Health Information?

Eighty-three percent of patients (35/42) were interested in having access to their health information (Fig. 3).

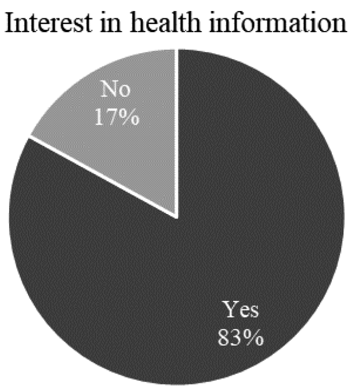

Fig. 3. Shows patients' interest in having access to their health information displayed as percentages.

3.4 Are Patients Aware that a Patient Portal Is Available to Them?

Only 55% (23/42) were aware of the availability of a patient portal and only 21% (9/23) were signed up to access the patient portal. Thirty-six percent (13/36) of patients responded yes when asked if they wanted assistance in signing up (Fig. 4).

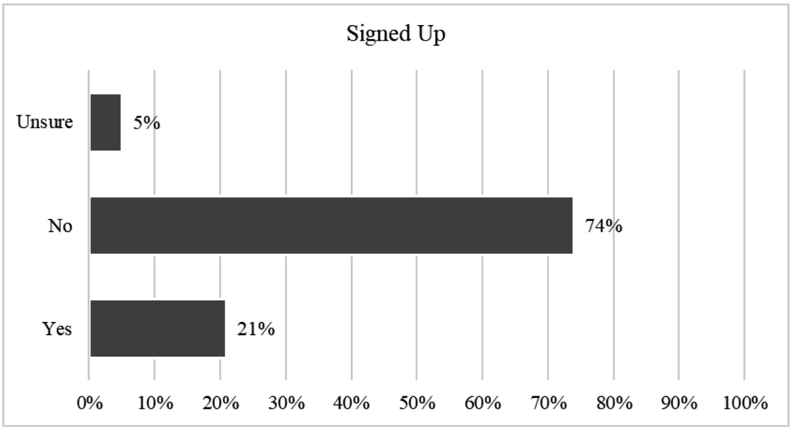

Fig. 4. Percentage of patients signed up to access the patient portal.

3.5 What Functionalities Do Patients Find Useful in a Patient Portal?

When asked what functionalities participants would be most interested in using in the patient portal, 30 participants provided a response. Majority of participants (77%, 23/30) were most interested in viewing personal health information such as: recent doctor visits, after visit summaries, medication list, lab results, etc., and 50% (15/30) were interested in securely messaging their doctor (Fig. 5).

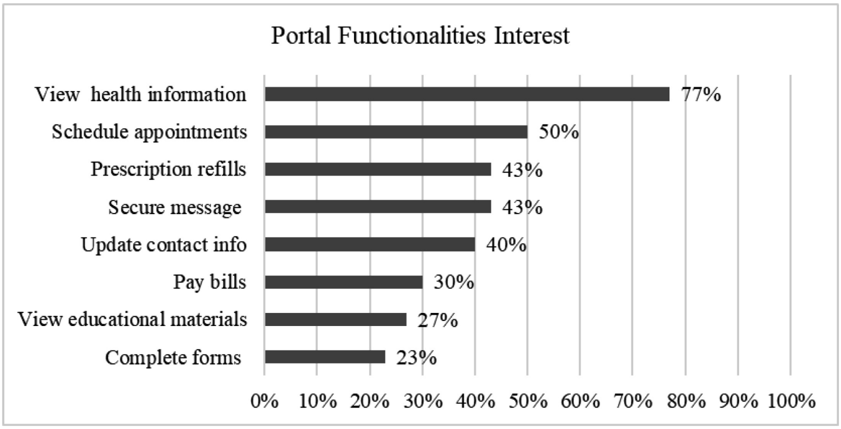

Fig. 5. Functionalities patients would be most interested in using in their patient portal displayed as percentages.

3.6 Why Are Patients Not Signed Up to Access Their Patient Portal?

Twenty-three participants provided reasons for not signing up for portal access: 35% (8/23) were unaware of service, 30% (7/23) had no interest in accessing the patient portal, 26% (6/23) lacked internet access, 17% (4/23) forgot to sign up, and 9% (2/23) lacked email access (Fig. 6).

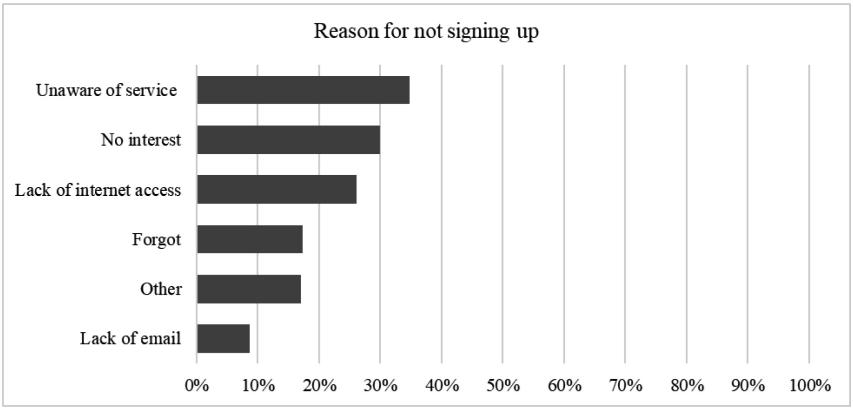

Fig. 6. Reasons for patients not signing up for patient portal access displayed as percentages.

4 Discussion

4.1 Majority of Patients Own Smartphones

Our results showed that majority of respondents owned a smartphone. These results are similar to the results of surveys conducted by Pew Research Center [20] that shows that most Americans (95%) own a cellphone. The survey also revealed that 77% of Americans currently own smartphones compared to 35% in 2011. Our results also showed that 58% owned a desktop/laptop and 45% owned a tablet or iPad. Pew's surveys [20] also found similar results where many U.S. adults (75%) own desktop or laptop computers, approximately 50% own tablet computers, and about one-in-five own e-reader devices. With the increase in device ownership, patients now have convenient access to their personal health information and to reliable health information for use in improving the management of their health.

4.2 Patients Are Comfortable Using Computers

Our results show that majority of respondents were comfortable with using a computer. These results are supported by a study by Tarrell et al., [21] that reported computer skills as decision drivers for personal health record use. They found that computer efficacy and attitude were the dominant factors that influenced patients' personal health record use. These results suggest that computer skills need to be a part of any effort implemented to increase patient portal use.

4.3 Patients Are Interested in Having Access to Their Health Information

Most respondents in this study were interested in having access to their health information. Previous studies have also shown that patients are interested in having access to their health information [12, 13]. With government mandates in place, patients have the right to access to their health information to assist them in making informed health care decisions.

4.4 Not All Patients Are Aware that a Patient Portal Is Available to Them

One of the main reasons patients were not signed up to access their patient portal was because they were unaware of the service. Similarly, a literature review by Wildenbos, Peute, and Jaspers reported limited to no prior knowledge on patient portal existence, as a barrier to personal health record use [22]. Powell, in a systematic review, also reported lack of awareness as a barrier to personal health record adoption [23]. Increased promotion of the patient portal is one way to increase portal adoption.

4.5 Patients Want to Schedule Visits Online

Patients found viewing their health information as well as scheduling appointment as useful functionalities of the patient portal. Multiple studies have identified scheduling and managing appointments as one of the most commonly used portal functions [14, 15, 24, 25]. There is also a potential to reduce cost by placing the task of appointment scheduling in the hands of patients [26]. These results suggest that patients prefer the convenience of online scheduling as opposed to traditional scheduling over the phone that is limited to standard business hours.

4.6 Patients Don't Perceive the Benefits of the Patient Portal

In addition to being unaware of the availability of the patient portal, patients also had no interest in accessing the patient portal. Previous studies have also reported patients' lack of motivation to use the patient portal [22] and not recognizing the benefits of using the portal for health management [27]. These results suggest that patient don't fully understand the purpose and benefits of the patient portal. Interest could be increased by discussing with patients the benefits of accessing the portal and demonstrating functionalities of interest. Another implication is that patients may not have a severe illness that requires continuous monitoring, which may be a reason the portal is not of value to them.

4.7 Limitations

The first limitation of this study was that it was restricted to primary care practice; therefore results may not be generalizable to patients seen in specialty practice because of their unique information needs [28, 29]. We also had a small sample size that comprised of patients from a single healthcare system, which also affects generalizability.

5 Conclusion

Providing patients with convenient access to their personal health information is necessary to support their engagement in their health, and to fully understand their treatment plan, which may improve patient outcomes. These results show that patients are overall unaware of the patient portal, which is the main cause for a low sign up rate. This suggests that increasing promotion of the portal will improve sign up rates. These results can be used to develop a strategic plan to increase patient adoption of the portal.

These results provide valuable information about patient's interest in accessing the patient portal and provides information on functionalities of interest. Awareness of patients' technology access and interest in portal functionality will assist in developing useful and user-friendly patient portals. Future research should evaluate the impact of the patient portal on patients' compliance to their treatment plans.

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The Challenge of Designing New Work Systems Towards Effective e-Health Interventions

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Abstract. The design of novel mobile applications for healthcare improves the access, convenience, education, care-quality/effectiveness. To increase the cost-value of integrated healthcare system, new health-related work design should be developed. As the patients are more informed and take an active control decision about their healthcare options, they force the healthcare systems to redesign and change inevitably. The patient empowerment lies to the access of different clinical outcomes information: diseases reliable information, available treatments and management of therapeutically outcomes. This needs to be aligned with caregivers, providers and financiers. Our overall objective is to understand how Portuguese population will respond to eHealth technology design and development for information exchange within healthcare systems and how the healthcare systems cope with new work systems design. Four core interactive work design features were identified that may mediate the effects of intervention in the healthcare outcomes: Social context and support, Contacts with intervention, Tailoring, and Self-management.

Keywords: Human factors in eHealth · Work systems design · Healthcare platform design

1 Introduction

The driving forces to develop our societies will depend directly on the sustainability of our health and economy systems. To know how to design an integrated care management will be the focus for future sustainability in health (by reducing overall costs, increasing disease prevention and increasing knowledge next to the population). Thus, it is essential to understand the importance of technology both in achieving these goals for a near future and in designing new Work Systems towards effective e-health interventions. Technology enables online access to healthcare information generated by other providers at any point of care delivery, therefore it is expected to improve the quality and efficiency of care and reduce the operating and administrative costs of

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healthcare providers [1]. In times when it is faced with a reduction of resources towards physicians, and downsized budgets it is necessary to reduce costs and make sure that money invested in any initiative is well planned. Designing digital approaches as base operation for future strategies will enhance costumer-level communication and putting the patient perspective at the center of initiatives concerning their own health condition [2, 3] concluded in their systematic review that designing mobile and tablet apps improve health outcomes within symptom management thought disease self-management interventions. This means that patients with chronic conditions can increase their effectiveness in symptom control.

Studies of literature have shown gaps of knowledge on e-health and the power of information exchange between health organizations and patients. Despite several works studying the impact of eHealth on the quality and safety of health care, not all authors indicated that the benefits of developing eHealth are positive and guaranteed to be achieved. So, further evidence towards the perception of population is needed. A major finding from review literature is that empirical evidence for the beneficial impact of most eHealth technologies is often modest. Accordingly, it is highly important that deployments already commissioned are subject to rigorous, multidisciplinary and independent evaluations towards the design of new eHealth applications considered for healthcare delivery for near future [4].

Designing integrated care and integration systems have an essential play to develop sustainable systems to reduce costs. A major change is needed to develop cost-effectiveness systems that are used for exchange information between care services and empower patients. Only by understanding the outcomes of an integrated care system and the importance of information and knowledge exchange we will understand where to move forwards. Considering this, two questions arise: RQ1 – Will the design of health-related mobile apps will benefit their health and reduce healthcare costs? RQ2 – Will patients adhere and engage positively to healthcare information within an integrated healthcare services by using eHealth?

With these questions in mind, and considering the relevance of global healthcare delivery, economic sustainability in healthcare, integrated care systems, patient empowerment, and the link towards eHealth, this study seeks to understand if the design of an eHealth platform can reduce costs by increasing knowledge to the population and in consequence the patient empowerment within any treatment, disease prevention or management of a chronic condition itself. Focusing on the idea that information and knowledge exchange reduce the misused of medication; lack of information; reduce readmission to healthcare service aftercare or treatment. In parallel, it also has the objective to put the design of new Health-related Work Systems into perspective to some degree, considering eHealth Interventions.

2 Literature Review

2.1 Global Healthcare Delivery and Its Costs

Global healthcare has expanded drastically over the past decades and offer great promise to improve live quality. The development of new pharmaceuticals and new vaccines, the advance in new treatment strategies, the application of brand-new technology in healthcare, the design of new medical devices and the conception of new and sustainable layouts in hospitals, represent a challenge in designing new Work Systems towards effective healthcare interventions.

The dynamics of globalization and sustainability is reliant on a healthy population. It is easily understood that a healthier population is indeed more productive and therefore higher economically driven regions [5]. Healthcare systems develop local procurement of goods and foster design of new services and infrastructures, such as cell phone towers, clean water supplies, and Internet access, that have a wider economic benefit to any population [6]. As worldwide population is aging exponential and increasing, particularly in developed countries, there is an urgent need to develop and redesign the healthcare system to become sustainable in long-term. Knowing that integrated care management will be the focus for future sustainability in health by reducing overall costs, increasing disease prevention and increasing knowledge next to the population, is essential to understand the importance of technology in achieving these goals for a near future.

The difficulties encountered to achieve the Millennium Development Goals towards health targets constitutes a big concern worldwide. The growing consumer demand is forcing health planners to design and innovate healthcare outcomes of overall public health. Health systems must address diversity, high-quality services either in rural or urban areas; tackling rich and poor population; improving training and support healthcare workers.

To increase the value of healthcare is to understand the core level of value creation in prevention, diagnosis and efficient treatment [6]. In turn, an efficient diagnosis also depends on the design of new medical devices, on the development of new products, and on the appliance of technology that increases the health-related work effectiveness. Only by defining and structure these processes it is possible to reduce costs in global healthcare systems and overcome the challenge of designing new work systems towards an effective healthcare.

Figure 1 develops a value increase chain of different sectors within the health sector. Information and engaging throughout any health-related process would increase the measuring rates and accessing any results.

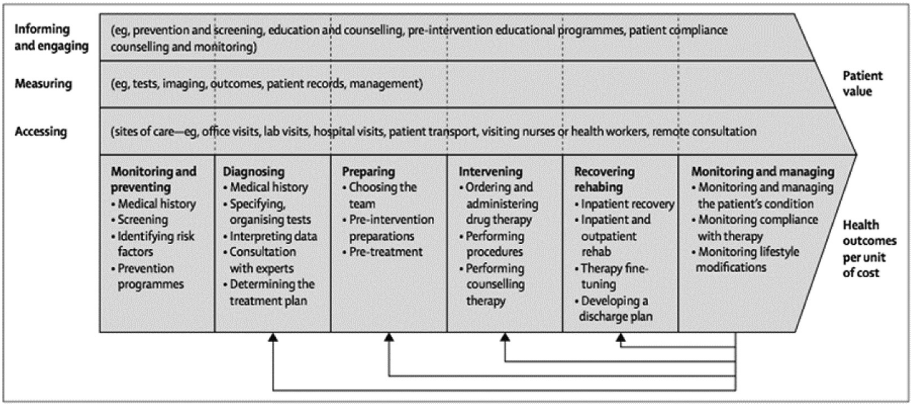


Fig. 1. Value chain for patient and health outcomes (adapted from [6])

Being informed educationally on prevention and screening diseases will increase patient compliancy, counselling and monitoring throughout the treatment. These will increase patient value from the service provided and its outcomes of accessing at early stages, during intervention. Moreover, monitoring the evolution will increase the health outcomes substantially for each unit cost [6].

2.2 Integration Delivery and Clinical Coordination Design

The literature review stress five main types of integration processes (Table 1), each one describes a wide range of integrative processes that differ within the healthcare provider. Some focus on systems and structure, while other focus on less tangible parameters such as healthcare employer's behavior and teamwork [7], but all processes need to ensure the design and development of structures and processes to enable teams and organizations to work for common goals centralized in-patient care value.

Table 1. Description of integrative processes (adapted from [7]).

Integrative processes	Description of types of integration
Systemic	Coordinating and aligning policies, rules and regulatory frameworks
Normative	Developing shared values, culture and vision across organisations, professional groups and individuals
Organisational	Coordinating structures, governance systems and relationships across organisations
Administrative	Aligning back-office functions, budges and financial systems across integrating units
Clinical	Coordinating information and services and integrating patient care within a single process

Integrated care initiatives work best depending on its population and healthcare system, it is an ongoing process to facilitate healthcare with a centralization on patient experience and to increase its cost-value. Integrated care based on patient experience includes: Provider coordinated services; care professionals to coordinate care; Manager to sustain organizational structures; Policy-maker and Regulator to ensure quality and safety; Evaluator to show evidence of integration; Community to shape local services and the patient/service-user to experience improved access and allow navigation across elements of care, including information-sharing [8].

2.3 Importance of Informational Exchange and Patient Empowerment

Information exchange between parties in the health system is fundamental to design and develop effective services. The service needs to deliver integrated information systems that consist in sharing clinical records and continuous patient monitoring. It should also increase common decision tools such as guidelines and protocols for different treatments. This centralized information is a base for efficient information exchange within care management. Successful integrated care models demand the ongoing involvement of patients and family members in the treatment process, implementation and actively taking part of decisions [9]. By increasing information and enabling patients to educate themselves, independently of the positively or negatively their clinical outcomes are, it empowers the patient to enter a more informal conversation with the healthcare providers [10]. Without integration and information exchange patients become lost, services fail to demand the necessity and satisfactory quality declines. So, the cost-effectiveness is reduced significantly [9]. Thus, Patient empowerment of decision-making will adhere to their own journey with confidence that will increase its treatment impact. Companies have increased the value given to offer redesigned personalized information to help patients manage their diseases and treatments throughout the disease management programs. So, companies are taking rapid responses to implement re-design forms of communication and information exchange within their own patients. This increases the implementation of information programs, with direct care teams such as doctors, nurses, pharmacy and others to increase the complex informatics websites or mobile applications for patient utility.

Self-management has become a primary focus for health care providers, with a great potential to increase its outcomes and decrease the demand for costly treatments. Reducing costs will only be accomplished by patient engagement in disease management by using data-storage on eHealth platforms. Remembering that the given data should be analysed by health and clinical personnel [11].

2.4 e-Health and Digital Design in Healthcare Systems

The Design of new Technologies plays a huge role in helping to personalize information, giving patients more control over their health and the potential of eHealth is to overcome challenges of modern healthcare [12], as seeing in Fig. 2. Also e-Health tools are planned to improve health systems by increase health observation, health-system management, health education, increase assertiveness diagnosis, allow quick decision-making and support behavioral changes.

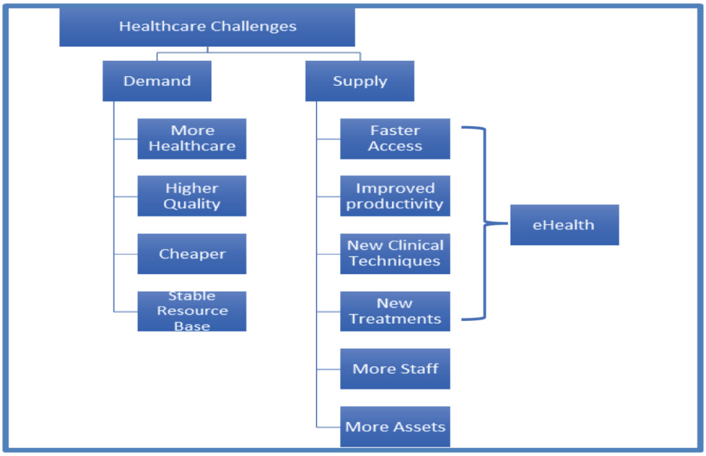


Fig. 2. Healthcare challenges and eHealth input (adapted from [12]).

Designing digital approaches in healthcare delivery enables more information decision-making within patients and family members. Mobile application design and development starts to tackle an unmet clinical challenge. The solution idea is developed, and throughout various step process is launched to the general population. These step processes identified by [11] are presented in Fig. 3.

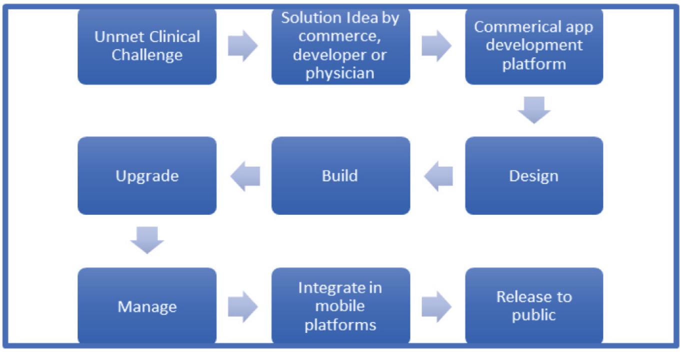


Fig. 3. Development process of eHealth service (adapted from [11]).

Even though design and developing process has proven to be successful, there are various considerations regards each step to promote eHealth projects. It is necessary to ensure highest level political support from public stakeholders, non-profit organizations, private healthcare sector and human resources available for any new implementation project. It is indispensable to carry out viable studies to develop a strategic planning and action plans [13]. This implies a new design of relations and work systems among all those stakeholders. But success design, implementation and development depend on the following main factors: political, regulatory, institutional and technological. It is necessary to have a political commitment to monitor and support project implementation towards a future vision. Regulatory factors are essential to promote environmental and ethical laws to protect patients and healthcare providers. Institutional and technological factors are directly linked to the development of eHealth projects in terms of business process engineering and development of technology infrastructures [13].

3 Design/Methodology/Approach

This research purpose is exploratory. Hypotheses about how the design of eHealth interventions may be associated with outcomes and intends to understand how Portuguese population will respond to eHealth technology design and development for information exchange within healthcare systems are developed, looking to the advantages of eHealth in exchange information amid healthcare providers and patients. Primary data was collected through a series of interviews and questionnaires in 2018. Secondary data was mainly used as an insight instrumental method to review literature for a good approach towards future needs. It was mainly used to understand flaws within research carried previously. The secondary data was vital to understand concepts and define the problematical hypothesis. With these concepts a chronological structure has been resembled to approach theory into a practical investigation.

The interview participants were selected to ensure a higher representation within integrated healthcare systems. Doctors and nurses were divided into a sub-group for different opinions and broader spectrum. To avoid bias all participations were selected on the same variables, while the same method of recording was assembled. No information about the subject and matter of the study were discussed with the participants to reduce any biased responses towards our focus.

The questionnaire was designed for the general population in the northern area of Portugal. It was planned to enlighten and collect information about the perception of the general population towards eHealth technology. Questionnaires were implemented in public and private health facilities, in a non-probability quota sampling due to time constrain. Thinking about any biased data collected, a quota sampling technique was a representative of various subgroups within the Portuguese populations. A total of 176 respondents were verified. To analyse data collected from interviews, it was applied the Roulston thematic analysis for further conclusion [14].

4 Results and Analysis

4.1 Interview Analysis

Most respondents referred the education level of patients as an important role towards the empowering of patients. Respondent 2 explained: "*I consider information the basis of instruction, and with more instruction, people, in general, can become more aware about diseases, from the symptoms to the prophylactic measures, therapeutic requirements and prognosis. This will bring clear advantage for predisposing people to be more cautious with their health, and, at the same time, they can recur earlier than later to Medicine, with obvious advantages, including economics*". It is also a major consensus that patients are higher educated overall throughout the years and becoming more demanding and curious towards their knowledge about any conditions. Respondent 5 clarified "*patients are more demanding in terms of knowledge towards any physical or clinical condition. Patients more often ask questions about a prescription, treatment, condition or examinations. This curiosity and the will to understand any physical condition increases the power of each patient to follow a given prescription*". Although the agreement is clear there are some correspondents that believe that there is the need to partnership patients and caregivers towards a communication that allows double responsibility. This will allow to increase doctor-patient responsibility towards a common goal and a distribution of tasks, however never reducing the command of the doctor or caregiver towards any given treatment or change with patient permission. This is also related to the influence of knowledge and the overreaction towards too much information or misleading information. With this is mind during the conversation it was also referred that many people are using information incorrectly without any scientific base behind many conclusions towards a given condition. It is also important to understand that these events can indicate or lead people to take wrong decisions towards their health condition. Respondent 6 remembers that "*some patient re-visits are due to misleading information towards a treatment prescribed and therefore a wrong approach towards the treatment indications. These re-visits bring complications due to the self-changing prescription by using the guidance of information found on the internet. Many people are reading opinions and ideas of non-medical staff*".

Considering the issue of Engagement of patients to eHealth services, the interviewees pointed out that patients that engage with healthcare providers are increasing due to the personal will to understand their own health conditions and its effect on their health. It is clear to all respondents that people more often want to play a role in their decision-making within their healthcare options, people inquire about their condition and about all different choices available for treatment. It is more often known that people are becoming more aware of lifestyle and how it changes their health conditions. Due to this major change in society, correspondents feel that people actively seek out for more information to be able to evaluate and make informed decisions regarding new treatments or different care delivery options. Respondent 1 believes that "*by educating patients with skills that allow them to take responsible decisions after studying resources apt to their health conditions it provides drive patient self-management of their treatment and in many cases, it allows long term changes in their lifestyle habits*". These skills will also allow patients to be more participant in symbiosis with their different healthcare providers and their healthcare plans.

It is also a perception that it might not always be quick and easy, the problem of adopting and develop empowerment and engagement of patients during the time that is required from healthcare workers to answer all queries from patients and their families and their own personal needs. Normally patients want to find answers to the condition or treatment and therefore have the need to explain in detail lifestyle and health background description. Respondent 7 contemplate that "*Empowered patients will require more time to deal with, they normally ask more questions, they are more curious and want to participate in their care and treatment decision*". Although respondents had a vague idea that eHealth could be used to increase patient empowerment, many didn't try to approach this matter. It was also the perception that older patients are not willing to try any new technology, as most are still not aware of its benefits.

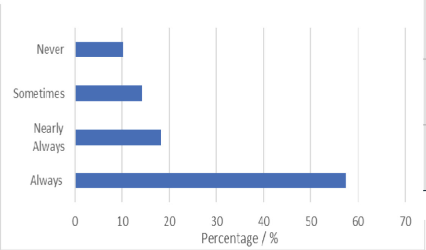
4.2 Descriptive Analysis

Analysing age groups that utilize and adhere to internet and mobile applications is important to understand where this new technology era is moving. As expected, population under 25 years old have the highest percentage of internet usage with a total of more than 96.1%. As the age group increases, the percentage of population using internet decreases significantly. Table 2 shows the percentage of people that use internet in each age group.

Table 2. Participants cross tabulation of age groups considering the internet usage.

			Internet Usage					
			Sometimes	At least once a day	2–3 times a week	4–7 days a week	Not Using	Total
Age Group	18 – 25	Count	74	1	0	2	0	77
		% within Age Group	96.1%	1.3%	0.0%	2.6%	0.0%	100.0%
		% within Internet Usage	49.0%	11.1%	0.0%	100.0%	0.0%	43.8%
		% of Total	42.0%	0.6%	0.0%	1.1%	0.0%	43.8%
	26 – 45	Count	65	4	0	0	0	69
		% within Age Group	94.2%	5.8%	0.0%	0.0%	0.0%	100.0%
		% within Internet Usage	43.0%	44.4%	0.0%	0.0%	0.0%	39.2%
		% of Total	36.9%	2.3%	0.0%	0.0%	0.0%	39.2%
	46 – 55	Count	8	0	0	0	0	8
		% within Age Group	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
		% within Internet Usage	5.3%	0.0%	0.0%	0.0%	0.0%	4.5%
		% of Total	4.5%	0.0%	0.0%	0.0%	0.0%	4.5%
	56 – 65	Count	4	1	0	0	5	10
		% within Age Group	40.0%	10.0%	0.0%	0.0%	50.0%	100.0%
		% within Internet Usage	2.6%	11.1%	0.0%	0.0%	38.5%	5.7%
		% of Total	2.3%	0.6%	0.0%	0.0%	2.8%	5.7%
	more than 65	Count	0	3	1	0	8	12
		% within Age Group	0.0%	25.0%	8.3%	0.0%	66.7%	100.0%
		% within Internet Usage	0.0%	33.3%	100.0%	0.0%	61.5%	6.8%
		% of Total	0.0%	1.7%	0.6%	0.0%	4.5%	6.8%
Total		Count	151	9	1	2	13	176
		% within Age Group	85.8%	5.1%	0.6%	1.1%	7.4%	100.0%
		% within Internet Usage	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
		% of Total	85.8%	5.1%	0.6%	1.1%	7.4%	100.0%

The results show that the higher percentage of population that is now using internet and mobile applications more often, are younger population. Thus, people that use internet were further questioned to give a more detailed information about how they use the internet towards health and healthcare (Fig. 4a).



		Age Group	Internet Usage	Internet usage for Health
Age Group	Pearson Correlation	1	.681**	.305**
	Sig. (2-tailed)		.000	.000
	N	176	176	176
Internet Usage	Pearson Correlation	.681**	1	.403**
	Sig. (2-tailed)	.000		.000
	N	176	176	176
Internet usage for Health	Pearson Correlation	.305**	.403**	1
	Sig. (2-tailed)	.000	.000	
	N	176	176	176

**. Correlation is significant at the 0.01 level (2-tailed).

Fig. 4. (a) Opinions about health online and in mobile applications use; (b) Pearson Correlation test between age groups/internet usage/internet usage for health purpose.

Most of the respondents, 58%, utilize the internet sometimes to look for information about health, 18% nearly always confirm the usage of internet for health information, 14% use always the sources and only 10% never use the internet for health educational purpose.

For further insight into the data and to be able to understand if there is any correlation between internet usage and internet usage for health issues, there was the need to carry statistical test by using *phi* de Pearson Coefficient shown in Fig. 4b. This measurement allows to understand if there is an analytical existence of relationship and how intense that same correlation is. Persons correlation coefficient ranges between −1 and +1, where it indicates perfect agreement or disagreement of the correlation; zero indicated no relationship between the two variables. Figure 4b draw a significant correlation between age groups and internet usage with a significant difference with $p < 0.00$, so it shows a significant value of $p < 0.05$. The correlation of the test shows a moderate high correlation between age groups and internet usage of Coefficient correlation = 0.681, positive relationship of moderate high intensity. The age group correlation with internet usage for health purpose is still significant $p = 0.000$ however the Coefficient correlation = 0.305 shows a low moderate correlation.

To look for overall experience of patients when engaging towards eHealth services and to understand their purpose and how they utilize the internet to find information about health, detailed information about participants that adhere to internet usage for health purposes – in order to find health information and how they categorise their own experience – was addressed.

Figure 5 shows the percentage of answers in each category where correspondents only had four answers: nearly always, sometimes, rarely and no knowledge when looking at different situations. Only 16,48% of correspondents always acknowledge about existing websites, 35,80% sometimes know and more than 39,21% show difficulty in knowing health existing websites. Along with this parameter, the percentages of correspondents that have knowledge of official websites decrease to 29.55% knowing about it nearly always, 31.25% sometimes and 40% having rare or have no knowledge.

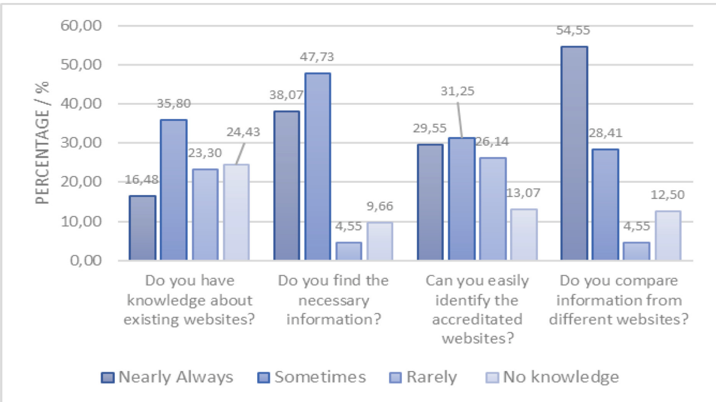


Fig. 5. Ratio of answers addressing the experience using different health websites.

On the other indicator, people tend to compare information from various websites, 54.55% of correspondents do it nearly always, 28.41% sometimes; 4.55% do it rarely and only 12.50% don't use it at all. When correspondents utilize internet to find information only 38,07% find the necessary information, 47.73% only happen to find their answers sometimes and 14.21% have rarely or no answers to their search.

5 Conclusion

eHealth can change and influence healthcare systems at three levels: micro- that will impact directly patients and carers; meso- will impact suppliers, distributors, partners; and at a macro level towards the healthcare system including: hospitals, clinics, pharmaceutical companies and all healthcare providers. Focusing on the idea that information and knowledge exchange reduce the misused of medication; lack of information; reduce readmission to healthcare service aftercare or while undergoing treatments, the design of eHealth application for information exchange can help towards reducing costs in Healthcare facilities. eHealth should have the basis to rationalise and make processes effective, by increasing its ability to reach the public awareness and reduce costs to the care provider. There is indication that new suppliers and the ability to acquire open source systems is important towards the national health system.

The following conclusions arose from the respondent's answers analysis.

Firstly, as regards RQ1, the design of specific types of eHealth technologies towards specific health issues, such as obesity and weight management, may be extremely interesting for future implementation. A more personalised approach should be designed, developed and studied in a near future to target the problem, e.g., young adults in reducing weight and reducing obesity levels nationally to reduce healthcare problems arising from overweight.

Implementing and studying a different approach should be the target, to reduce later care costs. The evidence of our questionnaire shows that younger population are engaging positively to our new era on mobile apps and are aware of the health control for a healthier future. The Portuguese national health system should have this in mind to develop new approach mechanisms in order to use positively the shift seen in younger adults to be able to sustain a better future regarding health management and reduce negative impacts on healthcare system.

App designers should work closely with public health practitioners to integrate evidence-based practices and expert recommendations towards developing apps suitable to the national healthcare systems. Developing technologies to integrate and increasing integration processes between healthcare providers in specialities and public health care system will increase the effectiveness of our input value.

However, there is no significant evidence that eHealth apps will be successful towards the mitigation of health issues by itself, there is still the need to integrate the app development with other healthcare programs in order to follow the patient effectively. It is extremely important that performance expectancy for patients is aligned within social influence, government policies, medical education and eHealth main objective. Increasing medical education will reduce inadequate medical knowledge, linked directly to the second research question.

Secondly, considering the RQ2, it was observed an increase in adherence to mobile applications towards new generations compared to older generations. This shows us a difference on the engagement to healthcare information in the public and private healthcare systems. Although the observation of the increase of younger population utilizing internet sources for health issues, the results show a still passive utilization in the implementation of eHealth and low patient engagement in the usage process felt by the healthcare providers.

Evidence is limited and mixed but argues for an impact of mobile app use on motivation and goal-setting behaviour and supports further study of the impact on health-related outcomes such as attitudes, perceptions, physical activity, and dietary habits. Considering the practice implications, healthcare-related professionals can use this evidence to discuss potential benefits of health promotion mobile apps with patients.

Even so, according the analysis of the obtained data, two main areas for APPs design improvement were defined: (a) the design of an APP should be based on a combination of thorough understanding of users and their contexts of use; (b) a more robust approach in evaluating the effectiveness of APP in terms of measures, length of observation periods and how and why certain features are successful in supporting behaviour change.

6 Future Approach & Research

Partially the difficulty arises due to the inability to predict the future of eHealth services and its market. The organizations and the public demand for new products will dictate the future of eHealth and its innovative services. Empirical studies should be further developed in order to validate the next steps effectively and proceed to understand the healthcare system demand. Next studies should be carried to understand the entire process from decision-making to its implementation towards the public population. This study should provide indications of what new demands, impacts, targets, costs are required to develop the next generation of eHealth services on our public healthcare system in order to increase patient empowerment and reduce costs of healthcare providers.

Trusting that innovation, optimization, modernizing and remodelling of the eHealth potential outcomes will increase patient information and it will deliver optimal healthcare services towards our population, this will be the key to the future of eHealth towards reducing healthcare delivery costs.

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Research on the Construction Method of the Hospital Information System Hourglass Model

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Abstract. The informatization construction of modern health care has gradually shifted from "hospital informatization" around 1993 to "health care intelligentization". The studies on Hospital Information System (HIS) are carried out from multiple perspectives: research review, theoretical proposal and case application. Based on user experience elements and Actor-Network Theory, the construction method of HIS "hourglass model" is proposed. The hourglass model consists of three parts: the upper structure composed of the hospital ethnographic research and the definition of medical staff's requirements, the connected pipeline structure composed of HIS architecture design, and the lower structure composed of HIS interaction and visual design and HIS design evaluation. By expounding the complete development process of the nurse station service system, the reproducibility of the hourglass model construction method is proven, and the three structures of the hourglass model are refined, providing reference solutions for the subsequent development and research of agile projects.

Keywords: Human factors · Hospital Information System · Hourglass model

1 Literature Review

Before starting the research on this project, I searched the research pertaining to medical wisdom, Hospital Information System (HIS), nursing station system and other related research published between 1990 and 2018. After excluding irrelevant content, 103 literature contents were analyzed and reviewed, and were explored from historical dimension, tool dimension and participant dimension, respectively.

The concept of medical wisdom has changed in the historical dimension from the "hospital informationization" around 1993 to today's "medical wisdom" [1] The key factor to promote its development lies in the reform of national macro-policies and industrial development model [2], including measures such as strengthening information sharing, business synergy and health resource information integration between hospitals after the new medical reform [3], like the system construction method centering on "cloud computing service platform", which, however, ignores the integration of doctors' service for patients to some extent. Although other scholars pointed out some issues in the construction of smart medical system: the information is not

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concentrated; the function is single; and only hardware upgrading is valued [4], the research lacks the research perspective of medical staff and also the exploration on and guidance for the specific methods for creating medical wisdom.

The study of HIS tool dimension can be significantly summarized as research on mobile devices and desktop devices. Among them, smart medical services based on mobile devices mainly include two categories: health management service used by patients and HIS collaborative terminal used by medical staff. First, centering on patients is the main research direction of current mobile medical wisdom. It technically simplifies user path through two-dimensional code, radio frequency identification, online medical guidance, etc. [5], and helps to improve patients' medical experience by using online health counseling, mental health mentoring, online registration and other services. Some scholars have proposed the design principles of medical wisdom – "intelligence", "co-creativity" and "systematization" [6], assessed the impact of medical wisdom on the transformation of the traditional medical industry [7], and built a cloud computing remote disease prevention and cloud computing care platforms based on the Internet of Things. However, all of these neglects the user service optimization in the medical staff port and increase the work intensity of medical staff to some extent. Second, mobile handheld device is the hotspot research direction for HIS contact point optimization. Its information verification module can significantly reduce the error rate of information transmission [8], but currently there are a few studies on PC-side HIS. The studies focus on the technical field and construct a relatively complete horizontal system and service category for medical wisdom, which is of a certain reference value. But at the meantime, the studies express that the HIS service system used by medical staff should be patient-centered for process optimization which, to a certain extent, violates the user-centered design principle, confuses the relationship between users and service objects, and lacks human factors thinking.

Nursing station service is an important part of HIS. Nurses are both service providers and service beneficiaries, so related research shows differences in terms of the role dimension [9]. When nurses are service beneficiaries, the design of the nursing station needs to pay attention to the psychological impact of environment on nurses, which not only affects nurses' perception of work stress, but also influences nurses' actual work intensity [10]. Additionally, some studies have found some problems, including transcribing medical orders leads to mistakes easily; special patients cannot be treated preferentially; and bed turnover rate is low, carried out relevant statistical tests, and confirmed that the solutions of electronic medical records and hospitalization process optimization in the studies can improve the efficiency of medical staff.

The above three main dimensions related to this study focus on policy orientation, technology orientation, and environmental orientation. Despite there is a long history of research on the field of medical wisdom, research on the fields of human factors engineering, service design, and user experience is still deficient in the literature. This study utilizes user experience and project development theories to establish an "hourglass model" construction method for smart medical service system, providing a new research direction for this research field.

2 Interest Research in Hourglass Model

2.1 Brief Description on the Concept of Interest Research

Interest research aims to create designs that are more in line with stakeholders' expectations and to create more valuable services for them, by analyzing and interpreting the "nature" and "relationship" for medical staff, and using observation and reasoning to analyze and integrate the various materials obtained during the research process. Methods commonly used in the field of user experience, such as focus groups, in-depth interviews, metaphor analysis, abstract surveys, projection techniques, voiced thinking, ethnographic research, PEST analysis and SWOT analysis, can all be applied in the course of constructing a smart medical service system. The phenomena and other data observed at this stage are the supporting materials for the demand and insight in the next stage, which have a profound impact on the development of subsequent research.

2.2 PEST-SWOT Model

The PEST-SWOT model enable to complete the market surveys on external environment and macro factors. The analysis on the PEST-SWOT model of smart medical services is shown in Table 1.

Table 1. PEST-SWOT model of smart medical services.

	Politics	Economy	Society	Technology
Strengths	The government work report pointed out that it is necessary to improve medical supervision efficiency via the Internet, big data, etc., value the research and application of AI, as well as the Internet plus medical care. The overall political environment is favorable for industries like medical wisdom	In 2016, China's total health expenditure reached 700 billion US dollars; *"Health China 2020" Strategy Research Report* pointed out that by 2020, the expenditure will account for 6.5% to 7.0% of GDP	China will enter a deeply aging society, and the current aging population exceeds 200 million; the attention to "health preserving" paid by young people brings new opportunities to health preventive care	In medical wisdom, there is a large demand for various sensors for wearable devices, and currently 35.6% of three-level hospitals in China have implemented cloud medical solutions

(*continued*)

Table 1. (*continued*)

	Politics	Economy	Society	Technology
Weaknesses	As an industry that relates to the people's livelihood, medical care still needs government power to intervene in industry norms. China's *Invitation for Advice on Developing Administrative Measures for Internet Diagnosis and Treatment* has made more regulations on Internet diagnosis and treatment, but there are still uncertainties	Insufficient supply of resources and concentration of high-quality resources have caused that it is quite common for patients to directly seek medical advice in high-level hospitals rather than in primary hospitals first, increasing the cost of the entire health system	From a psychological and social point of view, patients are more inclined to seek medical advice in high-level hospitals rather than in primary hospitals; the doctor-patient relationship becomes tense	There is a big gap between its core technology plus production technology and those of developed countries; enterprises engaged in the development of medical sensors in China are in small quantities and scales
Opportunities	Medical wisdom brings patients their familiar Internet thinking mode of seeking medical advice, which saves both time and effort; medical wisdom can help medical staff to assist in diagnosis and treatment, which improves service level and service efficiency			
Threats	The decline in the ease of learning has increased the learning cost of users who are not good at using the Internet; aside from normal consultation service, medical staff need to maintain online information, increasing their working intensity			

2.3 Ethnography Research

Ethnography is a method of conducting systematic study on people and cultures based on anthropology. The network of stakeholders of the nursing stations is involved deeply for a long term, and stakeholders' behavioral habits and the relationships therebetween are objectively observed and described by using qualitative methods. This study conducts ethnographic research on four public hospitals with significant differences and a software provider (including the Department of Orthopedics and Traumatology of Wuhan Red Cross Hospital, Department of Ultrasound Imaging of Tongji Hospital, Tongji Medical College of Huazhong University of Science and Technology, Department of Brain Treatment of Wuhan Hospital of Traditional Chinese Medicine, Department of Respiratory and Critical Care Medicine of China-Japan

Friendship Hospital, and Cloud of Practicing Medicine), collects the personality elements of the nurse group, such as lifestyles, behavioral habits, interests and hobbies by means of informal interviews, direct observation and participation in their lives, observes all touch points.

Nurses, doctors, nursing stations, nursing station service systems, pharmacies and other actors are equal and in a stable actor-network structure. Therefore, the phenomena are just recorded and described objectively at this stage, and a series of the obtained unstructured research findings and results will be analyzed in depth in the architectural optimization section. Four typical problems are found in the observation: firstly, nurses generally have their body and head tilted forward in the process of using the nursing station service system. Secondly, nurses are only familiar with the functions they often use, and there are even many interfaces that they have never seen. Thirdly, nursing and medicine belong to two systems and don't share the same developer, which needs to switch for operations. Fourthly, nurses need to refresh system pages from time to time to see if there are new medical orders, resulting in that viewing is not timely and operational burden is large.

3 Value Definition in Hourglass Model

3.1 Brief Description on the Concept of Value Definition

Value definition refers to defining the value for each stakeholder, derives from previous research and serves all follow-up work. Value definition requires a deep analysis of the findings during the interest research phase, constructs an unstructured "user demand cluster" and digs out the relationships among stakeholders, and refines them into information such as product characteristics, product functions, and demand priorities.

3.2 User Needs and Core Value

Finding user needs is the core of constructing a service system. At this stage, we need to try to understand the findings and results obtained during the interest research phase, like the problems users are most concerned and desire to address, and the degree of feasibility. In the hourglass model, the way to summarize user needs is to structure user needs, build a "user need cluster" and then mine the relationships between stakeholder clusters. Up to now, 46 typical user needs are summarized, and after fully exploring the relationship between clusters, the user needs are classified into four actors according to task needs: "patient management", "medical orders management", "drug management" and "charge settlement".

Through the interest research, it is concluded that the nurse group hopes the nursing station service system can not only be used to better manage and serve patients, but also serve nurses themselves, alleviate the work intensity of the nursing station and relieve their nervous psychological emotions, expecting to release more working hours to care for patients and other nursing activities. Consequently, this study defines the core value as constructing a nursing station service system that is clear in its structure, easy to use and close to nurses' life, weakens nurses' occupational attributes, and conforms to users' mental model.

3.3 Product Strategies

Product strategies focus on external user needs and internal product goals, which plays a guiding role in all subsequent strategies and implementations. Hence, the foundation of creating a friendly user experience is to have concise and specific strategic needs. According to literature research, ethnographic research and user interviews, the following product strategies can be summarized:

The nursing station service system is a branch of the nurse system in HIS, and a system service centered on the nurse user group needs to be built;

It should fit the interconnection and interworking properties of the "Internet +", and cooperate with multi-terminal equipment and multi-platform data;

The product emphasizes novelty and overall conforms to the characteristics of commercial end product services in the Internet era;

The services provided by the system need to meet the nurse group's behavioral habits, cognitive patterns and way of working.

4 Architecture Combing in Hourglass Model

4.1 Brief Description on the Concept of Architecture Combing

The most important task of architectural design is to clarify the information architecture based on stakeholders and their relationships. The organization of information architecture needs to transform the abstract relational network into concrete actors that influence user experience, and appropriately group the actors to further clarify the presentation mode and order of actors and sub-actors. The design part medical staff can perceive needs to regulate the interaction process between the product and users, including the scope of interaction between users and the product, the product's mode of response to user interaction, as well as the distribution and zoning of product functions. And the priority arrangement of interface elements should be in line with the thinking and usage habits of medical staff. The most needed functions should be considered arranging in high-priority positions, and interaction design cannot be done entirely according to functional logic. During the architectural design phase, as many solutions as possible ought to be found. Agile iterations should be performed by using low-fidelity prototypes in order to choose the best ideas and solutions.

4.2 Architecture Combing

The existing service system architecture extracts the five-nursing station service system architectures in three levels of depth. Through analysis, the following four questions can be obtained: first, second-level pages are designated according to the functions of hospitals, which does not meet the thinking mode of medical staff when they receive tasks. Second, the function points in the second-level pages are unevenly distributed, resulting in a certain area being too large. Third, the number of third-level pages is huge; the functions are scattered, disordered and even duplicated. Fourth, although most of the function points are functions required in the work, the presented state tends to be unstructured functional clusters without optimization, which fails to meet users' thinking mode.

In the actor network theory, each element acts as an actor. When dealing with different relational networks, actors can be grouped into a new actor. Conversely, each actor can be a collection of multiple sub-actors, just like the relationship between a car and car parts. The four need clusters of "patient management", "medical orders management", "drug management" and "charge settlement" are used as the breakthrough points for structural optimization, which is in line with the mental model of nurses' work and greatly reduces cognitive difficulty. The description of sub-actors' relational network extracts the architectures in three levels of depth, as shown in Fig. 1.

Fig. 1. Comprehensive combing on the optimized nursing station service system architectures, including "Patient Management", "Medical Orders Management", "Drug Management" and "Charge Settlement", each of which contains a large number of functional clusters.

5 Cognitive Design

The focus of cognitive design lies in the five-sense cognitive styles of the nursing station service system, that is, the sensory presentation of architectural functions. The nursing station service system is a business-oriented server. Its presentation design needs to make full use of Gestalt psychology, schema theory, projection method, etc. for guiding the designs, such as the composition of point, line and surface, the shape and size of elements, the font, font size and color of texts to fully influence medical staff's function and emotional perception of the service system, so as to meet the conclusions, strategies and goals of the other four construction elements, alleviate the work pressure of the medical staff and reduce their operational burden.

5.1 Prototype Iteration

The prototype design of this study was made through three iterations, including a paper prototype and two computer prototypes. The second version of the prototype guarantees its basic use, but after click testing, it is found that there are many invalid clicks for completing a task, and some interactions are inefficient. The third version of the prototype made a large adjustment to the functional zoning. The four actors on the homepage after logging in facilitate nurses to locate their required tasks; the focus level of working area is improved; the left resident navigation bar facilitates nurses to

Fig. 2. Three versions of prototypes, including a paper prototype and two computer prototypes.

quickly switch between 12 functional clusters; and the navigation dynamic change at the top facilitates quick operations as shown in Fig. 2.

5.2 Visual Design

The visual design of the current nursing station service system is consistent with that in the literature research. The design of most interface elements is in a relatively early design style, among which the software system of Cloud of Practicing Medicine is overall more uniform. The typical visual elements in the five-nursing station service system interfaces are extracted as shown in Fig. 3. These elements play a certain role of suggestion and interface division, but they are rough, which fails to improve efficiency, reduce cognitive difficulty and enhance the basic aesthetic of interfaces.

Fig. 3. Typical visual elements in the nursing station service system.

The first version of visual design adopts a dark-colored “L”-shaped navigation partition to converge the working area in order to form a visual focus, making the visual line of working difficult to break; the information to be handled on the homepage and navigation partitions uses “little red dot” tag people in the Internet age are familiar with to quickly show the to-be-handled issues, reducing the operational burden of constant refreshing; illustrations are used to express the concept of four actors, enriching visual effects; cards of patient information use the concept of “bed”, enhancing fun and reducing cognitive burden; the interface of medicine distribution can be displayed according to medicines and patients, and the beds are allocated according to the medicines, which is more in line with nurses' operating habits. However, during testing, nurses fed back some defects. For instance, the meaning of different background colors in the medical order list is not obvious; the position of logging out cannot be found quickly; and beds don't look obvious. These defects were then improved in the second visual iteration.

By changing the pillow element familiar to patients into patients' condition splint, it is more in line with the graphic language familiar to nurses, and by using dark-colored background plane to make a visual distinction, better zoning effects are created. The pages including long-term medical advice, temporary medical advice, patient drug, drug check, drug application and account management not only use different background colors for partition, but also add elements similar to the "in-operation status light" outside operation rooms to further define "unfinished" and "finished". Because the amount of page information in list details is large, in addition to reducing information density, the necessary signature elements such as "prescribed by", "reviewed by" and "executed by" adopt interesting forms of "signature", so that different personalized signatures for each person increase a sense of ritual, as shown in Fig. 4.

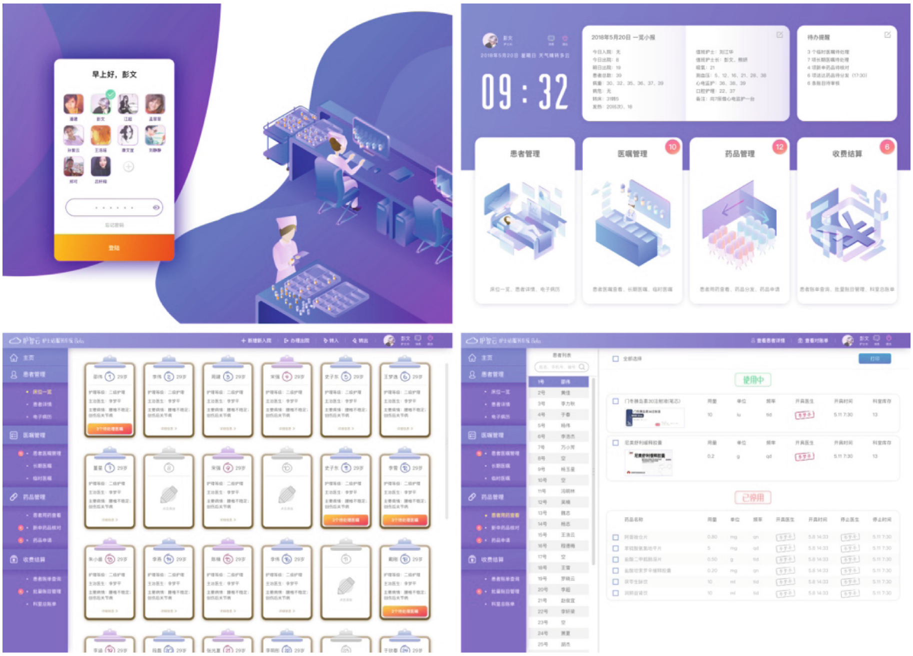

Fig. 4. The final version of visual design.

6 Design Assessment

Design assessment runs through the entire design process: during the interest research phase, it can be used to verify whether research results are distorted; during the value definition phase, it can be used to verify if it truly brings new value to hospitals and medical staff; during the architecture and cognitive design phases, it can be used to timely assess whether the nursing station service system meets medical staff's expectations. The participation of medical staff in the entire hourglass model allows software providers to directly know how medical staff use the system to ensure that the design of medical wisdom is centered on real users. According to implementation methods, design assessment can be divided into cognitive reflection assessment and physiological data assessment. Cognitive reflection assessment makes testees reflect on their own experience by designing experiments and experiencing products, and uses quantitative forms to collect user feedback. Physiological data assessment acquires the content that testees cannot verbally express through obtaining and analyzing the physiological data of the testees.

6.1 Geneva Emotion Wheel Assessment

The Geneva emotion wheel is a scale tool that measures the emotion a person experienced as accurately as possible. Proposed by the Geneva emotional psychologist Klaus R. Scherer, it consists of discrete emotional terms. The emotional terms are distributed in four quadrants: positive emotion—negative emotion, controllable—uncontrollable.

Even if the intensity of some emotions is very low, emotions are mixed and diverse in many cases. Therefore, in the assessment of this study, 10 testees assessed the intensity of each emotion after they experienced the nursing station service system, and for emotions they didn't feel, ticked in the lowest circle of the emotions. The data for the final detailed score distribution and the positive emotion valence quadrant are shown in Fig. 5. According to this, it can be intuitively seen that the emotional feelings of "joy", "enjoyment", "gentleness" and "disburdening" are intense, accounting for

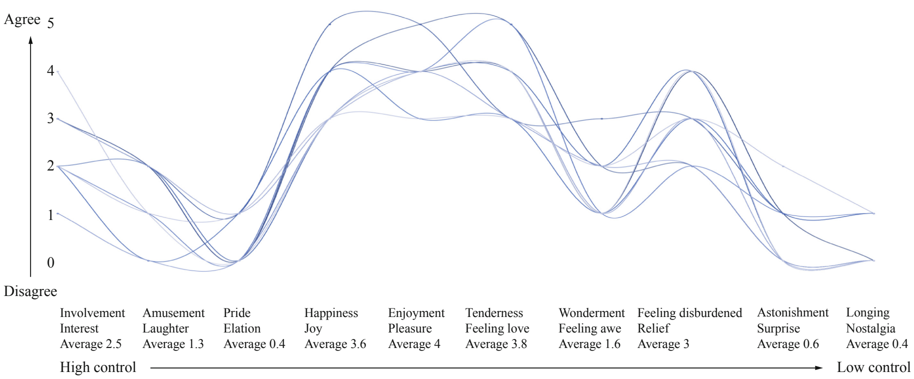

Fig. 5. Detailed score distribution and positive emotion valence quadrant score distribution.

66.05% of the overall feeling. The average feelings are higher than other emotions by 58.21%, and high feelings are mainly within the range of active and moderately controllable emotions, which is suitable for nurses' working environment.

6.2 User Satisfaction Test

Apart from emotional perception, after the test, the testees are asked to fill out the user satisfaction test scale to evaluate the service system currently used and the service system of the test, respectively. The currently used service system SUS scored 52.75 (D), and the new service system SUS of the test scored 90.25 (A+). In addition, the easy-to-learn subscale scored 90, which is 41.17% higher than the current system; and the availability subscale scored 90.31, which is 80.62% higher than the current system. It can be seen that the nurse group shows lower overall satisfaction with the current working system. In this assessment, it cannot be excluded that the surprise emotion might affect the overall score of SUS, resulting in a high score, but it can still be considered that this study has made significant contributions to improve the user experience and emotional experience of the nursing station service system.

6.3 Physiological Data Assessment

Eye movement experiment aims to find the cognitive differences between the current system and the improved system from the perspective of cognition, as well as to point out the direction for future system iteration and improvement. According to the purposes of the test, the interfaces are organized into 23 pictures for cognitive test; without specifying the time of attention, testees are asked to comprehensively cognize the interfaces; and data are collected via Qingyan r2-100 eye tracker.

Some hot zones and trajectories of the currently used service system are shown in Fig. 6. Since the interface partition is relatively confusing, from the test results, it can be clearly seen that saccades are frequent and of long distances and large angles, but show no obvious primary and secondary relationship, indicating users' relatively short time of fixation on interest areas, a few times of regression and decentralized attention, which undoubtedly increases the burden of use and unnecessary use time for medical staff with high-intensity operations.

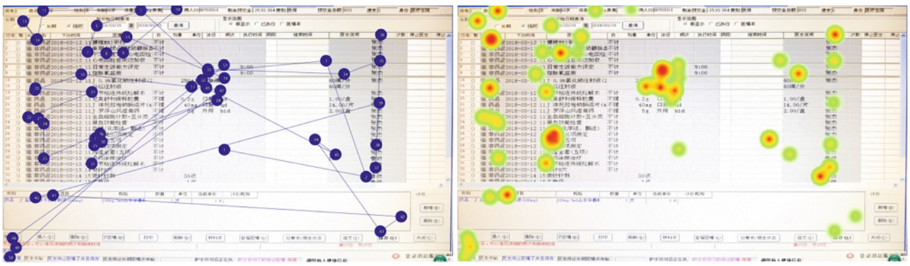

Fig. 6. Hot zones and trajectories of the currently used service system.

Some hot zones and trajectories of the system after optimization and reconstruction are shown in Fig. 7. The hot zones are distributed in the set interest areas. Important operations, important hints and main functional zones are all the main hot zones, and the fixation order accords with the order of functional priorities. For example, in Fig. 7, the fixation sequence starts from the login area, after gazing at the avatar area, password area and login button area, and glancing at the character image in the right illustration area in a small range, the fixation area returns to the login area. A reasonable sequence of saccades and hot zone distribution of interest areas indicate that users can unconsciously cognize the information architecture and function distribution on their first use.

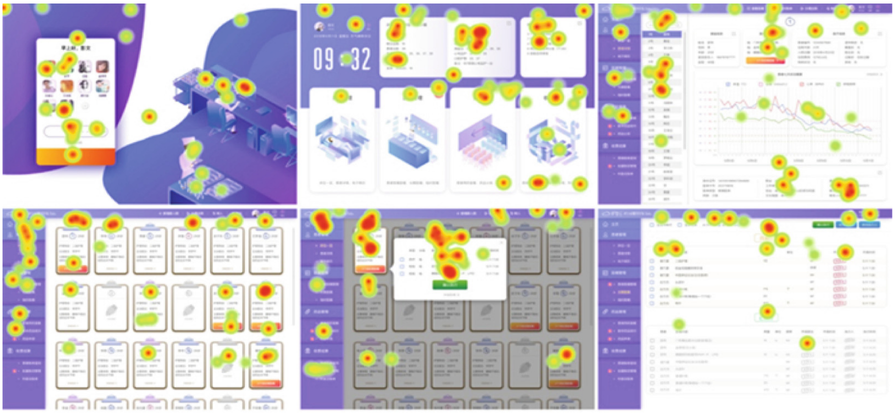

Fig. 7. Hot zones and trajectories of the system after optimization and reconstruction.

Fig. 8. Hot zone changes in the navigation bar of the system after optimization and reconstruction.

Besides, it is found that as users' familiarity with pages and navigation bar increases, the navigation bar is unconsciously ignored, and users become more focused on the working area, as shown in Fig. 8, which conforms to the strategy and goal of converging the working area in the architecture and performance design.

7 Conclusion

Designed to transform the user experience of the nursing station service systems from the perspective of service design, this study has supplemented technology-centered development approach in the current research, reshaped the HIS development perspective centering on medical staff rather than patients, elaborated the guiding process of the hourglass model construction theory of the smart medical service system through the introduction and case analysis of the hourglass model, and verified the effect of the hourglass model on improving cognitive efficiency by using design assessment. This paper focuses on the case part in order to truly share this user-centered development process of medical wisdom hourglass model with future researchers, in the hope of guiding the research and development of related projects.

Moreover, it needs to be specifically pointed out that the user-centered development perspective is not a denial of the technology-centered development perspective. In the future research, the two approaches should be combined with each other and take medical staff and a variety of actors as the core to probe into the various possibilities of technical support, and should complement each other to jointly promote the experience quality of medical staff's port in medical wisdom environment. This is also the deficiencies and shortcomings of this study. Due to the limitations of the author's background and resources, no real docking between the transformed project and HIS is carried out to test effects. Hopefully, researchers interested in this direction can complete the design and test in the dual field of experience and technology to gain further data reference.

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An Empirical Study of Information Visualization for Decision Support in an Emergency Department Information System

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Abstract. Emergency departments collect large amounts of data to make decisions regarding patient care. Implementation of decision support tools with information visualization (IV) techniques in Emergency Department Information System (EDIS) is difficult to achieve and thus an evaluation of the techniques is needed. The purpose of this study is to conduct a usability study of various IV techniques in EDIS and provide recommendations for developers. Fifty-nine participants were recruited in this study. Results indicate the density chart, tree map, and network diagram have lower times, higher usability scores, and lower mental workload ratings than the 3D scatter plot, scatter plot matrix, and parallel coordinates. Findings of this study can provide insights for the development of information visualization tools to support decision making in an emergency department information system.

Keywords: Information visualization · Emergency department · Information systems

1 Introduction

Since the mid-1980s, the emergency department in hospitals has virtually replaced regular physician visits for many persons in the United States as the cost of medical care has increased. In 2010, there were 123.8 million visits to the emergency departments (ED) throughout the country with 13% resulting in hospital admission [1]. As a result, professionals in the emergency department need to make their decisions quicker and better than before. One of the most important tools to support decision - making is through the technology of information visualization.

There is an enormous amount of data collected for each patient from their arrival time to the end of their follow up visits to the emergency department. The patient record is a composite of all the data acquired and created during a patient's path through the healthcare system [2]. The focus of patient care is not just on the period of

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illness, but also includes the cycle of wellness to illness to recovery, and back to wellness again. Therefore, a patient's record must integrate data from multiple sources across multiple providers and for various times. Two significant categories of decisions in healthcare are diagnosis and the treatment plan. The decision makers, usually physicians, must use the raw data acquired and the views of other staff members involved to make decisions.

An ED for this research is defined as a facility that specializes in acute care for patients without prior appointments, typically attached to a hospital or other primary care unit. An ED is a complex system with a high degree of complexity, fatality risks, uncertainty, and dynamic environment. In addition, there is a tremendous amount of patient data collected in various formats. An information system designed for emergency department use needs to be able to display collected patient information and support decision - making for healthcare practitioners. The system is a complex web of information in which analysis can prove to be difficult, affecting patient care outcomes.

In a complex healthcare environment, such as an emergency department, time is a key component. Good decisions made too late turn into bad decisions leading up to tragic consequences. Often there may not be a clear indication of positive or negative results when a person makes a decision. Decision making process can be influenced by the technological support a user receives, such as a decision support tool that employs information visualization.

Information visualization is not a novel technology and has been researched extensively over the decades [3]. This technology can simultaneously provide a "big picture" and a "small picture" for clarification in an on - demand format for users [4]. There are many types of information display designs, but information visualization can improve decision - making by influencing user cognitive resources. This relationship provides an avenue of human factors research into information visualization. Visualizations can be a significant display method for complex information systems, such as an emergency department information system (EDIS). There are various information visualization techniques in existence, and not all are appropriate for any decision - making situation in an emergency department. Therefore, there exists the need to analyze visualization techniques for their effectiveness and support in healthcare decision - making. Unfortunately, there is little research on the assessment of information visualization with an emergency department information system. Implementation of decision support tools with IV techniques in Emergency Department Information System (EDIS) is difficult to achieve and thus an evaluation of the techniques is needed.

The purpose of this study is to conduct a usability study of various IV techniques in EDIS and provide recommendations for developers.

2 Method

A comparative usability study was conducted to assess different IV techniques as used in EDIS. The following subsections describe the method used in the study.

2.1 Participants

Fifty - nine subjects were recruited from North Carolina A&T State University and from nursing programs at local universities. Of the participants, 41 were 18–25 years of age, 12 were 26–35 years of age, and 6 were 36–45 years of age. There were 28 males and 31 females. Table 1 summarizes the demographic statistics of the participants. Of the participants, 60% considered themselves more than average computer users and 60% were at least somewhat favorable towards new technology. In addition, 40% had worked in a hospital, and of those, 75% had experience using hospital information systems (either for scheduling or admission tasks).

Table 1. Demographic analysis of the study participants.

Discipline		Age			Gender		Primary hand		Visual acuity	
Engineer	Nurse	18–25 years	26–35 years	36–45 years	M	F	Right	Left	$\geq$ 20/20	<20/20
73%	27%	70%	20%	10%	48%	52%	92%	8%	92%	8%

2.2 Experimental Design

A within subject design was used. The subjects saw the visualizations in a randomized order. The independent variable was the type of visualization. The dependent variables were performance measurements (decision time, accuracy, and abandonment), user opinion on usability, and mental workload.

2.3 Stimulus Materials

Stimulus materials included the healthcare decision - making task scenarios. The visualizations were created by SAS JMP, XDAT, and VOS Viewer.

2.4 Procedure

Subjects' consent was obtained after the experimenter welcomed and explained the study's purpose. The experiment then followed with the collection of demographic data, visual acuity, and color blindness. Next, the subject was walked through a demonstration and training on how to interpret the visualizations. Subjects could ask any questions at that time about using the interface and completing the tasks. Following the training session, the testing session began where the subjects viewed a visualization technique, read a scenario and answered a question about the data. Each question had four responses including "I Don't Know". After the subjects answered the task question, they completed a five-question usability survey about the visualization and a six-question mental workload survey. This process repeated for all 6 visualizations. Upon completion of the tasks, the subjects completed a post test questionnaire and were thanked and debriefed.

2.5 Data Collection

There were three categories of data collected from this study: objective metrics, subjective metrics, and demographic information. The objective metrics included time to complete task, percent of correct answers, and percent of abandoned questions. The time was measured with a standard stopwatch. The number of correct answers was measured by a pre - defined answer key for the questions. The subjective metrics included user opinion about the usability of the visualizations and mental workload. The user opinion of each visualization technique's usability was measured using a post - test questionnaire using a Likert scale from 1 to 5. The mental workload associated with each visualization technique was measured using the NASA TLX survey. The demographic information collected in the pre - test questionnaire included age, gender, professional/academic field, degree level. The subjects' visual acuity was measured using a Snellen Eye Chart and color blindness was tested using the Ishihara test.

The National Aeronautic and Space Administration Task Load Index (NASA - TLX) is one of the most frequently used subjective mental workload scales and is based on multidimensional property of mental workload [5]. It measures mental workload employing six rating scales: mental demand (MD), physical demand (PD), temporal demand (TD), performance (PE), effort (EF), and frustration (FR) levels. NASA - TLX has been successfully applied in a number of human factors system assessments [6].

3 Results and Analysis

Data collected on performance measurements, usability measurements, and mental workload measurements from the empirical study were analyzed and results are summarized in the following subsections.

3.1 Performance Measurements

The performance measurements gathered include completion time, accuracy rate, and abandonment rate.

Data Pre - Processing. Box plots were constructed to identify outliers on completion time, which can be seen in Fig. 1. There were 9 data points that were out of range across the 6 visualizations, which were removed.

Descriptive Statistics. The descriptive statistics for completion time, accuracy, and abandonment for all subjects can be seen in Table 2. The highest mean time to completion for 3D scatter plot was 118.27 s (standard deviation = 45.63) while the tree map had the shortest mean completion time of 80.57 s (standard deviation = 35.69). For engineers, 3D scatter plot had the highest mean completion time and the network diagram had the shortest mean completion time. For nurses, parallel coordinates had the highest mean completion time while the tree map had the shortest mean completion time. The network diagram had the highest accuracy rate at 79% while the parallel coordinates had the lowest with 21%. For engineers, density chart had the highest accuracy and parallel coordinates had the lowest accuracy. For nurses, tree map and

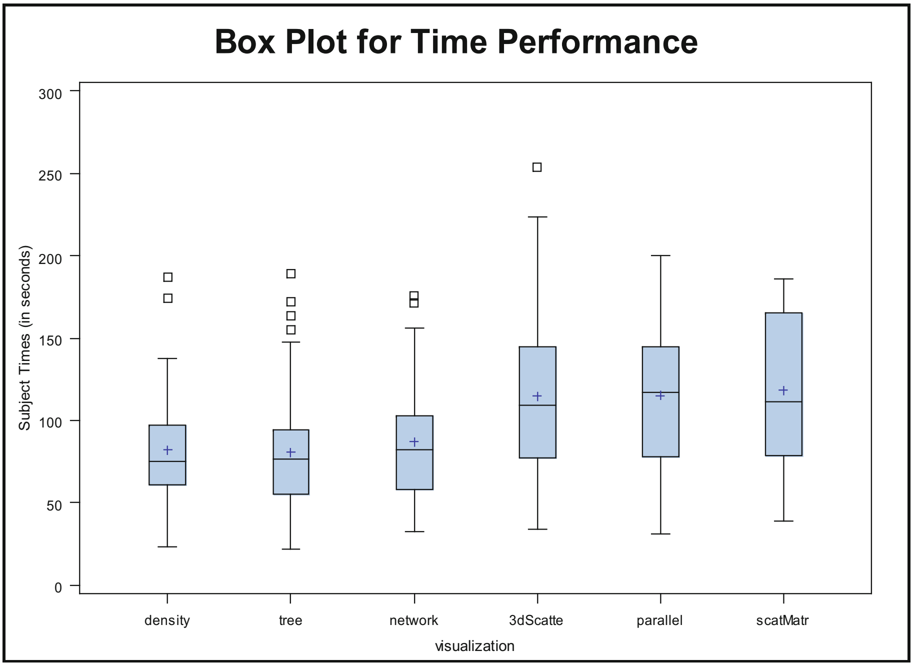

Fig. 1. Box plot of completion time.

Table 2. Descriptive statistics (mean and standard deviation) for performance measures.

Visualization	Time (seconds)	Accuracy rate	Abandonment rate
Density chart	82.31 (30.04)	0.75 (0.39)	0.23 (0.36)
Tree map	80.58 (35.69)	0.72 (0.44)	0.03 (0.18)
Network diagram	86.96 (35.28)	0.79 (0.39)	0.09 (0.28)
3D scatter plot	114.90 (47.75)	0.49 (0.54)	0.24 (0.42)
Scatter plot matrix	118.27 (45.63)	0.46 (0.50)	0.37 (0.48)
Parallel coordinates	115.21 (44.55)	0.21 (0.39)	0.39 (0.48)

network diagram had the highest accuracy while parallel coordinates had the lowest accuracy. Parallel coordinates also had the highest abandonment rate at 39%. The tree map visualization only had a 3% abandonment rate. For engineers, parallel coordinates had the highest abandonment rate. For nurses, density chart had highest abandonment rate.

Inferential Statistics. In this study, there is one independent variable with 6 levels and three dependent variables. A moderate correlation was shown between accuracy, time, and abandonment as see in Table 3. Due to this moderate correlation a multiple

Table 3. Correlation of performance metrics.

	Time	Accuracy	Abandonment
Time	1		
Accuracy	−0.462	1	
Abandonment	0.310	−0.630	1

analysis of variance (MANOVA) needs to be used to determine the variance between the performance variables for the 6 different visualizations.

Model adequacy check on the assumptions of normality, randomness, independence, and homogeneity of variance were done for each performance measure and no major violations were found.

The results of the MANOVA indicated a significant difference was present for visualization technique when all performance measurements were analyzed simultaneously (Wilks' Lambda = 0.6590, $F_{15,\ 930.71} = 10.12$, $p < 0.001$). In regards to each individual ANOVA for the performance measurements of time, accuracy, and abandonment there were significant differences present in the data. A significant difference was found for time ($F_{5,\ 339} = 9.88$, $p < 0.0001$). A significant difference was also found for accuracy rate and abandonment rate ($F_{5,\ 339} = 19.96$, $p < 0.0001$; $F_{5,\ 339} = 7.34$, $p < 0.0001$).

Post hoc analysis using Tukey test was done for pairwise comparison of the completion time for the 6 visualizations using significance level of 0.05 and results indicated that the tree map (mean = 80.58, standard deviation = 35.69) had significantly lower times than the network diagram (mean = 86.96, standard deviation = 35.28) and density chart (mean = 82.31, standard deviation = 30.04). The scatter plot matrix (mean = 118.27, standard deviation = 45.63) had significantly higher completion times than the network diagram and density chart. The parallel coordinates (mean = 115.21, standard deviation = 44.55) had significantly higher completion times than the network diagram and density chart. The 3D scatter plot (mean = 114.90, standard deviation = 47.75) had significantly higher completion times than the network diagram and density chart. The network diagram (mean = 86.96, standard deviation = 35.28) had significantly lower times than the scatter plot matrix, parallel coordinates, and 3D scatter plot. The density chart (mean = 82.31, standard deviation = 30.04) had significantly lower times than the tree map, scatter plot matrix, parallel coordinates, and 3D scatter plot.

Similarly, Tukey test results on accuracy rate for the 6 visualizations indicated that the scatter plot matrix (mean = 0.46, standard deviation = 0.50) was significantly lower than the density chart (mean = 0.75, standard deviation = 0.39), the tree map (mean = 0.72, standard deviation = 0.44), and network diagram (mean = 0.79, standard deviation = 0.39). The 3D scatter plot (mean = 0.49, standard deviation = 0.54) had significantly lower accuracy than the density chart and network diagram. The density chart (mean = 0.75, standard deviation = 0.39) had significantly higher accuracy than the scatter plot matrix, parallel coordinates, and 3D scatter plot. The tree map (mean = 0.72, standard deviation = 0.44) had significantly higher accuracy than the scatter plot matrix, parallel coordinates, and 3D scatter plot. The network diagram (mean = 0.79, standard deviation = 0.39) had significantly higher accuracy rate than all other visualizations. The parallel coordinates (mean = 0.21, standard deviation = 0.39) had significantly lower accuracy than all other visualizations.

Tukey test on abandonment rate for the 6 visualizations indicated that the scatter plot matrix (mean = 0.37, standard deviation = 0.48) was significantly higher than network diagram (mean = 0.09, standard deviation = 0.28) and tree map (mean = 0.03, standard deviation = 0.18). The network diagram (mean = 0.09, standard deviation = 0.28) has significantly lower abandonment rate than scatter plot matrix (mean = 0.37, standard deviation = 0.48) and parallel coordinates (mean = 0.39, standard deviation = 0.48). The density chart (mean = 0.23, standard deviation = 0.36) had significantly lower abandonment rate than parallel coordinates (mean = 0.39, standard deviation = 0.48). The tree map (mean = 0.03, standard deviation = 0.18) had significantly lower abandonment rate than the scatter plot matrix and parallel coordinates. The parallel coordinates (mean = 0.39, standard deviation = 0.48) had significantly higher abandonment rate than tree map (mean = 0.03, standard deviation = 0.18).

3.2 Usability Measurements

The usability survey had 4 items measuring overall usability, ease of use, ease of viewing, and value as a healthcare tool. The following sections investigate the descriptive and inferential statistics associated with the usability items for the visualization techniques.

Descriptive Statistics. Table 4 shows the descriptive results for all usability items. For overall usability, the density chart scored the highest with 3.88 (standard deviation = 1.05) and 3D scatter plot scored the lowest with 2.32 (standard deviation = 1.11). Nurses rated the parallel coordinates with lowest usability while engineers rated the 3D Scatter Plot the lowest. For the "ease of use" item, the density chart scored the highest with 3.57 (standard deviation = 1.35) and the 3D scatter plot scored the lowest with 1.98 (standard deviation = 1.05). Nurses favored the network diagram while engineers preferred the density chart. Density chart rated the lowest with nurses while engineers rated the 3D scatter plot the lowest. The tree map was rated the highest with 3.73 (standard deviation = 1.09) and the 3D scatter plot was rated the lowest with 1.98 (standard deviation = 1.05) for the "ease of viewing" item. Nurses favored the scatter plot matrix while engineers preferred the tree map for "ease of viewing". For "value as healthcare tool", the density chart was rated the highest with 2.29 (standard deviation = 0.74) and the 3D scatter plot was rated the lowest with 1.94 (standard deviation = 0.87). There is less variation in this item compared to the other usability items. Nurses favored the tree map while engineers favored the density chart. Parallel coordinates scored the lowest with nurses. 3D Scatter Plot scored the lowest with engineers.

Inferential Statistics. A correlation analysis depicted in Table 5 revealed there is moderate correlation among all the usability survey items. Model adequacy tests revealed no major violations.

Table 4. Descriptive statistics (mean and standard deviation) for usability survey.

	Usability survey item			
	Ease of use	Overall usability	Ease of viewing	Value for healthcare
Density chart	3.57 (1.35)	3.88 (1.05)	3.33 (1.16)	2.29 (0.74)
Tree map	3.20 (1.35)	3.43 (1.27)	3.73 (1.09)	2.18 (0.81)
Network diagram	2.84 (1.33)	3.24 (1.28)	2.82 (1.15)	2.14 (0.76)
3D scatter	1.98 (1.17)	2.32 (1.11)	1.98 (1.05)	1.94 (0.87)
Scatter matrix	2.33 (1.35)	2.48 (1.36)	2.63 (1.37)	2.11 (0.80)
Parallel coordinates	2.29 (1.25)	2.44 (1.32)	2.31 (1.35)	1.96 (0.90)

Table 5. Correlation of usability items.

	Ease of view	Ease of use	Healthcare value	Overall usability
Ease of view	1			
Ease of use	0.415	1		
Healthcare value	0.650	0.755	1	
Overall usability	0.480	0.812	0.780	1

Since all four variables were measured at the same time in a survey, a profile analysis was conducted and three research questions were addressed: overall difference, parallelism, and flatness. An overall difference among the groups was found indicating there was a significant difference for visualization type ($F_{5,\ 278} = 16.26$, $p < 0.0001$). The test for parallelism examines whether the distance between scores for the techniques on any of the dependent variables differs. Results revealed that the profiles were not found to be parallel (Wilks' lambda = 0.78464 and $F_{15,\ 762.32} = 4.67$, $p < 0.0001$). The last step is to check for the flatness of the profiles, which indicates that the visualizations show the same significance across the usability items. The results revealed that the profiles were not flat (Wilks' lambda = 0.645576 and $F_{3,\ 276} = 50.51$, $p < 0.0001$).

3.3 Mental Workload Measurements

The NASA TLX survey had 6 items measuring effort, frustration, performance, physical demand, mental demand, and temporal demand. The following sections investigate the descriptive and inferential statistics associated with the mental workload items for the visualization techniques.

Descriptive Statistics. The descriptive statistics are shown in Table 6. On the "effort to complete task" item, the parallel coordinates was rated the highest at 4.74 (standard deviation = 1.84) while the density chart rated the lowest with 3.21 (standard deviation = 1.57). For nurses, the parallel coordinates rated the highest with 6.75 and the density chart the lowest with 4.5. For engineers, the highest rated visualization was the 3D scatter plot with 4.68 and the lowest rated was the density chart with 3.12. On the "frustration" item, the parallel coordinates was rated the highest at 3.72

Table 6. Descriptive statistics (mean and standard deviation) for NASA TLX.

Mental workload item	Density chart	Tree map	Network diagram
Effort	3.21 (1.57)	3.77 (1.66)	3.4 (1.78)
Frustration	2.4 (1.3)	1.96 (1.32)	2.51 (1.65)
Mental	3.02 (1.48)	3.66 (1.62)	3.43 (1.81)
Performance	5.66 (1.34)	4.87 (1.76)	4.87 (1.73)
Physical	2.2 (1.68)	1.96 (1.350	2.36 (1.63)
Temporal	2.62 (1.57)	1.98 (1.26)	2.35 (1.46)
Mental workload item	3D scatter	Scatter matrix	Parallel coordinates
Effort	4.80 (1.69)	4.7 (1.92)	4.74 (1.84)
Frustration	3.75 (1.93)	3.51 (2.04)	3.72 (2.17)
Mental	4.4 (2.07)	4.13 (2.44)	4.7 (2.49)
Performance	3.55 (1.66)	3.65 (2.19)	3.67 (2.04)
Physical	3.42 (2.04)	3.12 (2.04)	3.12 (2.13)
Temporal	3.0 (1.7)	2.81 (1.92)	3.02 (2.01)

(standard deviation = 2.17) while the tree map scored the lowest at 1.96 (standard deviation = 1.32). For nurses, the parallel coordinates was rated the highest with 6.5 and the tree map the lowest with 3.25. For engineers, the highest rated visualization was the 3D scatter plot with 3.53 and the lowest rated was the tree map with 1.84. For "mental demand", the parallel coordinates was rated the highest at 4.7 (standard deviation = 2.49) while the density chart rated the lowest at 3.02 (standard deviation = 1.48). For nurses, the parallel coordinates rated highest with 6.75 and density chart the lowest with 3.5. For engineers, the highest rated visualization was 3D scatter plot with 4.28 and the lowest rated was the density chart with 2.98. On the "performance" item, the density chart rated the highest at 5.66 (standard deviation = 1.34) while the 3D scatter plot rated the lowest at 3.55 (standard deviation = 1.66). For nurses, the density chart rated highest with 6.5 while the scatter plot matrix and parallel coordinates were the lowest rated at 3.75. For engineers, the highest rated visualization was the density chart with 5.58 and the lowest rated was 3D scatter plot with 3.5. On the "physical demand" and "temporal demand" items the trends are similar. The 3D scatter plot and parallel coordinates rated the highest while the density chart rated the lowest. For nurses, the parallel coordinates were the highest rated and density charts the lowest rated. For engineers, the highest rated visualization was 3D scatter plot and the lowest rated was the density chart.

Inferential Statistics. A correlation analysis revealed there was moderate correlation among all the mental workload survey items. Model adequacy tests revealed no major violations. Since all six variables were measured at the same time in a survey, a profile analysis was conducted and three research questions were addressed: overall difference, parallelism, and flatness. An overall difference among the groups was found indicating there was a significant difference for visualization ($F_{5,256} = 5.64$, $p < 0.0001$).

The test for parallelism examines whether the distance between scores for the techniques on any of the dependent variables differs. Results revealed that the profiles were not found to be parallel. Figure 2 shows a graphical depiction of the profiles (Wilks' lambda = 0.73365 and $F_{25,\ 937.64} = 3.26$, $p < 0.0001$). The result indicated that the profiles were not flat (Wilks' lambda = 0.42156 and $F_{5,\ 252} = 69.16$, $p < 0.0001$).

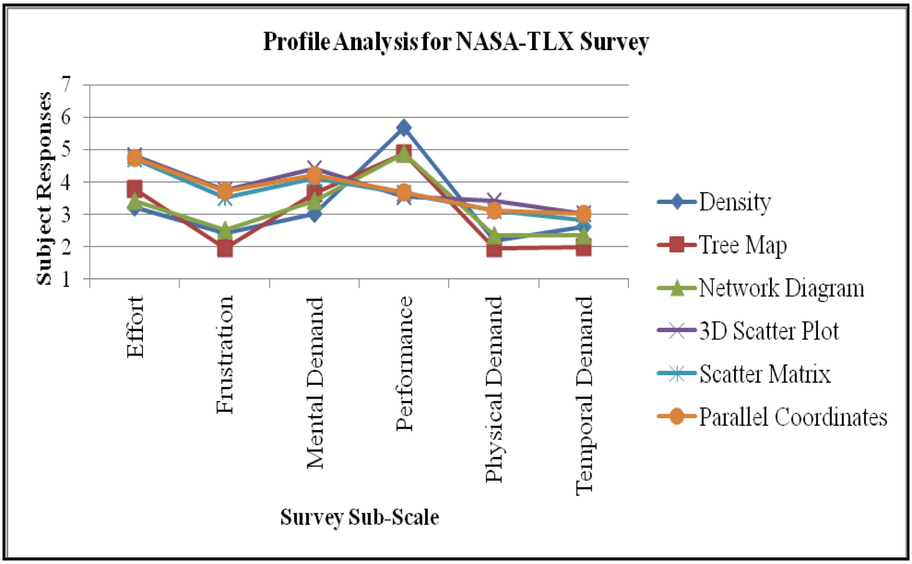

Fig. 2. Profile analysis of mental workload items.

4 Discussion and Conclusion

This study conducted a comparison usability study to evaluate information visualizations for emergency department information systems. Results of the study clearly indicate that visualization type has an impact on performance measurements for emergency medical data tasks. Previous research studies that measured performance on an individual task (instead of a set of tasks) have shown similar results that indicated that different visualization techniques performed differently for various tasks [7].

The general trend emerging from the results indicates the density chart, tree map, and network diagram have lower times, higher usability scores, and lower mental workload ratings than the 3D scatter plot, scatter plot matrix, and parallel coordinates. This trend could be a result of either the tasks or the data format. The tasks associated with the density chart, tree map, and network diagram asked users to compare variables, specifically by frequency or amount of a variable. However, the tasks associated with the 3D scatter plot, scatter plot matrix, and parallel coordinates asked the users to compare correlations of variables. Another possible reason for this trend is that the 3D scatter plot, scatter plot matrix, and parallel coordinates are based on numerical data, for example, blood pressure or pulse rate. However, the parallel coordinates does allow for a user to look at correlations of textual and numerical data, for example, the correlation between gender (male or female) and pulse rate. The other three visualizations were developed from textual data sources. The symptoms and diagnoses of patients in the emergency department were used to build the network diagram and density chart.

Information visualization is an effective way to view and understand large amounts of emergency medical patient data. However, the designers of emergency department information systems must be aware of the ways in which their system may be used to its fullest potential and estimate its impact on the end - user. Certain visualization techniques are appropriate for specific tasks and situations. An EDIS should be designed to integrate the usage of an appropriate technique for a health care decision - making task to mitigate potential usability issues.

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Healthcare Worker Risk

Are Teachers More Affected by Burnout than Physicians, Nurses and Other Professionals? A Systematic Review of the Literature

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Abstract. This article answers a main research question: Are teachers more affected by burnout than physicians, nurses and other various professionals? In order to answer this research question, a systematic literature review was conducted. All the articles included in the analysis used the Maslach Burnout Inventory (94 studies, 121 samples). Results show that occupations are impacted differently by burnout in the three sub-dimensions (emotional exhaustion, depersonalization and lack of accomplishment).

Keywords: Burnout · Maslach Burnout Inventory · Teachers · Nurses · Physicians · Working conditions

1 Introduction

Numerous scientific studies have shown the extent of burnout at work in different professions. In 2012, Maslach, Leiter and Jackson estimated burnout costs at US 300 billion. In Switzerland, according to data from the Federal Statistical Office (2018), more than a third of Swiss people feel stress at work, 18% feel emotionally exhausted. People who are overworked at work are five to six times more likely to suffer from depression than people who report job satisfaction. These data mean that about one in five active people has symptoms of depression that contribute to the explosion of medical consultations for psychological reasons [1]. This problem is so urgent that it is considered a priority of the Swiss long-term strategy [2].

The assertion that teachers face higher risks of burnout than other professions is a widely recognized idea in the common sense but ultimately poorly documented in research results [3]. Nevertheless, it must be acknowledged that burnout seems to reach more specifically occupations with high levels of social interactions, such as education and health [4]. In these fields of activity, the phenomenon is seen as a real epidemic.

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2 Definition

The most common definition of burnout is the one issued by Maslach, Jackson, Leiter, & Schaufeli (1996, p. 192): "Burnout is a psychological syndrome of emotional exhaustion, depersonalization, and lack of accomplishment that can occur among individuals who work with other people in some capacity" [5]. It is an emotional state that causes a loss of beliefs, positive feelings, optimism, respect and empathy for those around the person concerned. Psychic exhaustion is linked to physical fatigue and psychosomatic disorders. The scientific literature agrees that burnout is a disruption of the body due to a high and lasting level of stress correlated with external demands greater than the available resources. The symptoms reflect a psychic discomfort (mental or emotional exhaustion) that manifests itself in various ways [6]: mental and behavioral symptoms predominate over physical ones; the syndrome originates in professional environment; the symptoms are observed in individuals without a particular psychopathological background; decreased efficiency and lower performance are the result of negative attitudes at work; repercussions affect the person's physical and psychological functioning. The symptomatology of burnout is multiple, impacting people in their daily work and family.

The most widely used tool to measure burnout is the Maslach Burnout Inventory (MBI). This instrument (22 items) investigate three sub-dimensions to prevent burnout and improve working conditions: emotional exhaustion (EE), depersonalization (D) and personal accomplishment (PA) [6]. Emotional exhaustion is assessed through 9 items, depersonalization through 5 items and personal achievement through 8 items. Scores are considered in the danger zone if they are in the upper third of the normal distribution, in the risk zone, if they are in the second third and in the correct zone, if they are in the lower third. A low level of burnout is manifested by a low score in the EE and D dimensions, and a high score in the PA dimension [5]. The researchers note that if the EE and D scores are in the dangerous zone, the risk of being burnout is real, especially if the PA score is low.

3 Literature Search: Methodology

In order to answer the main question of the study, an electronic search was conducted in various databases: Medline, Pubmed, Sciencedirect, Springer, Eric, Scopus. The selected searches were based on several inclusion criteria: 1. Be based on the Maslach model; 2. Use the MBI as a questionnaire to assess burnout; 3. Present scores and standard deviations in the three sub-dimensions (EE; D; PA). 4. Present the sample clearly (teachers, specialized teachers, doctors, nurses, etc.); 5. Have been published in scientific journals between 1996 and 2016; 6. Understand a sample of at least 45 participants. This literature review is part of a larger project on burnout that will be the subject of a meta-analysis [7].

As a result of this selection process, 94 studies were selected for specific data analysis: 37 studies (teachers), 28 studies (nurses), 15 studies (doctors), 14 studies (various professionals). As the same study sometimes contained several sub-samples, this review allowed to code the scores of 121 samples in the three sub-dimensions of

Table 1. Example of coding

Studies		EE	D			PA	
	N	M	SD	M	SD	M	SD
Al-Bawaliz, 2015	200	18.13	10.66	2.63	4.21	5.29	5.82

burnout. For each sample, 7 categories were selected: N, EE mean and EE standard deviation, D mean and D standard deviation, PA mean and PA standard deviation (Table 1).

4 Results

The following table shows the distribution of average burnout scores of 45 samples of teachers in the three sub-dimensions (Table 2).

Table 2. Teachers and burnout

45 Samples N = 20'999	Correct zone	Risk zone	Danger zone
EE	16 samples n = 3'856 18.36%	25 samples n = 16'048 76.42%	4 samples n = 1'095 5.21%
D	24 samples n = 7'988 38.04%	19 samples n = 12'773 60.83%	2 samples n = 238 1.13%
PA	1 sample n = 78 0.37%	11 samples n = 2'674 12.73%	33 samples n = 18'247 86.89%

This table provides a comparison of the average scores obtained by teachers in the three dimensions of burnout. With regard to emotional exhaustion, among the 45 samples (N = 20'999; 100%), 16 samples (n = 3'856) reported a correct level (18.36%), 25 samples (n = 16'048) are in the risk zone (76.42%) and 4 samples (n = 1095) are in the danger zone (5.21%). With regard to depersonalization, average ranges vary between M = 2.63 to M = 18.00. Among the 45 samples (N = 20'999), 24 samples (n = 7988) indicate a correct level (38.04%), 19 samples (n = 12773) are in the risk zone (60.83%) and 2 samples (n = 238) are in the danger zone (1.13%). With regard to personal achievement, only one study (n = 78) reports a correct level (0.37%), 11 samples (n = 2'674) are in the risk zone (12.73%) and 33 samples (n = 18247) are in the dangerous zone (86.89%). These data suggest that the demands of the teaching profession necessitate important resources in terms of emotional adaptation. The impact of emotional exhaustion in teaching is worrying with only 18% of teachers in the correct zone, because this profession requires emotional management articulated to the needs of pupils. The depersonalization seems less affected than exhaustion with 38% in the correct area. Regarding personal achievement, only 0.37% of teachers report a correct level. The differences between dimensions in terms of dangerousness is unexpected. Considering all the studies (N = 45), only two studies report a level of burnout estimated to be dangerous in all the three dimensions [9, 10]. No study has found a satisfactory level of burnout in the three dimensions.

This first review of the literature on teachers indicates contrasting scores in all three dimensions. Is there a similar situation for nurses? The following table shows the distribution of average burnout scores of 34 samples of nurses in the three sub-dimensions (Table 3).

Table 3. Nurses and burnout

34 Samples N = 14'685	Correct zone	Risk zone	Danger zone
EE	13 samples n = 6'322 43.05%	21 samples n = 8'363 56.95%	0 sample
D	15 samples n = 4'090 27.85%	18 samples n = 10'421 70.96%	1 sample n = 174 1.18%
PA	2 samples n = 252 1.72%	15 samples n = 3'972 27.05%	17 samples n = 10'461 71.74%

With regard to emotional exhaustion, among the 34 samples (N = 14'685; 100%), 13 samples (n = 6'322) reported a correct level of exhaustion (43.05%), 21 samples (n = 8'363) are in the risk zone (56.95%) and 0 sample is in the dangerous zone. With regard to depersonalization, 15 studies (n = 4'090) indicate a correct level (27.85%), 18 samples (n = 10'421) are in the risk zone (70.96%) and 1 sample (n = 174) is in the danger zone (1.18%). With regard to personal achievement, averages range from M = 41.0 to M = 11.24. Only 2 studies (n = 252) report a correct level (1.72%), 15 samples (n = 3'972) are in the risk zone (27.05%) and 17 samples (n = 10'461) are in the dangerous zone (71.74%).

These data suggest that the demands of the nursing profession require emotional resources, but less than those of the teaching profession. Regarding depersonalization, 15 studies report a correct level, 18 samples are in the risk zone and only 1 study reports a dangerous level. Nurses seem more affected by depersonalization (27.85% in the "correct" zone) than by exhaustion (43.05% in the correct zone). The following table shows the distribution of average burnout scores of 20 samples of physicians in the three dimensions (Table 4).

With regard to emotional exhaustion, among the 20 samples (N = 7'033; 100%), 7 samples (n = 2'701) report a correct level (38.40%), 11 samples (n = 4'132) a level in the risk zone (58.75%) and 2 samples (n = 200) are in the dangerous zone (2.84%). With regard to depersonalization, 9 samples (n = 2'031) indicate a correct level

Table 4. Physicians and burnout

20 Samples N = 7'033	Correct zone	Risk zone	Danger zone
EE	7 samples n = 2'701 38.40%	11 samples n = 4'132 58.75%	2 samples n = 200 2.84%
D	9 samples n = 2'031 28.88%	8 samples n = 4'491 63.86%	3 samples n = 511 7.27%
PA	5 samples n = 914 13.0%	7 samples n = 3'571 50.77%	8 samples n = 2'548 36.23%

(28.88%), 8 (n = 4'491) a level at risk (63.86%) and 3 (n = 511a danger level (7.27%). Regarding personal achievement, only 5 samples (n = 914) report a correct level (13.0%), 7 samples (n = 3'571) a level at risk (50.77%) and 8 (n = 2'548) a danger level (36.23%).

These data suggest that the profession of physician requires a high number of resources in terms of emotional adjustment, as the scores are close to those obtained by teachers. Emotional exhaustion appears to be more prevalent among physicians than among nurses. Depersonalization seems to affect more doctors than nurses or teachers. The fact that only 13% of doctors feel personally accomplished at work is notable. Lack of achievement affects doctors, nurses and teachers alike (Table 5).

Table 5. Other professions and burnout

22 Samples N = 12'140	Correct zone	Risk zone	Danger zone
EE	11 samples n = 7'654 63.05%	11 samples n = 4'486 36.95%	0 sample
D	6 samples n = 1'046 8.55%	15 samples n = 10'820 89.93%	1 sample n = 178 1.52%
PA	1 sample n = 206 1.7%	7 samples n = 1'097 9.04%	14 samples n = 10'837 89.27%

This table shows the distribution of samples according to the severity of the average scores obtained by various professionals (booksellers, psychologists, priests, journalists, police officers, call center employees, etc.). With regard to emotional exhaustion, among the 22 samples (N = 12'140; 100%), 11 samples (n = 7'654) reported a correct level (63.05%), 11 samples (n = 4'486) a level at risk (36.95%) and 0 sample a level considered as dangerous. With regard to depersonalization, 6 studies (n = 1'046) indicate a correct level (8.55%), 15 studies (n = 10’820) a level at risk (89.93%) and one study (n = 178) a danger level (1.52%). With regard to personal achievement, only one study (n = 206) reported a correct level (1.7%), 7 studies (n = 1’097) a level at risk (9.04%) and 14 (n = 10’837) a dangerous level (89.27%). These data suggest that “various professionals” are less exhausted than nurses, teachers and doctors. Depersonalization seems to affect these professionals with only 8.55% in the correct zone.

5 Discussion

The adoption of a recognized theoretical model has facilitated the systematic review of the literature. The results of the review revealed some interesting differences. With regard to exhaustion, the averages from all-professionals [11–13] are lower than the other samples. According to these data, the average exhaustion score from physicians is higher than that from teachers (M = 20.60) and nurses (M = 19.0) [14–16]. Only the various professionals show an average exhaustion score in the correct area (M = 17.69). Physicians (M = 8.01) have higher depersonalization averages than various professionals (M = 7.34), nurses (M = 6.62) or teachers (M = 6.55), who obtain the highest average [9, 10]. It should be noted that the averages of all the samples are in the zone at risk for depersonalization. However, teachers, like nurses, are close to the correct area [17, 18]. At the level of personal achievement, scores are low, in the dangerous or at-risk area, indicating a lack of achievement at work [8, 10]. Teachers (M = 28.73) get the lowest score and are, like nurses (M = 30.49), in the danger zone [16, 19, 20]. Physicians (M = 35.54) have the highest personal achievement score, but their average score is in the zone at risk [21–23].

Teachers do not have the highest exhaustion averages, but the proportion of teachers in the correct area is the lowest among all the professional categories studied [24–26]. Teachers are less depersonalized than other professionals. However, teachers achieve the lowest personal achievement score among the professional categories considered. This descriptive and dimensional restitution showed that out of 45 studies involving a sample of 20,999 participants, only one study (N = 78) showed correct achievement [27]. The fact that there is such a low percentage of people accomplished on the job (regardless of the sample selected) shows the importance of considering this subscale with great caution. People who are less psychologically involved with their clients, such as call center employees, booksellers, police officers, seem more protected than other professionals [12, 28–30]. The heterogeneity of the results is startling. This situation can be explained through overestimation of small studies, biases related to cultural and geographical contexts, and even biases related to the timing of the questionnaire (busy calendar). This review of the literature documented the presence of burnout in all professions, as well as teachers, doctors and nurses.

The marked differences between the three dimensions in terms of dangerousness are unexpected. This study highlighted that personal achievement evolves in a different way and seems to be independent of the other two dimensions. These results suggest that personal achievement is the most independent dimension of the MBI three-dimensional model, as confirmed by other studies [6, 31, 32]. It is difficult to comment the consistency of these scores. Are all professionals missing so much achievement at work? How is it possible that the same person is neither depersonalized nor exhausted but lacks personal accomplishment to the point of being in the danger zone? On this topic, the same heterogeneity emerges regardless of the sample size or location of the study (USA, Netherlands, Turkey, China, Italy, Switzerland). Cultural belonging therefore does not seem to offer an explanation for the differences observed. Sample sizes could also explain these differences, but the same heterogeneity is evident regardless of sample size. These items certainly raise questions and deserve specific attention. Are the items covering this dimension well formulated? In other words, do these items measure what they are supposed to measure? Are the thresholds properly established? These results suggest that it is necessary to question the gradation of the MBI scale.

6 Conclusion

This theoretical review, based on 94 studies and 121 samples, established that the presence of burnout is documented in all occupations, especially among teachers, doctors, and nurses. Having considered the results of a single tool is an advantage in comparing averages, but the limitations of this approach should be noted. The use of the Maslach Burnout Inventory [5] conceptualizes burnout in a three-dimensional way. Therefore, possible manifestations not included in the test are in fact excluded [33, 34]. Its frequent use in research cannot overshadow disagreements about the relationships between its three dimensions. As it stands, this tool deserves further investigation, particularly regarding personal achievement. The heterogeneity of these results indicates the need for further analysis, though the results should be considered with caution. The heterogeneity of these results testifies to the need to deepen their analysis. Confirmatory factorial analyses should examine the structure of this instrument to verify its consistency. A meta-analysis - in progress - will provide additional information for this study.

Given the consequences of burnout, research in the field must continue to reduce the devastating impact of this syndrome. Preventing burnout requires concerted action at all levels of the system. The role of the political authorities is to keep preserving the health of their employees by providing them adequate working conditions.

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Evaluation of the Impact of the Ergonomics of Technical Systems on the State of Health of a Human Operator with Regard to His Functional Reserve

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Abstract. The paper studies the impact of the ergonomics of technical systems on the emergence and development of occupational diseases of a human operator, taking into account the functional reserve of his body. In view of the complexity of the analytical description of the interaction mechanisms of the human-technical system, a methodology for the synthesis of hybrid fuzzy decision rules, focused on solving poorly formalized problems, was chosen as the mathematical apparatus of research.

Keywords: Ergonomics · Functional reserve · Health status · Membership functions · Fuzzy logic

1 Introduction

Numerous studies of scientists from different countries of the world show that the quality of work of biotechnical systems of various types and purposes largely depends on the ergonomics of technical systems that are in contact with a human operator. The indicators characterizing the ergonomics of technical systems have a significant impact on the functional state and human health. It has been established that long-term contact of a human operator with technical systems that do not have well thought out ergonomics leads to the emergence and development of professional socially significant diseases of the cardiovascular, respiratory, nervous and urinary systems, musculoskeletal system, etc. Reducing the negative factors affecting the health of people from their contact with technical systems is one of the main tasks of ergonomics.

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A lot of work has been devoted to studying the influence of technical systems and industrial facilities on people's health [1–7]. Analysis of numerous works in the field of ergonomics shows that the majority of researchers spend significant efforts on studying the mutual influence of specific technical systems and working conditions on specific types of diseases, and the results obtained are rather difficult and sometimes impossible to transfer to objects of other nature. That is, the whole complex of research, including the choice of an adequate mathematical apparatus when switching to another object of research, should be repeated almost completely without guarantee of obtaining positive results. From a mathematical point of view, the creation of a unified approach to the study of the influence of technical systems of various types and purposes on the emergence and development of various types of diseases is hampered by the fact that the ergonomic properties of the systems under study and indicators describing the functional state and health of a human operator are described by a heterogeneous system of signs, often the information is incomplete and fuzzy, and the classes used for the state of human health have a complex, poorly formalizable and strongly intersecting structure of classes [1, 4–16]. Under these conditions, as shown by numerous studies, it is advisable to use fuzzy logic of decision-making [8, 10–12, 15–19, 20]. In works [1, 2, 4–7] was shown that good practical results, when solving problems of assessing the impact of ergonomic technical systems on the functional state and health of a person, can be achieved using the synthesis methodology of hybrid fuzzy decision rules developed at the Department of Biomedical Engineering of South-West State University (Russian Federation) [8, 11, 12, 21, 22].

2 Methods

In works [1–7] was described the methods of synthesis of fuzzy rules for deciding the functional state and state of human health, taking into account the fact that one of the leading risk factors is the level of ergonomics of technical systems.

In general, view a fuzzy mathematical model of decision-making is described by the expression:

$$UPF_\ell = F_\ell(UPE_\ell,\ UPI_\ell,\ UPEK_\ell), \tag{1}$$

where UPF_ℓ - confidence in the decision on the class of the state of the human operator ω_ℓ; UPE_ℓ - confidence in the class ω_ℓ on group of ergonomic indicators; UPI_ℓ - on individual risk factors; $UPEK_\ell$ - on environmental risk factors; F_ℓ - aggregation function.

If each of the particular decision rules UPE_ℓ, UPI_ℓ and $UPEK_\ell$ increases the risk in the transition of a human operator to a class of states ω_ℓ, then the decisive rule (1) is modified into E. Shortliff storage system [8, 11, 12, 21]:

$$UPF_\ell(q+1) = UPF_\ell(q) + Q_{q+1}[1 - UPF(q)], \tag{2}$$

Where–iteration number; $UPF_\ell(1) = Q_1 = UPE_\ell$; $Q_2 = UPI_\ell$; $Q_3 = UPEK_\ell$.

Considering that the mechanisms for obtaining private decision rules and the choice of their aggregation method are described in detail in [1, 7–13, 15, 17–20], we will dwell in more detail on the method of assessing the level of functional reserve of the human body. From the physiological point of view the experts cannot exactly define the concepts value and a level of functional reserve. Many experts compare these concepts to the balance of an organism to environment, its readiness to work, to resist to the external adverse factors and etc. Taking into account the indistinct nature of "functional reserve" concept and its possible classification the theory of fuzzy logic of decision-making was selected as the main mathematical device. We selected two ways from this theory. The way based on the usage of accessory function to studied classes of a state ω_l the construction mechanism of which was described in L. Zadeh papers [15], and the way using the confidence coefficient in the hypothesis ω_l the receiving and calculation mechanism of which was suggested by Shortliff [13] and their modification [21, 22]. As initial signs defining the classification and the level of functional reserve (FR) of an organism and its subsystems the power characteristics of meridian structures being changed at level changes of FR [23–25]; the level of psycho emotional pressure (PEP); the level of physical exhaustion (LPE); the level of intellectual exhaustion (LIE); pulse rate (PR); the value of systolic arterial pressure (SAP) and diastolic arterial pressure (DAP) were selected on the expert level [27–29].

The medico-technical capabilities and the features of solved tasks can expand this list.

According to the recommendations [30] the selected (or other reasonably imposed) features xi, defined during the measurement or calculated with the help of appropriate methods, are determined before and after dosed physical and/or intellectual loadings. After that the ration of the measured index before loading (x_{i_0}) to the meaning of the same index measured after load test (x_{i_H}) are defined:

$$Y_i = \frac{x_{i_0}}{x_{i_H}} \tag{3}$$

The obtained indices Yi can be used as basic variables of an accessory function to different classes characterizing functional reserve of an organism and/or its subsystems. For example, the following classes characterizing FR of an organism can be selected:

ω_0 is an optimal functional reserve of a healthy person allowing normally and reliably function at reasonably raised loadings;
ω_1 is a satisfactory functional reserve allowing normally function at usual conditions without considerable loadings;
ω_2 is an unsatisfactory functional reserve at which the risk of emergence and disease developments and/or unforeseen failures at work because of lack of reserve opportunities of an organism are high.

The example is shown on the Fig. 1, where the graphs of accessory functions to the selected classes of FR with the base variable Yi are shown.

The value $\mu_{\omega_l}^m \leq 1,0$ limited the maximum meaning of the accessory function describes the experts' point of view that how reliable the index Y_i at the classification of FR can be. If the experts believe that the selected index reliably characterizes such a concept functional reserve of an organism, then $\mu_{\omega_l}^m = 1,0$.

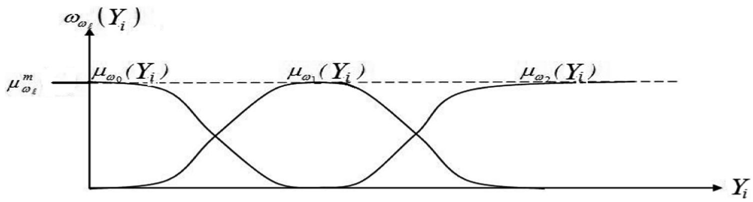

Fig. 1. The variants of distribution of an accessory function by the classes ω_l ($l = 0, 1, 2$ with the basic variable Y_i

In practical applications, a few indices defined from the ration (1) are used to estimate functional reserve and its classification. The confidence proportion at the given classification using one index can be small. If it happens, the task of reaching such certain (for each of used indices Y_i) accessory functions and ways of their aggregation which allow to get an acceptable quality of classifications for practice.

If the choice of indices and corresponding accessory functions is supplied in such a way that the usage of each does not reduce confidence in the accepted decision of the classification of FR, according to the recommendations [8, 12, 14, 29] the common confidence of studied hypothesizes ω_l can be defined by the Shortliff "accumulative" iterative expression:

$$\mathrm{QU\omega l(i+1)} = \ \mathrm{QU\omega l\ (i)} + \mu\omega\mathrm{l\ (Y * i+1)[1 -\ QU\omega l\ (i)]}, \tag{4}$$

Where QUωl (i) is a confidence coefficient in the classification ω_l ($l = 0, 1, 2$) after i of Yi indices was analyzed; μωl (Y*i+1) is the value of an accessory function calculated for the basic variable with i+1 at the point Y*;QUωl (1) = μωl (Y*1).

Among the allocated classes of states and their corresponding accessory functions, the class of optimal functional reserve with the accessory function $\mu_{\omega_0}(Y_i)$ is of great interest. Let us select this accessory function in such a way that the more the meaning of Y_i lags behind the coordinate meaning of Y_{i_0} according to the experts' point of view corresponding to the concept optimal functional reserve, the smaller $\mu_{\omega_0}(Y_i)$ and the smaller the level of this reserve. Thus, the value $\mu_{\omega_0}(Y_i)$ can characterize the level of functional reserve of an organism. The $\mu_{\omega_0}(Y_i)$ accessory function made for the solution of classified tasks can match with the $\mu_U(Y_i)$ accessory function made for level determination of functional reserve but cannot match with it. If a few indices are used for level assessment of FR each of them allows to make a positive investment at level assessment of studied subsystems and the whole organism function, then as (4), the integrated levels of FR can be assessed by:

$$\mathrm{UF(i+1) = UF(i)} + \mu_{\omega_0}(Y*_{i+1})[1 - \mathrm{UF(i)}]; \tag{5}$$

$$\mathrm{UF(i+1) = UF(i)} + \mu_U(Y*_{i+1})[1 - \mathrm{UF(i)}]; \tag{6}$$

Where UF(i) is a level of functional reserve defined after adding i indices to the calculations: $\mu_{\omega_0}(Y*_{i+1})$ is a value of an accessory function to the ω_0 class. By the index with i+1 defined in the Y* point at the conditions that the classification of an accessory function to the ω_0 class used for the level assessment of FR; $\mu_U(Y*_{i+1})$ is an accessory function to the ω_0 class on purpose defined for the level assessment by the experts. The main characteristic of expressions (5) and (6) is their accumulative property consisting of that at every input to the calculations of each used indices Yi the increase of settlement level of FR is provided. In practice, such mechanism of level calculation of FR is not always acceptable. There is a possible variant of such an expert conclusion when the violation in functioning of one of the subsystems leads to the violation in functioning of the whole system and subsystems of higher level, then the level assessment of FR by the combined calculated parameters Yi characterizing the level of FR of subsystem with i should be carried out according to the following ration:

$$UF = \min_i(\mu_{\omega_0}(Y_{\mathrm{i}})) \tag{7}$$

$$UF = \min_i(\mu_U(Y_{\mathrm{i}})) \tag{8}$$

The conduct analysis of the original features at parameter determination Yi (exp. 1) shows that at carrying out load tests at first the change of xi takes place from xi0 to xih, and then the current meaning of xi with different speed (depending on the level of FR) heads to return to the meaning xi0. This tendency at the conduct of xi allowed the experts to come to the conclusion it is wise to include not only the ration (1) to the level calculation of FR, but also the indices of return dynamics of xi to xi0. In the given work paper the dynamic record of xi at level determination of FR is suggested to carry out by the input of two illegible corrections to $\mu_{\omega_0}(Y_i)$ or $\mu_U(Y_i)$ increasing the assessment precision of the studied level. To obtain the illegible corrections let us input two extra indices: thi is a supervision time, tbi is a return time of xito xi0 after load test. Supervision time is derived from reasonable restrictions on research time.

To obtain the illegible corrections for each parameter of Yi let us define the accessory function to the concepts of the maximum corrections of the chosen basic variable. As the first basic variable let us choose return time of xi to xi0, if tbi<thi. As the second basic variable Ci it is necessary to choose the value of difference size between xi and xi0, if tbi>thi . Taking into account that for different parameter types the meaning of xi can be as bigger as less of xi0, the size of the basic variable Cican be defined from the rations:

$$C_i = \begin{cases} \mathrm{x_{i0} - x_i}, & \text{if} \quad \mathrm{x_{i0} \geq x_i} \\ \mathrm{x}_i - \mathrm{x_{i0}}, & \text{if} \quad \mathrm{x_{i0} < x_i} \end{cases} \tag{9}$$

The maximum meaning of μ_{1i}^m and μ_{2i}^m of the entered accessory functions of the first and the second basic variables will be defined as an experts' point of view of what maximum meaning the levels of FR defined by the accessory function of $\mu_{\omega_0}(Y_i)$ or $\mu_U(Y_i)$ can have if return dynamic of xi to xi0 is taken into account.

If creating the accessory function to the meaning of the maximum corrections of the basic variables of tbi ($\mu_P(t_{\mathrm{bi}})$) and Ci($\mu_P(C_i)$) the additional conditions are done, their current meaning reflects the experts' images about the current corrections to $\mu_{\omega_0}(Y_i)$ or $\mu_U(Y_i)$, then the accessory function defining the level of functional reserve by Yi parameter can be corrected by the ration of algebraic sum:

$$\mu \overset{*}{U}(Y_i) = \begin{cases} \mu_U(Y_i) + \mu_P(t_{bi}) - \mu_U(Y_i) \cdot \mu_P(t_{bi}), & if\ t_b \leq t_h \\ \mu_U(Y_i) + \mu_P(C_i) - \mu_U(Y_i) \cdot \mu_P(C_i), & if\ t_b > t_h \end{cases} \tag{10}$$

The accessory function of $\mu_{\omega_0}(Y_i)$ is corrected the same way.

Considering that a high level of functional reserve prevents the emergence and development of the state ω_l, the UF indicator should be considered as a measure of mistrust to the classification ω_l [12–14]. Since the level of functional reserve for different classes of state ω_l affects this state differently and, basically, is nonlinear, we introduce the concept of the function of belonging to the concept of a high level of protection in a class ω_l with a basic variable UF − $\mu_{Z\ell}(UF)$.

Taking into account $\mu_{Z\ell}(UF)$ the certainty UW_ℓ that the subject is in class ω_l in accordance with the recommendations [4, 5, 12, 13] is determined by the expression:

$$UW_\ell = \begin{cases} UPE_\ell - \mu_{Z\ell}(UF),\ if\ UPE_\ell > \mu_{Z\ell}(UF); \\ 0,\ if\ UPE_\ell \leq\ \mu_{Z\ell}(UF). \end{cases} \tag{11}$$

3 Results

As a specific example the Problem of the Mathematical Model prediction synthesis nervous system diseases provoked ergonomics Russian manufacture tractor according to individual risk factors and the functional reserve of the organism. The primary features used to assess the level of ergonomics of the tractor cab at the expert level were: temperature in the cab (x1); cabin noise level (x2); the average level of load on the hands (x3); the average level of load on the legs (x4), vibration of the whole body (x5), vibration on the hands (x6), vibration on the legs (x7), angle of inclination of the seat (x8), seat height (x9), distance to the main controls (x10); the level of psycho-emotional stress associated with professional activity (x11) and the level of chronic physical fatigue (x_{12}) [1, 2, 7, 31, 32]. The signs x_{11} and x_{12} characterize the individual properties of a person, but since they "strongly depend" on the level of ergonomics of technical systems with which the operator contacts, they can indirectly characterize the level of ergonomics. Therefore, experts in the appropriate block of signs of ergonomics included these signs.

For the construction of private functions of the level of ergonomics on the signs x_1, …, x_{10}, two approaches were chosen: the method of psychophysical scaling and the construction of specialized test questionnaires.

Signs x_1, …, x_{10} are measured using appropriate technical means and computer questionnaires.

Levels of psycho emotional stress x_{11} and fatigue x_{12} are determined by the methods described in [12, 23, 19, 32].

In accordance with the general methodology for the synthesis of hybrid fuzzy decision rules in conditions of poor formalization, it is advisable to use the interactive package RUMM 2020, the use of which is described in [8, 12] in conditions of poor formalization.

In the course of evaluating the information content, six informative features x_2, x_5, x_6, x_7, x_{11} and x_{12} were selected from the entire set of features describing the tractor cabin ergonomics for the task of predicting the onset of nervous diseases.

1. The sign x_2 was measured with an electronic device in decibels. For a quantitative assessment of signs x_5, x_6 and x_7, a specially designed questionnaire with a point estimate was used.
2. Working conditions are not connected with vibration $x_5 = 0$.
3. Working conditions are associated with low-intensity physically poorly perceptible vibration without causing physical discomfort $x_5 = 1$.
4. Working conditions are associated with noticeable tangible vibration without causing physical discomfort $x_5 = 2$.
5. Working conditions are associated with a well-perceptible vibration causing some physical discomfort by the end of the day, but over time there is a feeling that the discomfort "does not accumulate" $x_5 = 3$.
6. Working conditions are associated with significant vibration, which causes pain to the end of the work shift and with significant work experience (over 25 years) leads to pathological changes $x_5 = 3$.

Using these characteristics as basic variables in accordance with the recommendations [12, 13, 19, 23], the membership functions $\mu_H(x_2)$, $\mu_H(x_5)$, $\mu_H(x_6)$, $\mu_H(x_7)$, $\mu_H(x_{11})$ and $\mu_H(x_{12})$ were constructed to class ω_H "high risk of diseases of the nervous system."

In accordance with the recommendations [8, 10, 12, 16–18], a fuzzy model was built to predict the occurrence and development of nervous diseases from human contact with a machine (tractor):

$$UPF_H^*(p+1) = UPF_H^*(p) + \mu_H\left(x_{j+1}^*\right)\left[1 - UPF_H^*(p)\right], \tag{12}$$

Where $UPF_H^*(1) = \mu_H^*(x_2)$; $x_2^* = x_5$; $x_3^* = x_6$; $x_4^* = x_7$; $x_5^* = x_{11}$; $x_6^* = x_{12}$;; j = 1, 2, …,5.

Considering that a significant risk factor for the class of risk of the onset and development of diseases of the nervous system is the work experience, taking into account the recommendations [2, 4, 5, 12, 13], was obtained the function of time accounting $\gamma_{E_H}\left(t_p\right)$ with basic variable t_p – work experience.

Confidence in the appearance and development of nervous diseases from contact with a tractor for expressions (1) and (2) with due regard for recommendations [4, 5, 12, 33] and work experience is determined by the expression:

$$UPF_H = \gamma_{EH}\left(t_p\right) \cdot UPF_H^*, \tag{13}$$

For the indicator UPI_H of expressions (1) and (2), at the expert level, the following composition of informative features was determined; medications that have a harmful effect on the nervous system; alcohol intake; diseases of the nervous system in close relatives; imbalance of the energy characteristics of the meridian biologically active points (BAP) associated with the situation of the disease of the nervous system (points P9, G5, V43, V60, R9, VC7).

In accordance with the recommendations [8–10, 12, 13], a predictive model of the form was synthesized for this group of characters:

$$UPI_H(q+1) = UPI_H(q) + R(q+1)[1 - UPI_H(q)], \tag{14}$$

where $UPI_H(1) = \mu_H(L_s)$; $R(2) = \mu_H(AL)$; $R(3) = \mu_H(Br)$; $R(4) = UB_H$; Ls – a sign describing the conditions for taking medicines; AL – alcohol consumption; Br – diseases of the nervous system in close relatives; UB_H – confidence in the appearance and development of diseases of the nervous system, determined by the energy characteristics of the BAP in accordance with the recommendations [23–27].

Considering the fact that the studies were conducted in a relatively clean ecological region of the Kursk region (Russia), the component $UPEK_l$ for expressions (1) and (2) was not determined.

When assessing the level of functional reserve by the method described in the work using expression (5), the membership function $\mu_{ZH}(UF)$ is:

$$\mu_{ZH}(UF) = \begin{cases} 0, \; if \; UF < 0,1 \\ 1,28\, UF \; - \; 0,13, \; if \; 0,1 \leq UF < 0,8 \\ 0,9, \; if \; UF \geq 0,8 \end{cases}. \tag{15}$$

In the course of the conducted clinical trials on control representative samples according to the method described in [4, 5, 12], it was shown that the number of erroneous forecasts using mathematical models of type (2) is 0,86, and using model (10) – 0,94.

Thus, the simultaneous consideration of ergonomic risk factors and functional reserves of the human body in the considered example allows to increase the quality of the forecast by 8%.

4 Conclusion

The reliability of human-machine systems is largely determined by the ergonomics of technical systems, which in the long run can lead to deterioration in the functional state and health of a human operator. Moreover, having an appropriate functional reserve, the human body can significantly reduce the harmful effect not only of technical systems with which it contacts for a long time, but also from other environmental factors (environmental factors). The paper proposes a method for the synthesis of hybrid fuzzy decision rules, which allows to take into account the influence of heterogeneous risk factors on the human body, taking into account its protective properties evaluated through a functional reserve. On a practical example (forecast of the onset and development of diseases of the nervous system) it is shown that the simultaneous consideration of ergonomic risk factors and the size of the functional reserve allows to improve the quality of decisions made about the state of health of the human body.

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Low Back Pain and Work Ability Among Thai Nurses

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Abstract. The work ability (WA) of nurses is of concern in several countries, including Thailand. Low back pain (LBP) is a major occupational health problem among hospital nurses and it impacts the nurses' work ability. Limited research concerning the relationship between LBP and WA in hospital nurses has been conducted in Thailand. The aims of the present study were to study the levels of intensity of LBP during the previous seven days and the previous 12 months and the WA level of nurses in order to examine the relationship between individual factors, work factors, and the intensity of LBP and WA, and to determine whether individual factors, work factors, or the intensity of LBP could predict the WA of 312 nurses working in the general hospital under study. A self-reported questionnaire that was confirmed for its quality and that was composed of individual factors, work factors, LBP complaints, and the work ability index (WAI), was used for collecting the data, which were analyzed using descriptive statistics, correlation, and multiple regression. The results showed that the nurses had intensity of LBP during the previous seven days and the previous 12 months at a moderate level. More than half of the nurses had WA at a moderate level. Back muscle exercise was seen to be positively related to WA ($r = 0.157$, $p < .05$). The intensity of LBP during the previous seven days and the previous 12 months was inversely related to WA ($r = -0.211$, $p < .05$ and $r = -0.239$, $p < .01$). Further, the intensity of LBP during the previous 12 months and the back muscle exercise were seen to be important predictors of the WA among the nurses ($p < .05$). Hospital administrators can use the findings of this study to promote WA among nurses.

Keywords: Low back pain · Work ability index · Hospital · Nurses

1 Introduction

Work ability is a concept that assesses and promotes nurses working in hospitals and is of concern in several countries, including Thailand. It is important for the quality of nursing care. Nursing work includes caring for and promoting the health of clients and patients, and therefore their work and workload are at risk of occupational health problems, especially LBP, the most common problem [1]. LBP can result in persistent pain and decreased ability to work [2].

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Several studies have shown that many factors, including age, work demand, work roles, work stress, physical exercise, musculoskeletal disorders, and intensity of LBP contribute to WA among nurses [1–5]. In this study, the individual factors included age and frequency of back muscle exercise, and work factors, including work experience in the current unit, work hours, and work stress. The LBP in this study emphasized the intensity of LBP during the previous seven days and the previous 12 months.

Most studies regarding the relationship between intensity of LBP and WA among nurses have been conducted in other countries, while there has been limited research on the relationship between the intensity of LBP and WA among hospital nurses in Thailand. Therefore, it is expected that this study will provide a better way to help improve or promote WA among the nurses in Thailand.

2 Objectives

The aims of the study were to study the levels of intensity of LBP during the previous seven days and the previous 12 months and the nurses' WA level in order to examine the relationship between individual factors, work factors, and the intensity of LBP and WA, and to determine whether individual factors, work factors, or the intensity of LBP could predict the WA of the nurses.

3 Methodology

3.1 Study Design

This cross-sectional study was performed with 312 nurses working at Singburi Hospital, a secondary care hospital in Singburi province, Thailand.

3.2 Subjects and Ethical Approval

The research protocol was approved by the research board of Singburi Hospital for permission to carry out the study. All of the nurses, the study population, in the nursing department of the hospital were invited to participate in the study and were informed about the objectives of the research. Participation in the study was voluntary and they were asked to provide written consent before the beginning of the study. Finally, 260 completed questionnaires were returned for a response rate of 83.3%.

3.3 Data Collection

The data collection was carried out from June to July, 2016, using a self-administered questionnaire. The questionnaire was divided into four parts: demographic characteristics and individual factors (9 items); questions regarding work factors and work stress (37 items); and questions about low back pain complaints (2 items); and work ability (10 items).

The demographic characteristics and individual factors included age, gender, weight, height, pregnancy, smoking, and frequency of back muscle exercise. The work factors consisted of types of nursing units, work experience in the current unit, work hours, and work stress. The work stress among the nurses was measured using the nursing stress scale (NSS) of Gray-Toft and Anderson [6] in order to assess the sources of stress experienced by the nurses. The NSS consists of a 34-item Likert scale with seven sub-scales, including death and dying (7 items), conflicts with physicians (5 items), conflicts with other nurses (5 items), lack of support (3 items), workload (6 items), inadequate preparation (3 items), and uncertainty concerning treatment (5 items). A 4-point Likert scale was used to indicate the frequency of work stress from never (1), to occasionally (2), to frequently (3), and to very frequently (4). The results were calculated from the total points, ranging from 34 to 136. A higher score indicated a higher frequency of work stressors experienced by the nurses.

In this study, the low back pain complaints included the intensity of LBP during the previous seven days and the previous 12 months. The intensity of LBP means the level of LBP among the nurses who had LBP and it was measured using a numerical rating scale (NRS). A numeral 11-point scale was used to collect the data on the intensity of LBP among the nurses. The scale was a visual analogue scale (VAS) ranging from zero to ten points, where “zero” means absence of pain and “ten” means unbearable pain. The intensity of LBP was divided into three levels: low (less than or equal to 3 points); moderate (more than 3 to 7 points); and high (more than 7 to 10 points).

Perceived work ability was measured using a questionnaire [7] and the WAI scores were calculated according the standard method provided by the Finish Institute of Occupational Health (FIOH). The following seven items were (1) current work ability compared with the lifetime best (0–10 points); (2) work ability in relation to both physical and mental demand of work (2–10 points); (3) number of current diseases (1–7 points); (4) estimated work impairment due to diseases (1–6 points); (5) sick leaves during the past year (12 months) (1–5 points); (6) one’s own prognosis of work ability 2 years from the time of filling out the questionnaire (1, 4, or 7 points); and (7) mental resources (enjoying daily tasks, activities and life spirit, and optimism about the future) (1–4 points). The WAI scores were calculated by summing up the estimated points for each item. A higher score indicated better work ability. The total WAI scores ranged from 7 to 49 points and the scores were classified into four levels as poor (7–27), moderate (28–36), good (37–43), and excellent (44–49).

The self-reported questionnaire, which was confirmed for quality and validity, was examined by five experts. The reliability of the questionnaire on work stress and work ability was tested using Cronbach’s alpha and was found to be 0.81 and 0.89, respectively.

3.4 Statistical Analysis

Descriptive statistics, including frequency, percentage, mean, and standard deviation, were used to describe the characteristics of the study population, the intensity of LBP during the previous seven days and the previous 12 months, and work ability. The analytical statistics comprised Pearson's product correlation and stepwise multiple linear regression analysis. The level of statistical significance was set at 0.05.

4 Results

4.1 Characteristics of the Participants

Most of the respondents were registered nurses (90.7%) and were female (96.3%). The participants' ages ranged from 25 to 59 years, with a mean age of 39.5. The BMI of the nurses ranged from 16.9 kg/m^2 to 36.2 kg/m^2, with a mean BMI of 23 kg/m^2. The number of work experience in the current unit of the participants ranged from 1 to 35 years, with a mean years of 9.7 (S.D. = 0.38). Most of them (96.6%) worked in the direct patient care units including surgical wards, medical wards, an outpatient department, obstetric and gynecological wards, a labor room, an operating room, a pediatric department and a nursery unit, and an emergency department. Most of the participants (87.6%) had never experienced an accident or back trauma from work. Almost none of the participants (98.6%) had ever smoked.

4.2 Levels of Intensity of LBP During the Previous Seven Days and the Previous 12 Months

The mean score for the intensity of LBP during the previous seven days was 4.20 (S.D. = 1.63, Min = 1 Max = 9), while the mean score for the intensity of LBP during the previous 12 months was 5.56 (S.D. = 1.63, Min = 1 Max = 10). The mean scores for the intensity of LBP during the previous seven days and the previous 12 months indicated a moderate level.

4.3 WA Level of Thai Nurses

The nurses had WA at a moderate level (52.8%), an excellent level (24.9%), a good level (21.9%), and a poor level (0.4%) (Fig. 1).

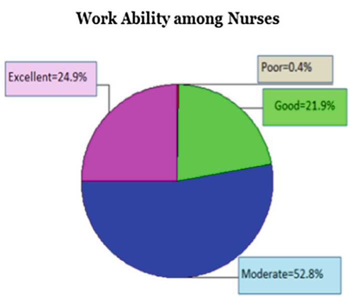

Fig. 1. Work ability of the Thai nurses classified according to the level of WA

4.4 The Relationship Among Individual Factors, Work Factors, and the Intensity of LBP and WA and the Predictors of WA Among the Nurses

Back muscle exercise was seen to be positively related to WA at the 0.05 level of statistical significance (r = 0.157). The intensity of LBP during the previous seven days was seen to be inversely related to WA at the 0.05 level of statistical significance (r = −0.211). The intensity of LBP during the previous 12 months was inversely related to WA at the 0.01 level of statistical significance (r = −0.239). On the other hand, age, work experience in the current unit, work hours, and work stress were not related to WA at the 0.05 level of statistical significance (Table 1).

Table 1. The relationship among individual factors, work factors, and the intensity of LBP and WA using Pearson's product correlation analysis

Variables	Correlation coefficient (r)
Individual factors	
1. Age	−0.035
2. Back muscle exercise	0.157*
Work factors	
3. Work experience in the current unit	0.168
4. Work hours	−0.025
5. Work stress	0.095
LBP	
6. Intensity of LBP during the previous seven days	−0.211*
7. Intensity of LBP during the previous 12 months	−0.239**

*Correlation was significant at the 0.05 level.
**Correlation was significant at the 0.01 level.

Prior to analysis, the Komogorov-Smirnov test indicated that age, back muscle exercise, work experience in the current unit, work hours, work stress, the intensity of LBP during the previous seven days and the previous 12 months and the WA scores had a normal distribution. Multicollinearity verified by examining the correlation among the seven variables was carried out and the results showed a low to moderate correlation with each other (r = .021 to 0.386).

The results of the stepwise multiple linear regression analysis showed that the predictors of the WA were back muscle exercise and the intensity of LBP during the previous 12 months. The two variables altogether explained 89.0% of the variance in WA at the statistically significant level of 0.01 (R2 = 8.9, p-value < .01). Table 2 presents the predictors of WA using stepwise multiple linear regression analysis.

Table 2. The predictors of WA using stepwise multiple linear regression analysis

Variables	b_0	Standard error	Beta	t	p-value
- Intensity of LBP during the previous 12 months	−0.527	0.162	−0.227	−3.252*	.001
- Back muscle exercise	1.358	0.520	0.182	2.611*	.010
Constant	45.131	1.478		30.357	

R = 29.9%, R2 = 8.9%, Adjusted R2 = 8.0%
*p-value < .05

The equation explaining the variance in WA is as follows.

$$Y = b_0 + b_1X_1 + b_2X_2. \quad (1)$$

where Y = WA

b_0 = constant value

b_1 = regression coefficient value of the intensity of LBP during the previous 12 months

b_2 = regression coefficient value of back muscle exercise

X_1 = the intensity of LBP during the previous 12 months

X_2 = back muscle exercise

Therefore, the predicted WA = 45.131 − 0.527 (the intensity of LBP during the previous 12 months) + 1.358 (back muscle exercise).

This equation means that if the intensity of LBP during the previous 12 months increases 1 unit, WA will decrease in an identical way by 0.527 units, controlling for other variables. Conversely, the equation means that if back muscle exercise increases 1 unit, WA will increase in an identical way by 1.358 units, again controlling for other variables.

5 Discussion

5.1 The Levels of Intensity of LBP During the Previous Seven Days and the Previous 12 Months

The study's findings demonstrated that Thai nurses experienced a moderate level of the intensity of LBP during the previous seven days and the previous 12 months. The results are consistent with the study of Souza and Alexandre [2], where it was seen that Brazilian nursing personnel experienced a medium intensity of LBP. The findings of the study are also similar to a study of Rasheed, Rasshid, and Javeed [1], who conducted a study of Pakistan nurses and found that a majority of the nurses perceived moderate severity of LBP. However, the results of the present study are different from the findings of Sikiru and Hanifa [8], where a majority of Nigeria nurses reported mild intensity of LBP. This could be due to the different nature of nursing work in Nigeria, the workload there, the classification of the intensity of LBP, and the types of questions used to collect the data.

5.2 The WA Level of Thai Nurses

The results of the present study revealed that more than half of the nurses had WA at a moderate level (52.8%) and some at a very good or excellent level (24.9%), compared with the research findings from previous studies conducted among Thai nurses in a university hospital [9], where the nurses reported their WA at a good level (59.9%) and at a moderate level (21.3%). The findings of another study of Satsue, Siritarungsri, Subtaweesin, and Wiratchpintu [10] revealed that a majority of the nurses rated WA at a good level (64.1%) and at a moderate level (22.2%). The difference may be due to the different health status and health behaviors of nurses, the characteristics of nursing work, and the work environment of each hospital. In this study, the data were collected from nurses at a secondary care hospital, whereas the data from the other studies were collected from a university hospital or a tertiary care hospital. The findings from previous studies conducted among nurses in Brazil [11], where the nurses reported that they had WA at a good/excellent level (56.6%). The difference could be due to many factors, including the health status and health behaviors of nurses, the characteristics of nursing work, and the work environment, as indicated before.

5.3 The Relationship Among Individual Factors, Work Factors, and the Intensity of LBP and WA and the Predictors of WA Among the Nurses

As the results indicated, back muscle exercise was positively related to WA. The findings of this study were consistent with the findings from the work of Jacobsen and colleagues [3], where it was found that physical exercise was positively associated with WA among healthcare workers. Performing physical exercise at least twice a week was effective in preventing the deteriorations of WA [3].

The results of the present study also indicated that the intensity of LBP during the previous 12 months was inversely related to WA. A study of Magnago and colleages [11] reported that the intensity of musculoskeletal pain was inversely related to the WA among nursing workers. Additionally, a study of Iyaoromi, Madaki, and Dankyau [4] reported that the duration of LBP was inversely related to the mean WAI scores among nurses in Nigeria. Further, the results of the present study were supported by the results of the work of Ge, Sun, Liu, and Zhang [5], where it was found that musculoskeletal disorders, including LBP, had an influence on WA.

6 Conclusion

The nurses in this study had intensity of LBP during the previous seven days and the previous 12 months at a moderate level. More than half of the nurses had WA at a moderate level. The intensity of LBP during the previous 12 months and back muscle exercise were the important predictors of WA among the nurses. This study confirmed that the intensity of chronic LBP and performing back muscle exercise influence the WA of the nurses.

7 Implications/Recommendations

The findings of this study can be used to promote the WA among Thai nurses in hospitals. Hospital administrators should provide back muscle exercises to promote the health and improve the WA of the nurses. Moreover, education programs on the prevention of LBP and the treatment of LBP should be developed and provided in order to decrease and even prevent the intensity of LBP on the part of nurses. Future research would be needed to test the effectiveness of such programs.

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Conflicts of Interest. No conflicts of interest are declared by the author.

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Understanding the Challenges to the Safe Delivery of Care in the Mexican Healthcare System

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Abstract. Safety and quality challenges have been identified by national and global organizations highlighting the need for health sector improvements in Mexico. The current research investigates healthcare workers' perspectives of factors affecting their job performance and wellbeing, ability to provide effective care and overall patient safety culture within a public hospital in Guadalajara. A total of 30 hospital staff took part in a card sorting task to elicit the perceived impact of eight pre-identified organizational factors. Results showed that healthcare workers identified the top contributory factors as 'Finance/budget' and 'Resources'. 'Staff numbers and competency' was chosen for having more significant impact in delivering safe and effective healthcare, while 'Communication' was perceived to have more impact on the way their do their job. The findings from this study helped to identify areas for future applied research projects and provisional direction to the Hospital Quality Managers for targeted improvements projects.

Keywords: Healthcare · Quality improvement · Staff performance · Patient safety · LMIC

1 Introduction

Initiatives for improving healthcare staff and patient safety and wellbeing within Low and Medium-Income Countries (LMIC) are less well developed and established than in more developed countries. Over the last 20 years, the UK and US have developed

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programs for safety improvement that have, in varying degrees, started to improve the working conditions and demands on healthcare staff [1]. In contrast, some LMIC's are just starting on this journey. Mexico is one such example where safety challenges have been identified [2] and national and global organizations have highlighted the need for health sector improvements regarding quality and safe care provision [3].

In response to this need, the current feasibility study was conceived by collaborating research teams from the UK and Mexico to investigate healthcare staff perspectives of the challenges encountered in the safe delivery of care in regard to personal job roles, work environment and organizational structure.

According to the [3], Mexico's health system must change to deliver people-centered, high-quality care. It is also claimed that there is a need for higher standards for safe and effective care across all Mexican providers, including the private ones [3]. The PAHO [4] Latin American Study of Adverse Events (IBEAS) reported that up to 20% of patients experience at least one harmful incident during their hospitalization [4]. Additionally, the study acknowledged that more than half of these harmful incidents could have been avoided. This shows that the health system in Mexico still needs to increase awareness and implementation of an improved safety culture.

In Mexico, patient safety is a relatively new subject. [2] comments that although it is a known and discussed topic within the different healthcare institutions, associations, faculties, medical equipment and pharmaceuticals companies, and the diverse array of professions working in those institutions; to date there has been little action to address this issue and to embed patient safety culture in the healthcare practice. Around the same time [5] investigation into the nursing practices and environments evidences the need to fully understand the context of work and sign post to the need for further investigation.

In regards to staff wellbeing and performance [6] identified that healthcare staff in the north of Mexico presented with work-related injuries, which could have been avoided with the intervention of the human factors/ergonomics. Specifically in nursing staff, some of the factors linked to work-related injuries included the mobilization of overweight patients, excessive numbers of patients and the duration of postures sustained for long periods of time [7]. Healthcare workers reported that the lack of support from directive staff when presenting work-related injuries could affect also their mental wellbeing [7].

There is significant evidence that staff mental wellbeing is also diminished due to work overload, organizational culture and negative experiences in regard to patient interaction, all of which can contribute to stress [8, 9], fatigue or even burnout [10, 11].

The literature provides evidence for further investigation into these important issues and as such this study aims,

- to understand healthcare staff perspectives about the impact of different factors affecting their efficiency and wellbeing and patient safety within a public hospital in Guadalajara.
- to develop a framework for exploring healthcare challenges within a large teaching hospital in the city of Guadalajara.

2 Method

This feasibility study took place within a large teaching hospital in Guadalajara, Mexico. A total of 30 healthcare staff participated in the workshops. Five workshops took place on five consecutive days. Each workshop involved at least three moderators to coordinate the activities and a maximum of nine participants.

Participation in the workshops was completely voluntary. The study protocol was reviewed and approved by an Ethics Committee at the University of Nottingham, the UK academic institute co-leading the project. The invitation to healthcare workers to participate in the workshops came from the hospital Quality Management Office and was issued to each chief of service who then passed it onto their staff.

2.1 Study Design

Each workshop included a hybrid card sorting task, combining a closed card sorting activity (with categories provided to participants) with the opportunity for participants to produce their own categories, also known as open card sorting [12]. This method was implemented to enable participants to consider and reflect on their wellbeing and safety challenges present in their own healthcare system in relation to eight pre-identified categories. The eight factors used in the card sorting activity were previously identified from a thematic analysis of a data set in the UK [1]. The factors used as the card sorting categories were: 'Staff number and competency', 'Organizational culture', 'Risk management culture', 'Pressure of work', 'Communication', 'Finance/budget', 'Resources' and 'Patient complexity'. In order to avoid cultural limitations; in regard to UK specificity of the categories, and to explore the possible inclusion of different contextual factors in the card sorting, blank cards were provided to participants to give them the option of contributing factors not already listed in the pre-identified categories (open card sorting strategy). Participant proposed factors should relate to how healthcare workers carry out their jobs and the way they deliver care. This would then provide opportunity for the card sorting activity to not just be dictated by the findings of a study in a non LMIC healthcare service but to also be inclusive of and reflect experiences in Mexico.

2.2 Procedure

Participants were asked to provide informed consent and were asked to fill in a participant background questionnaire to obtain their demographic data and work role details. The workshop started with an introduction video about system thinking theory [13], a brief icebreaker activity encouraged healthcare workers to reflect on their job roles. This was followed by focus group discussions, which set the scene of the card sorting activity. The workshops and materials used were in Spanish. This paper only reports the findings of the card sorting activity, which was the final task within the workshop.

In the card sorting, participants were handed two sets of nine cards in which the eight categories (listed previously) were written. The remaining two cards were blank for participants to write any extra factors they considered important and relevant to the task.

Participants were able to ask for more blank cards if needed. Two grids were presented to the participants. See Fig. 1 for an example of the grids. The first grid asked the question (Q1) How do these factors impact the way I do my job? The second grid asked the question (Q2) How do these factors impact the delivery of safe and effective healthcare? These two questions would elicit reflections from participants on two levels, a personal individual work level and higher organizational level. The impact categories participants could allocate the cards were: high impact, medium impact, little impact, very little impact and no impact at all (Fig. 1).

How these factors impact the way I do my job?				
No impact at all	Very little impact	Little impact	Medium impact	High impact

Fig. 1. Example of one of the card sorting grid: how these factors impact the way I do my job?

2.3 Data Analysis

The factors were scored according to their perceived impact. Factors allocated in high impact category added four points; medium impact, three points; little impact, two points; very little impact, one point; and no impact at all that added no points. This means that the higher the total points on each factor the higher the perceived impact of the categories on each question (Q1 and Q2).

3 Results

The statistical analysis used IBM's SPSS software (version 21 for Windows) and Microsoft Office Excel (version 10 for Windows) to generate the database. Non-parametric tests were used in comparing results. When comparing results from Q1 with Q2 a Wilcoxon Signed Rank test was used. To compare between groups a Kruskal Wallis test was used; post-hoc analysis was made with a Mann-Whitney U test between pair groups with a Bonferroni adjustment applied (p = 0,025). All tests considered a p = 0,05 of significance level.

The card sorting included 30 participants, 19 were women with an average age of 48 years old (±16) and ten were men with an average age of 46 years old (±12), one participant refrained from reporting the gender information. According to job role, ten participants were nursing staff, eight were medical staff, seven were allied health professionals (social workers, psychologists and dietitians), six were hospital operational staff (chiefs of operations, chief of floor, stretcher bearer), one participant was had a non-clinical management role and one participant did not record their job role. Before starting the card sorting activity one of the participants had to leave the activity due to an emergency.

The total points score that each card received were calculated and are presented in Table 1. According to the perceived impact to each question (Q1 and Q2) based on those score, the factors were ranked from first place (1) to last (8), with 1 being the top factor with the highest impact and accumulation of points and the 8th factor indicating the one with smallest impact.

When comparing the impact of each factor from Q1 to Q2, a Wilcoxon Signed Rank Test revealed that participants perceived that 'Communication' impacts more in how they do their job than in providing safe and quality healthcare, z = −2,15, *p* = 0,032, with a small effect size (*r* = 0,28). In contrast, 'Staff number and competency' was perceived to impact more in providing secured and quality healthcare than in the way they do their job, z = −1,98, *p* = 0,047 (small effect size, *r* = 0,26). No other factor showed a statistical difference (Table 1).

Table 1. Aggregated value and rank of eight different factors in Q1 and Q2

	Q1		Q2		z	*p*
	Aggregated value	Rank	Aggregated value	Rank		
Finance/budget	88	1	91	2	−0,44	0,661
Resources	87	2	95	1	−0,99	0,320
Pressure of work	84	3	75	4	−1,86	0,063
Communication	71	4	55	8	−2,15	0,032
Organizational culture	68	5	59	6	−1,40	0,162
Staff number and competency	63	6	76	3	−1,98	0,047
Risk Management	62	7	72	5	−1,45	0,148
Patient complexity	54	8	58	7	−0,73	0,447

A comparison between the four staff groups was made in order to identify differences in the perceived impact of each factor regarding job performance (Q1) and safe and efficient healthcare (Q2).

The Kruskal-Wallis Test revealed a statistically significant difference in the impact of 'Patient complexity' in how quality and effective healthcare is provided to the patient (Q2) across four different staff groups (Nursing staff, n = 9: Medical staff, n = 8: Allied Health Staff, n = 6: Hospital Operational Staff, n = 6), x2 (3, n = 29) = 8.877, *p* = 0,031. Median values given by staff group to Q2 are presented in Table 2. The Nursing staff recorded the highest median score on impact (Md = 3) and the lowest recorded by Allied Health Staff (Md = 1) and Hospital Operational Staff (Md = 1). In post-hoc test (Mann-Whitney U test) when comparing Nursing staff (Md = 3,00, n = 9) to Allied Health staff (Md = 1,00, n = 6), results showed statistically significant difference in the impact of the 'Patient complexity' in how they provide safe and quality service to the patient, U = 6,50, z = −2,51, p = 0,012, r = −0,65. Nursing staff compared with Hospital Operational staff (Md = 1,00, n = 6) also showed significant difference, U = 8,50, z = −2,30, p = 0,021, r = −0,59.

Table 2. Median ranks of the impact of eight factors in delivering safe and effective healthcare according to staff groups (Q2).

	Nursing staff	Medical staff	Allied health professionals	Hospital operational staff
	n = 9	n = 8	n = 6	n = 6
Staff number an competency	2,0	2,5	2,0	2,5
Organizational culture	1,0	1,0	1,0	3,0
Risk management	3,0	3,0	3,0	2,5
Pressure of work	2,0	2,5	2,0	2,5
Communication	2,0	1,5	2,0	1,5
Finance/budget	3,0	3,0	3,0	2,5
Resources	4,0	4,0	3,0	4,0
Patient complexity	3,0	2,5	1,0	1,0

Only one blank card was used by a participant to add in a factor which they perceived impacted Q1. On the card the participant wrote “Patients with little or lack of general knowledge” (empathy).

In Q2 there was also only one blank card used with the statement: “Null or deficient assessment of the workers/professional profile for each role. Bad human resources”, somewhat related to the ‘Staff number and competency’ factor already contained in the card sorting activity.

4 Discussion

The majority of the factors analysed in this study were perceived with a similar impact (no significant difference) on the two questions used in the card sorting activity in the way healthcare staff do their job and in delivering safe and effective healthcare.

‘Finance/Budget’ and ‘Resources’. These were factors with more perceived impact on both questions, this could be due to the fact that those factors are related, less budget could translate to fewer resources in delivering healthcare services. Previous research by [14] in different regions of Mexico with high maternal mortality, collected the opinion of local practice communities, in some regions finance and resources came up as a top-level obstacle to improve maternal healthcare.

The Mexican health sector has presented funding cuts for around ten years, this issue when combined with the fact that some of the health centers were built in the 1950s, contributes to a system whereby healthcare institutions have to provide healthcare with less budget and resources [15]. Other problems arise when distributing the resources within healthcare institutions, the current distribution is based on the hierarchical order determined by profession (doctors on top) and other status markers (educational level, seniority), and not planned around the needs of a patient, type of unit or institution [16]. This situation is therefore a problem component of the

'Organizational Culture' factor. [15] and [16] show that facilities, equipment and furnishings in public healthcare institutions are usually not well maintained but still used and often staff has to improvise non-tested solutions, especially in the case of damaged equipment. These problems are compounded due to the culture which could promote the view that Mexican health authorities perceive this standard to be the norm for public healthcare services rather than perceiving it to be a substandard or unacceptable situation.

The current study is unable to change the funding system within the regional hospitals involved, however working towards a progressive strategic framework to improve education and implementation of patient safety and improved staff wellbeing and performance may positively impact through the avoidance of occupational health problems and costs associated with unsafe acts or errors.

'Pressure of Work'. Placed in overall third place and presenting as the most impact factor in Q1 and fourth in Q2. This result is in agreement with the Sociotechnical Systems Analysis in Healthcare proposed by [17]. The authors suggest that high workload or work pressure have detrimental effect in safe provision of care. It is also consistent with the thematic analysis performed by [1] in which 'Pressure of work' is ranked in third place in terms of impact on challenges to safe delivery of care.

'Pressure of work' may include full/blocked departments, time pressures, improved coping strategies and excessive workload to name a few [1]. In a Chilean study, it is mentioned in regard to an increasing number of patients and the understaffing to be linked to fatigue and burnout [11]. In a similar study carried out with nursing staff in Mexico staff reported workload as one factor that impacts in their wellbeing and can potentially affect their job performance [8]. An investigation with nursing staff at the same hospital in 2006 had reported similar outputs, with reported workload and lack of support from the organization as factors contributing to increased stress levels in their professional life [18]. In another study Mexican medical staff reported to have high and severe stress related to the excessive burden of supervision, medical workload, constrained freedom to perform their job, long shift hours and more patients than they can handle [9].

These references provide evidence of the excessive workload experienced by different healthcare professionals and it is reflected in a similar way in this study. It might be difficult to diminish workload due to the number of patients, some solutions can be proposed from the human factors perspective to improve work distribution through a healthcare staff centered solution.

'Staff Number and Competency'. Participants reported that this factor significantly impacts more on the way they deliver safe and effective healthcare to patients than on a personal job role level. According to [3], Mexico is the country with the lowest number of nursing staff compared to other OECD countries, with 2.6 nurses per 1000 population compared to an average of 9.1. Medical staff has similar numbers with 2.2 per 1000 compared to the OECD average of 3.2. It is not a problem specific to Mexico, in the UK [3] reports 2.8 doctors per 1000 habitants. The number of nurses per 1000 population in UK is higher than in Mexico, 7.9 per 1000 population, but not as high as Denmark, Switzerland and Norway whom double the number (at least 16.9 per 1000 population) [3]. This finding is also exacerbated by non-clinical workers within hospital settings, for example the work of [19] highlighted how poor administration and processes of human resources within healthcare systems led to inefficiency.

Less experienced staff will have fewer established competencies than more experienced staff and so could need more time and resources to perform their tasks and this may affect the patients perceived quality of healthcare provided to patients as reported by [20] in Mexican ambulatory health services. This could be one of the reasons for which the participants in this study suggested that the competency and amount of coworkers affects their job performance at a personal level but it affects more how the system works and could translate to an unsafe and inefficient health care.

'Organizational Culture'. In this study 'Organizational culture' was ranked in fifth place for Q1 (how I do my job) and sixth in Q2 (delivery of safe and effective care). A possible explanation for this is suggested by [16], since the health sector has experienced funding cuts it has led to continuing to provide healthcare but with fewer and less functional resources. At the same time informal practices (such as hierarchical resource and workload distribution) have been created within healthcare institutions in order to keep up with healthcare demand but do not address the real problems causing pressure in the system. The distribution of workload is distributed according to a hierarchical order instead of the needs of healthcare [16]. The hierarchical order is first defined by profession (with doctors having more power, and influence within the hierarchy), other status markers that could influence hierarchy are educational level, seniority, type of employment and proximity to authorities. This kind of work and role distribution is one of the contributors to conflict creation among healthcare staff and departments. Without evidence for novel approaches for improving quality and safe delivery of care the current status quo will continue as it is currently embedded in the hospital culture as the only way to reach suggested productivity goals.

'Risk Management Culture'. This feasibility study supports this finding and coincides with the experiences of [1], with participants reporting that this factor has more impact in the delivery of safe and efficient healthcare than in the way they do their job. 'Risk management culture' include proactive safety processes such as risk assessments and baseline knowledge of safety by all workers in an organization [1]. It is known that Mexican risk management culture does not focus on prevention, for example there are documents and procedures for the analysis of root causes of adverse events in Hospitals [21] but not for fostering a pervasive risk management culture [22]. According to healthcare institutions' normative operations and policies [21], there should be records of all accidents and adverse events in Mexican hospitals in order that action can be taken to protect against repeat occurrences. However, in practice this does not always happen [22] compared five Mexican studies about the perception on safety culture, and found that the majority of accidents and adverse events are not reported due to fear of punishment, blame culture or participants not considering or understanding the need to report. Recommendation was made to sensitize Mexican healthcare staff on the importance of this issue in order to host and promote a more safety oriented culture in health institutions. These recent findings align with the current study, whereby human factors and systems thinking are being utilized with a sample of hospital staff (clinical and non-clinical) to encourage transparent working, communication and awareness of risks to safe and effective healthcare delivery.

'Communication'. This factor was identified as impacting significantly more on the way participants do their job than the provision of effective and safe care to patients on a macro scale. In contrast with this, other studies have identified 'Communication' to have more impact in the latter, safe delivery and care on an organizational level. [23] mention that failing to have appropriate ways of communicating with the patient and between the services/staff represents an inadequate use of resources, loss of efficiency and may affect service quality. [24] indicates that effective communication could avoid accidents or harm to patients. The [3] recommends improving information systems in order to standardize communication templates and tools in order to improve and effective communication.

[25] concludes that information and communication technologies (ICT) could help to restructure processes in health services and may represent a cost-effective intervention to improve quality and safety in healthcare. Since then much work has been done to understand how those ICT tools can help to support communication and effective teamwork in improving patients outcomes [26], better work [27], to deliver safe and high quality healthcare [26, 27].

The current landscape of health information technologies (HITs) in Mexico is limited and still in infancy, with a sustained interest from 2001 but with ups and downs on its implementations or creation of official norms regarding the use of HIT [28]. The implementation of HIT in Mexico has been focused on administrative and management areas [28], on implementing electronic patient records [28, 29] and the creation of an e-Health portal initiative [29]. Even though some strategies are implemented, they are not fully established due to the unequal use of HIT tools and software caused by the lack of coordinated actions of the institutions taking part on these strategies, constrained in part by the Mexican legal framework [29]. This study highlights the need for further investment and research into the impact of ICT in the Mexican healthcare system.

'Patient Complexity'. Nursing staff participating in this study identified 'Patient complexity' as one high level factor that impacts the way they deliver effective and quality healthcare in compared to two other groups of healthcare workers. Overall it was ranked as the least impactful factor (8th place) in Q1 and 7th place in the Q2, similar to the UK results of [1] study.

A study carried out in another state of Mexico suggest that nursing staff experience stress as a result of workload and possibly exposure to patient suffering [8]. This idea may explain to some degree the difference found in this study, whereby exposure to patient suffering may be linked with the concept of 'Patient complexity'. The same author suggests that there is null or little concern regarding staff health from the institutions they work for, highlighting the need for occupational health and psychological support programs within the same institutions. This aligns with the idea that better support to staff from governance structures, appropriate training programmes and ongoing systematic support mechanisms can enhance the performance of healthcare staff, can lower cost and improve satisfaction rates. One notable example of this practice is the strategy used within Norwegian healthcare service providers [3] and whilst this exemplar of best practice cannot be lifted into the Mexican system there are points of learning which can be considered in the Latin American context. Even as the least impact factor of the eight, the difference found among staff groups suggest an initial pathway to action and evidence the idea that some factors have not the same impact among all the hospital staff.

4.1 Limitations

One limitation in the ranking of the cards was that there was not possible to allocate more than two cards by a participant in each impact category, this included the blank cards to be written in. The no impact at all category was the only one with no minimum or maximum of necessary cards. This was perceived to be a limitation by some participants however the study was designed in this way to force participants to prioritize the factors against each of the two research questions.

There is the possibility that participants were reluctant or did not have time to consider what factors above and beyond those presented may be relevant to the Mexican healthcare service in which they worked. Whilst the opportunity was presented via the blank cards for participants to offer their own suggestions, only two acted on that opportunity. This may be due to the fact that participants needed to return to their clinical and non-clinical work activities or that they did not feel empowered in offering up their own suggestions.

Another limitation of this study might be that not all of the studies used in the discussion section were from a human factors perspective, thus these comparisons should be taken with caution.

4.2 Future Work

This study only reports hospital staff perspectives about the impact of how the eight factors presented impact their work and the delivery of safe and effective care. Whilst they do not have full insight into the operationalization of the hospital and the factors which influence healthcare staff work, the experiences of patients are an important contributor to developing and improving health service delivery. Patients could potentially have insight into and assess some of the factors such as ‘Communication’, ‘Risk management’, ‘Resources’ and ‘Organizational culture’. According to [20], patient perceived quality of service is ordinarily reported by factors like type of institution, waiting time, time in consult and improvement of health after consultation. In further research, it would be important to elicit patient perspectives in order to provide a more complete and inclusive view of the challenges experienced within the Mexican healthcare system.

This study provided insight into the current challenges faced and future opportunities for improvement within the hospital. The findings provide a pathway for further research using human factors methods to improve design of work and the whole system, additionally continued collaboration will see not only research pathways but also applied targeted projects to develop better ways of working. More analysis is needed to clarify possible hypothesis about the differences found between staff groups. Further work analyzing the other activities in the focus groups needs to be done in order to corroborate some of the findings of the card sorting activity.

A natural progression of this study is to explore the relationship between job performance and patient safety in the Mexican context. Here those concepts were explored as separate but related topics. Follow on enquiries would take a systems thinking approach to understand the inter-relationships between how work is done in the hospital by staff, the efficiency and performance of the system and the resulting patient outcomes and safety.

5 Conclusion

This feasibility study has investigated challenges to the safe delivery of care in a Mexican hospital. It has provided understanding of how staff perceives those challenges in regard to their personal experiences of providing care and what they think are the priorities at an organizational level. Whilst the findings do not contribute applied interventions, they provide knowledge from which the research team and hospital collaborators can focus resource and capacity for future safety and quality improvement initiatives.

The impact of factors affecting care delivery were prioritized, this allowed comparison with other Mexican studies in order to corroborate our findings and add to the limited existing literature specific to a Latin-American context. Where staff groups identified different factors as impacting them in their job there is a call to investigate these differences further so that work design and organizational policies can meet the needs of a wide range of staff groups and not just those who are 'higher up' in the hierarchical standing of Mexican healthcare institutes.

The study has introduced HF/E to the hospital Quality Managers and healthcare staff as a discipline which can contribute to their internal improvement processes by taking a systems approach and through understanding the needs of workers within the system.

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Diagnosis Systems

Development of a Sleep Monitoring System by Using a Depth Sensor: A Pilot Study

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Abstract. Sleep is an essential part of health and longevity persons. As people grow older, the quality of their sleep becomes vital. Poor sleep quality can make negative physiological, psychological, and social impacts on the elderly population, causing a range of health problems including coronary heart disease, depression, anxiety, and loneliness. Early detection, proper diagnosis, and treatments for sleep disorders can be achieved by identifying sleep patterns through long-term sleep monitoring. Although many studies developed sleep monitoring systems by using non-invasive measures such as body temperature, pressure, or body movement signal, research is still limited to detect sleep position changes by using a depth camera. The present study is intended (1) to identify concerns on the existing sleep monitoring system based on the literature review and (2) propose to developing a non-invasive sleep monitoring system using an infrared depth camera. For the literature review, various journal/conference papers have been reviewed to understand the characteristics, tools, and algorithms of the existing sleep monitoring systems. For the system development and validation, we collected data for the sleep positions from two subjects (35 years old man and 84 years old women) during the four-hour sleep. Kinect II depth sensor was used for data collection. We found that the averaged depth data is useful measure to notify the participants' positional changes during the sleep.

Keywords: Sleep quality · Sleep movement · Sleep pattern · Kinect II depth sensor

1 Introduction

Advances in the healthcare and medical field have resulted in prolonged human life, thus causing an increase in the elderly population. According to the United States Census Bureau, it is estimated that the U.S. elderly population over age 65 will grow from 43.1 million in 2012 to 83.7 million in 2050 [1].

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The elderly that are isolated and neglected can lead to an increased likelihood of age-related sleep disorders and sometimes emergency medical conditions, such as heart failure during sleep. Proper diagnosis and treatments for age-related sleep disorders such as REM-sleep behavior disorder, narcolepsy, periodic leg movements, and restless legs syndrome can be achieved by identifying sleep patterns through long-term sleep monitoring. Therefore, an unobtrusive and yet precise sleep monitoring system, once developed, will be useful at home, assisted living or any other elder-care facility.

There are two main goals in this study. The first goal is to understand the characteristics of the existing sleep monitoring system. The second goal is to develop an unobtrusive automated sleep monitoring system that can measure the sleep behaviors of elderly people by using touchless sensors.

2 Literature Review

Early diagnosis and prompt treatment of sleep disorders for elderly people can be achieved through an accurate and seamless sleep monitoring system, such as a wearable smart device for monitoring sleep quality. However, many elders oppose the idea of having to wear or place sensors to the body during sleep [2]. Therefore, new touchless technology needs to be developed that can unobtrusively measure a senior's sleep behavior data and can provide an accurate diagnosis based on the real-time monitoring sleep behaviors. Currently, there are three key varieties of commercialized sleep monitoring techniques.

The first is the polysomnography (PSG) device that is highly regarded in the medical field as the standard for highly accurate sleep sensing data. The only disadvantage to PSG technology is that it is very expensive and can only be used in a lab/hospital environment. The PSG device is also highly obtrusive to the user because it incorporates several sensors and electrodes. This sensor will be worn during sleep.

The second group involves a common method, using smart devices such as a smartphone, smart watches, and fitness trackers. For example, the smartphone app Sleep Cycle Alarm Clock is one of the most famous sleep monitoring systems, and it's free to download. It is very cost effective. The smart devices use built-in accelerometers to detect body motion and correlate high motion with restless sleep [2]. However, this method does not produce results with reliable accuracy in sleep monitoring.

The third group of devices includes the DoppleSleep and Wi-Sleep systems that use wireless signal changes to detect sleep motion. The DoppleSleep sensing system uses Doppler radar technology. In a lab setting, it is known to provide an 86% recall rate for physical movement detection. There was only an 8% error for heart rate detection and an 11% error for breathing error detection [3]. Further literature reviews lead to Wi-Sleep, a system that generates data similar to DoppleSleep but uses Wi-Fi signals instead of Doppler radar to interpret sleep quality. The key aspects of Wi-Sleep fall into signal processing, outlier detection, noise filtering, and interpolation of data to create a map of sleep quality patterns [4]. The drawbacks are that the devices do not obtain as many measurements as the PSG and the accuracy of measurements is unstable due to the environmental interruptions, such as other moving objects.

Table 1 shows a comparison between the three categories mentioned above. The low-cost aspect associated with high accuracy in the unobtrusive form factor is the main focus of the proposed study.

Table 1. Comparison of the existing sleep monitoring systems

Sensing system	Sleep sensing parameters								
	Cost	Accuracy	Easy to carry	Body-motion	Breathing rate	Heart rate	Brain activity	Snoring	Muscle tone
SmartWatch/fitness tracker	Low	Low	X	X					
Frequency sleep system	Low	Medium		X	X	X			
Polysomnography device	High	High		X	X	X	X	X	X

3 Development of a Sleep Monitoring System

This study has utilized multimodal touchless sensor technology (i.e., Microsoft Kinect II depth sensor) that can unobtrusively and precisely collect a sleeping person's body positions. Two adults participated in this study. One is a male who is 33 years old (YO), 170 cm in height, and 75 kg in weight. The other one is an older female who is 84 YO, 155 cm in height, and 45 kg in weight. As shown in Fig. 1, the Kinect II depth sensor was located next to the bed, and it captured the participant's movements during sleep, for around four hours, for one night. The resolution of the depth image is 512×424 pixels, and each pixel has a distance in millimeters between the sensor and the participant. If the participant changes the sleep posture or position, the depth values will be continuously changed due to the minor distance changes between depth sensor and participants' body (note that the depth sensor is located in a fixed position). The sampling rate of the data was 30 frames per second. A computerized program was developed to record the data as shown in Fig. 2. The system calculates and shows an

Fig. 1. In-home experimental setup: MS Kinect II depth sensor.

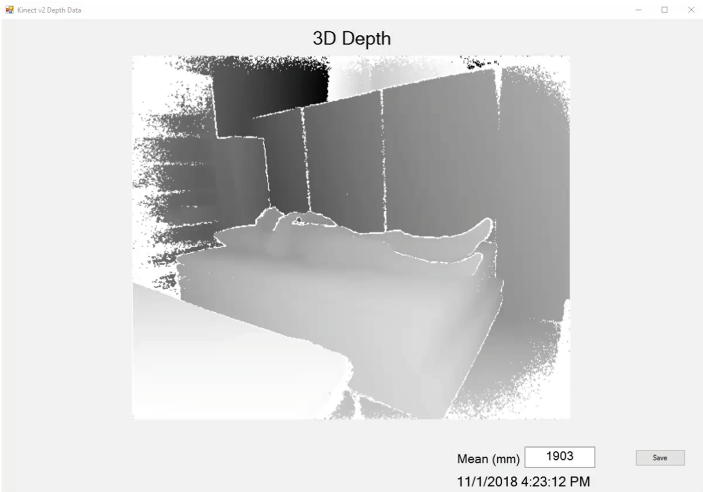
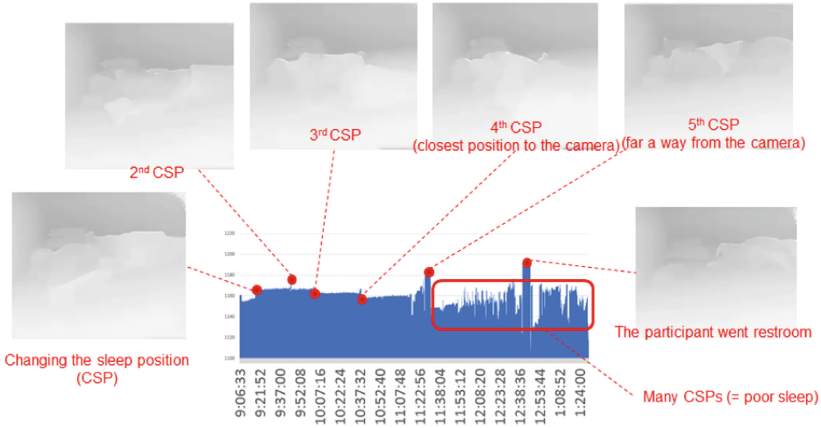


Fig. 2. The proposed system for recording changes in depth between the sensor and the participant.

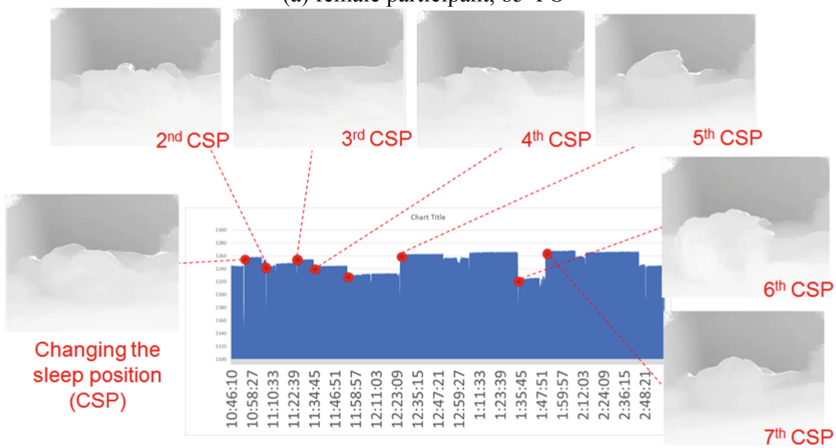
average distance of all the distances in each pixel. To protect the privacy of the participant, we didn't collect any identifiable images, such as a colored or infrared facial image.

4 Results

Figure 3(a) shows the mean distance changes as well as infrared images of the 85 YO female participant. Based on the visual analysis on the graph, it is anticipated that the first changing sleep position (CSP) occurred at 9:21:52 pm (hh:mm:ss). At that time, we anticipated that the participant changed her sleep position, so that the average depth data changed, which causes a small spike in the graph. If there is no spike (flat height in the graph), then we can anticipate that the participant does not change the sleep position over a certain amount of time. Similarly, the second CSP occurred at around 9:37:00 pm. However, after 11:22:56 pm, many spikes were shown in the graphs, which indicate many postural changes during that time, ultimately causing poor sleep quality. On the other hand, as shown in Fig. 3(b), the male participant showed relatively stable sleeping pattern throughout the experiment compared to the female participant. The male participant changed the sleep posture more frequently than the female participant, but once the position change occurred, then the male participant could stay the position more stable than the female participant. We can conclude that the young male participant well maintained the sleeping position compared to the older female participant, which indicate better sleep quality.



(a) female participant, 85 YO



(b) male participant, 33 YO

Fig. 3. Measured mean distance for the two participants during the testing.

5 Discussion

Based on the literature review, we can conclude that an accurate, non-obtrusive, and cost-effective sleep monitoring system needs to be developed. A 3D depth sensor could be one of the possible solutions since it shows acceptable accuracy, a non-invasive technique, as well as a cost-effective method. For future study, we need to collect more human subject data to develop a computerized algorithm to detect sleep position changes. The system presented in this study could be applicable in senior care facilities since the data was collected from a home-based environment without attaching any sensors or wearables. Therefore, the system with the developed algorithm would be particularly useful to readily detect an abnormal sleep pattern change for a senior person.

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Quantitative Evaluation of Pulse Diagnosis Using Capillary Blood Flow of Images

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Abstract. In this research the purpose is to evaluate pulse diagnosis in "medical medicine" from a scientific point of view. Also it is scientifically assessing the relevance of the pointed out diet contents and pulse diagnosis. By evaluating and examining above, evaluating the usefulness of pulse diagnosis to health.

Keywords: Pulse diagnosis · Capillary blood flow

1 Introduction

When checking the pulse diagnosis as shown in Fig. 1, it is said that "Pulse diagnosis is a method of examining the state of disease by touching the pulse of the patient, grasping the strength and rapidness of the pulsation, hardness and thickness, ups and downs, etc.". Pulse diagnosis was generally used for examination because it is described in the medical book "Yellow Emperor Naka" which was around 220 BC, and has been involved in health care in a long history. Previously Western medicine also had a pulse diagnosis, and it was said that "I will diagnose the disease in the future" [1, 2].

As an example, when looking at the carotid artery and the radial artery at the same time, if both are coincident and striking a pulse, there is no abnormality in both the body and the environment at present, but if they do not match, either the current body or the environment is in a state where there is abnormality. Currently, the popularity of pulse diagnosis is low, we do not know exactly what to know by examining a pulse, "unclearness" is persistent as an image.

Also, individual differences greatly appear in the amount of information obtained by the skill of the technician performing pulse diagnosis. The data can be said the experience value. There is a present situation that it takes a very long time to master pulse diagnosis by getting that experience. One of authors took the data of the pulse of 40 thousand people and made decisions based on it. She spent about twenty years. As one of the factors that causes such a long period of time, since there are few scientific databases for pulse diagnosis, it is greatly influenced by the leadership skill of the

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Fig. 1. Method of pulse diagnosis

expert. In other words, there is not much teaching curriculum, even if there is, it has become a sense world.

The purpose of this research was to quantitatively evaluate the pulse using the blood flow of the capillary and to compare with the result of the pulse diagnosis. Because there is no tool to judge the diet that really exists in each patient, it is important to communicate dietary care using pulse diagnosis. Although it is very effective as a tool, it is currently the case that there is no scientific database related to pulse diagnosis and food curing. Therefore, another purpose is that by using the meal content pointed out database was created.

2 Experiments

In order to measure the blood flow of the capillary, SC-10 scope manufactured by Vascular Beauty Co., Ltd. was used. All of the subjects and the capillary blood flow image of the left side of the ring finger were taken at the observation site. The reason why the fingertip of the fourth finger was used, the sympathetic nerves are gathered, so it is easier to measure the capillary than other fingers.

After the subject received a pulse diagnosis, one of authors pointed out and then it was recorded the contents of the speech with a voice recorder and raised it in letters.

3 Pulse Diagnosis Method

The method of the pulse diagnosis was as shown in Fig. 2;

Fig. 2. Method of pulse diagnosis, the position of the finger, ① was assigned the index finger, ② was for the middle finger ③ was for the ring finger respectively.

- Check with left hand, this is because of the hormonal relationship.
- Using the pulsation of the radial artery, the radial artery runs throughout the body, and as a result, weak parts with strong pulse can be judged by pulsation from the body surface.
- Concerning the position of the finger, ① was assigned the index finger, ② was for the middle finger ③ was for the ring finger respectively. Organs are assigned each finger.

The reason for dividing this single pulse into three is that in medicine, Yin and Yang are assigned to the pulse of the wrist and divided into upper focus, middle focus, and lower focus, so that the part of the pulse of ①, ② and ③ was separated.

The pulse diagnosis method in this paper was based on statistics. The pulse of ① pulse is accompanied by arrhythmia, when we feel arrhythmia in a shallow place, it related to the heart. When we feel arrhythmia in the deep place it related to the large intestine. When the heart activity begins to decline, the peristalsis of the large intestine also decreases. When there is no arrhythmia, it means a drop in the lungs. If the lung drops, it means a decrease in the brain. When the liver of ② pulse expresses abnormality, it accompanies itching and pain in the body, when the liver declines, absorbing amino acids from the small intestine starts to decline. When the pancreas, the pulse feels strong, as the pancreas starts to decline, absorption of hormones also begins to decrease in the gallbladder. ③ pulse represents kidney decline. The digestion problems arise when the peristaltic movement of the stomach starts to decline. The view of the viscera is described. In medicine, because of the idea divided into Yin and Yang, the organ is heavy, so think it as a shade, feel it downward. The understood is thought as hollow, feel it upward. From the relationship of hormones, peristalsis movement is detected in the depths below.

The judgment of pulse diagnosis was mentioned as follows; First, when a pulse is pressed with a force of 8 g or less, a state of pulse is called "magma pulse" And if we apply pressure more than 9 g, it is "glacier pulse" state. In short, magma pulse means a state with heat in the body and the connection with sympathetic nerve is strong and also sympathetic nerve moves blood flow quickly. The glacial pulse is a state in which the parasympathetic nerve is dominant and the pulse is also decreasing due to some activity of the internal organs. The grade, level, stage of the pulse was described. When evaluating the strength of the pulse, it is not only the feeling but also a five-point evaluation using numerical values. These five stages can be applied to each pulse number and quantified. The pulse rate is measured by hitting in one minute.

There are 90 participants with 50 males and 40 females.

4 Results

4.1 Examples

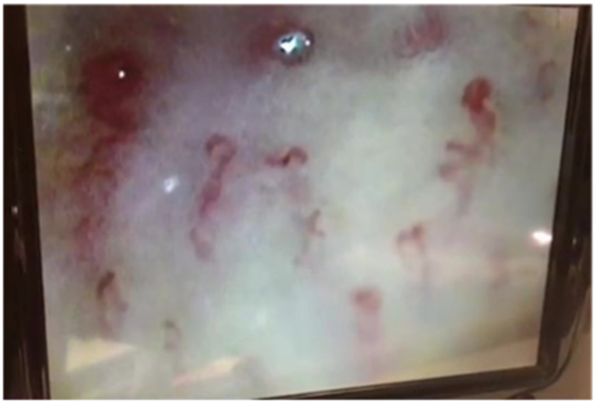
The evaluation method of capillary image as shown in Fig. 3 was mentioned. The evaluation items are five items of length, thickness, twist, size of the loop and collapse. Ideally it is a state in which blood vessels on straight hairpins are lined up regularly. For five items was evaluated as ◯ △ × , three grades.

- Length is given as ◯, slightly short is △ and short is ×.
- The thickness of this figure is ◯, if it is thin, it is Δ, and if it becomes thick, it is ×
- In the middle of this figure the veins crossed. If it is up to one, ◯ is score, and 2 to 3 is Δ, 4 or more is ×.
- The size of the loop is this state ◯. If the loop is thin, Δ is score and × is score if the loop is thick
- In the collapsed state, the middle part of the blood vessel seems to be collapsed. The photograph was evaluated as ◯, and 2 to 3 is Δ, 4 or more is ×.

Figure 4 is an example of the data. For comparison with the previous good condition, it is all ×. It is obvious from the previous case, because both the length and thickness are all not good condition.

Figure 5 is a state of poor blood flow. In such a good state and a bad state, there is a big difference in the capillary blood vessel image. This is no longer showing the blood vessel image well. The evaluation of the three stages is also not enough. This state is a picture that took a whole lot also, but this is that the basic physical strength is declining.

Fig. 3. Good example of capillary image



length	×
thickness	×
twist	×
size of the loop	×
collapse	×

Fig. 4. Bad example of capillary image; five items of length, thickness, twist, size of the loop and collapse are all ×.

4.2 Relation Between Pulse Diagnosis and Capillary Image

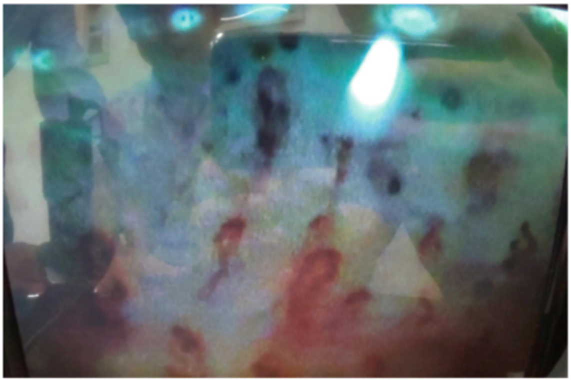
In this section Relation between pulse diagnosis and capillary image was mentioned by using 5 examples in which participant's disease was known. In the next section the food regulation for each participant are described.

Allergies. The first example was shown in Fig. 6 and this is the result of the blood flow measurement image of those who have allergies. The evaluation level of length,

length	△
thickness	×
twist	×
size of the loop	△
collapse	×

Fig. 5. Example of poor blood flow

thickness, twist, size of the loop, collapse is indicated. When to see this allergy, the size of the loop was pointed out.



length	×
thickness	×
twist	×
size of the loop	△
Collapse	×

Fig. 6. The example of the blood flow measurement image of those who have allergies. The pulse diagnosis results; "glacier pulse", grade ①1②2③2

This is the result of pulse diagnosis for this person. First of all, this person is a glacier pulse, the grade of the pulse ① was 1, that of the pulse of ② was 2 and for the pulse of ③ the grade was 2. The allergy of this one comes from the drop of the small intestine. Noteworthy point is the size of the loop. Pulse rate was normal.

Dialyzed. Figure 7 is a pulse that tends to be dialyzed. The point to pay attention to in a pulse that is likely to be dialyzed is the length. The result of pulse diagnosis is a characteristic in grade. ① It is like a pulse with the pulse of the pulse ② of the pulse ② in the same, like a straw. And pay attention to the length of blood flow measurement image. Pulse rate is early.

length	×
thickness	△
twist	△
size of the loop	△
collapse	△

Fig. 7. The example of the blood flow measurement image of those who tends to be dialyzed. The pulse diagnosis results; "glacier pulse", grade ①3②3③3

Allergies (2). The next example is also allergic as shown in Fig. 8, so the size of loop was paid attention just as before. The result of pulse diagnosis is indicated. Since allergy of this person felt in the shallow part of ②, allergy is coming from a decline of the liver. The pulse was normal.

length	○
thickness	○
twist	△
size of the loop	△
collapse	○

Fig. 8. The second example of the blood flow measurement image of those who have allergies. The pulse diagnosis results; "glacier pulse", grade ①1②2③2

Hay Fever. The next one is the result of those who have hay fever as shown in Fig. 9.

The five-grade evaluation is as described, because it becomes the classification of allergy, the size of the loop was paid attention. The result of the pulse diagnosis is indicated. In the glacial pulse, the pulse of ② is falling. In this case poll enosis from the pancreas is occurring, and the pulse rate is normal.

length	△
thickness	△
twist	×
size of the loop	△
collapse	×

Fig. 9. The example of the blood flow measurement image of those who have hay fever. The pulse diagnosis results; "glacier pulse", grade ①3②2③3

Thyroid Gland. This person is a pulse that tends to be a thyroid gland as shown in Fig. 10. The grade is all the same 3, in this case the twist was paid attention. The vibe was felt, so that thyroid activity is low. The pulse rate is early.

length	△
thickness	△
twist	○
size of the loop	△
collapse	×

Fig. 10. The example of the blood flow measurement image of those who tends to be a thyroid gland. The pulse diagnosis results; "glacier pulse", grade ①3②3③3

4.3 Dietary Regimens

In this section dietary regimens for each person were described. For person of allergic, it is in a state that additives are accumulated in the body, because it is allergic. The digestive enzymes of the small intestine are lowered, so that the convenience store foods, dishes, canned coffee, supplements, etc., should not be taken, because there are many additives. The recommendation was to eat pork with abundant vitamin B1, and to drink water up to 500–1500 ml a day. The small intestine is the final stage of digestion, and it can be said that the intestinal environment has declined due to food additives.

The result of Dialyzed patient is the content of such guidance. In the case of this person, because kidneys were reduced by potassium, a lot of potassium should be refrained. Also, to eat ingredient with a lot of folic acid of hematopoietic vitamin was recommended.

The result of example 3 was mentioned as following guidance. When the liver is declining, it is susceptible to the influence of the toxicity of solanaceae, so it should be refrained from it.

Regarding to example 4, the recommendation was that this person should refrain from this food so as not to further enhance sympathetic nerve, and conversely, this person eat the food whose parasympathetic nerves rise.

For example 5, this person also needs folic acid. Because of thyroid gland, this food that iodine will go up should be refrained.

5 Conclusion

According to this research, in the future, in order to inform the general public of this pulse diagnosis, persuasive power will increase and awareness will be raised. Accumulation of data, pulse diagnosis will be also collected data with a view to mechanization. The relationship between pulse diagnosis and disease can be evaluated by accumulating data of more diseases.

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Medical Device Development

Finding Health Care Usability and Safety Issues in Consumer Product Reviews

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Abstract. Multiple techniques exist for eliciting usability and safety information related to product design. These methods work well for some types of use scenarios but have limitations. This work proposes a supplemental method of obtaining information relevant to usability and safety by systematically evaluating consumer reviews of medical devices using Natural Language Processing (NLP) techniques. Results include valuable information about categories of use, user priorities, and sources of user confusion. This project described a new method for gathering information from end users of medical devices. The information extracted may be useful to clinicians, manufacturers, and patient educators.

Keywords: Human factors · Usability · Patient safety · Safety · Natural Language Processing (NLP)

1 Introduction

Practitioners in the fields of human factors, usability, and user experience employ multiple methods for identifying and understanding usability concerns. Some commonly used examples include heuristic evaluation, usability testing, structured interviews, and surveys.

Accessing a large pool of representative end users can be a significant challenge. When selecting clinician users, it can be difficult to find participants who have the time in a busy clinical schedule for a usability evaluation. When targeting patient end users, finding a representative sample can be a challenge.

In addition, in most usability studies, users interact with a device or system over a short period of time in a controlled laboratory setting. For example, Hornbæk found that the median duration of product use in traditional usability studies was 30 minutes [1]. While this study format has advantages in terms of controlling variability, reducing confounders, and increasing statistical power, it can be difficult to ensure participants behave as they would in their everyday interactions.

Within the field of health care, usability issues often create patient safety concerns. Patient harm may result when a medical device or product is used incorrectly or cannot be used due to confusion over instructions or the device interface. Increasingly, health care is being performed in the home setting, and the user may be the patient.

This work explores a new and supplemental avenue for identifying safety and usability concerns with health care products by using Natural Language Processing

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(NLP) to explore online reviews. This is the first example we have found of mining consumer product reviews of patient-facing devices and equipment for information on usability and patient safety concerns.

1.1 Usability, User Experience, and Patient Safety

Designers, purchasers, and end users are often interested in the usability and user experience (UX) of a particular product. Within the field of health care, usability concerns can be associated with safety hazards. For the purposes of the discussion in this paper, we will use the following definitions of usability, user experience, and patient safety, from the International Organization for Standardization (ISO) and the World Health Organization (WHO).

Usability. The extent to which a product can be used by specified users to achieve specific goals with effectiveness, efficiency, and satisfaction in a specified context of use [2].

User Experience. A person's perceptions and responses that result from the use and/or anticipated use of a product, system, or service [3].

Patient Safety. The absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum [4].

Five classic dimensions of usability are effectiveness/errors, efficiency, satisfaction, learnability, and memorability [5]. There is variability among researchers in the dimensions of UX, but some sample dimensions are likeability, trust, support, and frustration [6].

1.2 Previous Research on Consumer Text

Due to limitations of traditional usability and UX experimental methods, some researchers have explored utilizing alternate sources such as consumer-generated text from existing online sources for usability information. Hedegaard and Simonsen proposed looking at online product reviews for dimensions of usability that require longer term evaluations such as learnability and memorability [6]. They attempted to quantify the amount of usability and user experience (UUX) information and dimensions in online reviews within the domains of software and video games and found that 49% of sentences in studied reviews contained information relevant to usability or UX [6].

Other work has focused on identifying language describing product use and assessing online reviews in the context of marketing research. For example, Lahiri and colleagues performed text classification to identify portions of online reviews with usage expressions [7]. Zhang and colleagues studied electronic word-of-mouth (eWOM) to determine how users evaluate its usefulness [8].

Researchers have also explored the use of consumer text in the field of health care. Pharmaceutical companies have monitored online social conversations for post-market drug research [9–11]. Vydiswaran and colleagues used phrases from consumer-generated text to identify consumer health vocabulary [12]. Torii and colleagues searched online product reviews and utilized machine learning to locate health-related information [13].

Previous attempts at machine learning solutions have had mixed results [e.g., 6, 14]. Therefore, we used a manual approach aided by NLP software to filter reviews and identify ones with likely information for close review.

2 Methods

This work included identifying a health care product with patient end-users, acquiring reviews, and processing the resulting text to identify usability themes. Because of the large volume of consumer reviews, we sought an efficient approach to extract enough relevant information to facilitate a deeper understanding into the design of a medical device.

2.1 Product Selection and Review Extraction

For the purposes of this proof-of-concept work, we selected a health care product that is commonly used by non-clinicians: a glucometer.

For simplicity, we focused on two models that represented a large share of the market and pulled reviews from an online retailer. There were 463 total reviews considered for one model and 160 reviews for the second model. Because the purpose of this study was to determine what types of usability information can be gleaned from online reviews, the findings were aggregated rather than used to compare the models to each other.

2.2 Review Analysis Techniques

We employed natural language processing in PolyAnalyst™ [15] to retrieve reviews and analyze the language of the reporters. In an iterative approach, we used text clustering techniques to explore themes and sentiment analysis to identify processes or components of the device that users found worked well or were difficult.

We extracted individual consumer reviews into a spreadsheet format utilizing regular expressions. Next, we performed sentiment analysis on this data set through the extraction of a subject, an evaluation, and the object of the evaluation. This was used as a filter to identify positive and negative sentiment in reviews.

Features were manually reviewed and expanded as necessary to review context. Conceptualization from review of the sentiment analysis and context informed the design of subqueries and formulation of a taxonomy of negative and positive sentiment towards use types, use settings, and user characteristics. This method grouped similar concepts for focused review.

The focus of this inquiry was not on quantitative results such as number or proportion of users experiencing a problem. Instead, the goal was to efficiently identify positive and negative attitudes towards the use of a medical device that might describe safety and usability characteristics related to design.

3 Results

3.1 Categories of Users and Use Environments

Information provided in some of the reviews suggested different types of users. By utilizing the query node, we were able to search for additional categories with which users self-identified or types of user concerns that could be used to group users into categories. The user categories identified in the reviews are shown in Table 1.

Table 1. Self-identified categories of users from reviews.

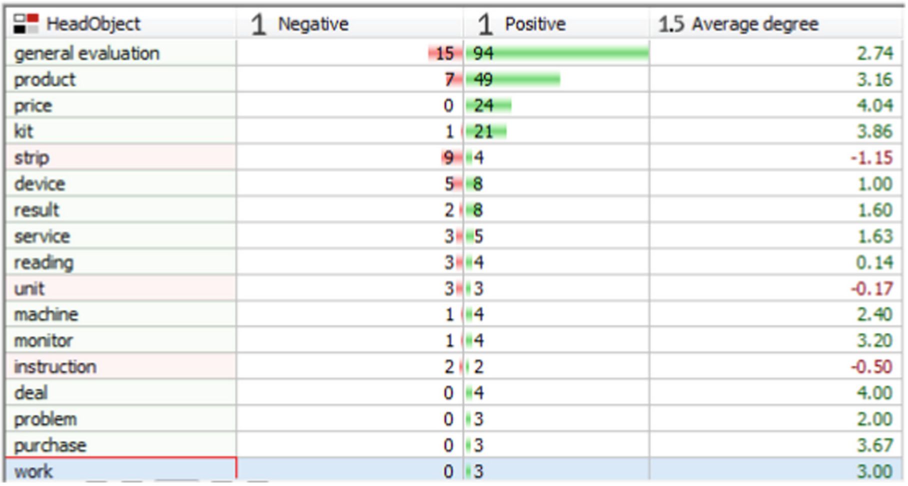
User category/concern	Example(s)
Diabetes (Type I)	Using device to determine insulin dosing
Diabetes (Type II)	Using device to determine how to modify diet
Gestational diabetes	Monitoring blood sugar to determine whether it can be controlled by diet or medication is necessary
Pre-diabetes	Monitoring blood sugar due to concerns with high blood sugar but not diagnosed as diabetic "I have recently been told that I am prediabetic" "I had gestational diabetes during my previous pregnancy, so I bought this meter to monitor my level before I was tested and referred to the diabetes center"
Low blood sugar	Monitoring blood sugar due to concerns with low blood sugar
Following a diet	Monitoring blood sugar for ketogenic diet Using to determine impact of an artificial sweetener on blood sugar level
Emergency responder	Paramedic/EMT Firefighter Gym owner
Caregiver	"My mom is 60 years old, and she has type 2 diabetes, high blood pressure, high blood sugar, and high cholesterol…We use it every evening, and it's helping us stay on track with her blood sugar levels"
Curious	"I am not diabetic, but like to check my blood glucose every so often"
Pet owner	Used for diabetic cat or dog

Reviewers also identified characteristics of users that may affect device usability. For example, one reviewer noted difficulty using the lancet to draw blood and stated, "I have some thicker skin from being a mechanic a long time ago."

Some of the reviews also identified specific use environments that may have distinct characteristics and usability requirements. One example is travel or, more generally, use of the device outside the home. Reviews that identified this issue focused on portability. Another category of use was in low light conditions, such as at night. A reviewer noted that the lack of a display backlight makes it difficult to use the device to check blood sugar in the middle of the night.

3.2 User Opinions

When end users described features that they liked or found frustrating, they often used words that conveyed positive or negative emotions. Sentiment analysis allowed us to extract such reviews to manually review how users described their experiences with specific features (Fig. 1).



HeadObject	1 Negative	1 Positive	1.5 Average degree
general evaluation	15	94	2.74
product	7	49	3.16
price	0	24	4.04
kit	1	21	3.86
strip	9	4	-1.15
device	5	8	1.00
result	2	8	1.60
service	3	5	1.63
reading	3	4	0.14
unit	3	3	-0.17
machine	1	4	2.40
monitor	1	4	3.20
instruction	2	2	-0.50
deal	0	4	4.00
problem	0	3	2.00
purchase	0	3	3.67
work	0	3	3.00

Fig. 1. This example sentiment analysis output suggests areas of user satisfaction and concern.

The term co-occurrence network provided a visualization of the interactions and relationships between key words and phrases found in the reviews (Fig. 2). These visualizations both suggested useful starting places for manual review of the reviews and called attention to phrases within the reviews that identified particular user concerns regarding both functionality and usability of the glucometers.

The primary concern identified in the reviews was one of accuracy of the glucometer, including a lack of match with the expected value for the test solution. Multiple users described designing their own tests to measure repeatability and finding variability in readings taken over a short period of time. In addition, one user wrote about obtaining the same value on four tests spread out over approximately 36 hours.

Some users also expressed concern that the test solution permits readings within a range of values that is too wide to be clinically useful. In addition, users identified the lack of availability of the test solution as a barrier to use of the glucometer.

A lancet is a component of the blood sugar testing system that was included with both glucometers. The lancet is used with a needle to prick the user's skin to obtain a blood sample for testing. Some of the reviews identified concerns with the lancet such as difficulty opening it to insert new needles and difficulty removing the cap, inability to draw blood with it, and the impression that it breaks easily.

One user identified an issue that violates the flexibility heuristic [16], writing, "My only issue is that I can't erase individual results. If I want to erase one result I have to

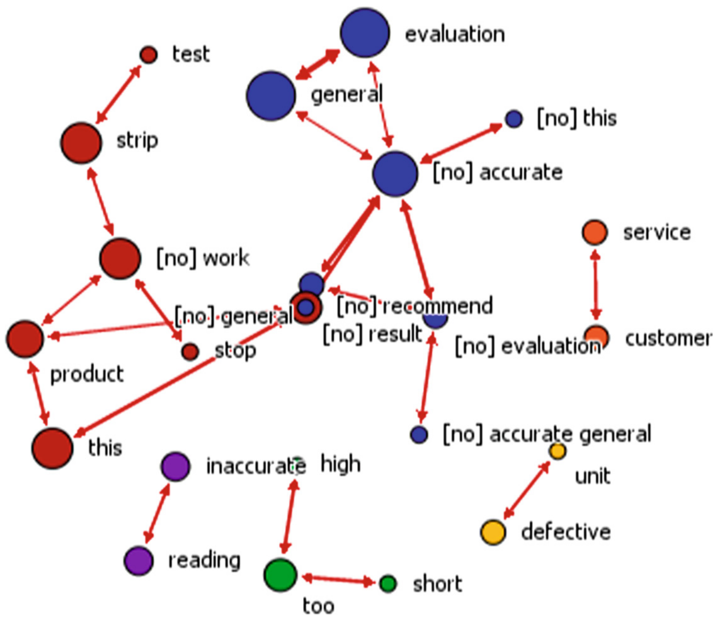


Fig. 2. This term cooccurrence network provides a visualization of the relationships between important terms in the reviews. The colors aid in visualizing meaningful cooccurrences.

erase all results." Another noted, "During the meter setup, I set the date and time. The setup process skipped over the AM/PM setting, meaning that you can only set the time during PM hours."

Other concerns that were mentioned in reviews included the unit not beeping even when sounds were enabled and the unit ceasing to work after a short period of time, including after checking and changing the batteries. In many of the above examples, there was not enough detail in those reviews to make a definitive determination of whether these were functionality or usability concerns.

It would not be surprising to find that some of the complaints issued by users were related to poor usability of the instructions and learnability of the device. Multiple reviewers noted that the instructions were difficult to understand. These included statements such as, "instruction [sic] were impossible," and, "the instructions for the lancet are exceptionally poor." One user stated the device came with multiple instruction manuals that contained different instructions.

There were also complaints about the frequency of error messages, as illustrated by the following sample reviews:

- "I've used it 10 times now and got an error 5 times. At which point, I have no choice but to poke myself again and pray it works."
- "Also, each time i check, I have to use at least 3 test strips because I get 'error' messages. One time I had to use 7!!"

3.3 User Priorities

The positive sentiments found in the reviews were useful in identifying user priorities for a glucometer and, more generally, a blood sugar testing system. For example, there were many positive reviews related to the low price, indicating this is a priority for patients.

Another subset of positive reviews focused on how the glucometer required only a small amount of blood. Example statements included:

- "A small amount of blood is needed for the reading."
- "Needs a little blood to work."
- "Measures with a small drop of blood."

Several reviewers noted that using the lancet device was less painful than expected. One reviewer wrote, "The lancing device is also great. I didn't know there was a difference in them. I didn't think it worked till I squeezed my finger! I didn't even feel it!" Reviewers also appreciated the ability to use different test sites to draw blood.

Based on reviews, the ability to obtain rapid results and the ability to obtain accurate results were also user priorities.

3.4 User Workarounds

A subset of the reviews identified a user concern along with a technique the user had found to make the system work as desired. For example, one user wrote, "My ONLY Complaint is the way the test unit is shaped…. the sides of the unit where you grip it are tapered in at the bottom and very smooth with no place to get a good grip, It constantly popped out of my grip if I squeezed the sides… I FIXED that problem by placing thin strips of textured tape to the sides to give me a grip and no problems since."

A related theme identified in reviews is patients' desire to use a device outside of the intended parameters. Multiple users described their frustration at the inability to use expired test strips with one of the glucometers. Reviews suggest that this is something they are accustomed to doing with other devices.

4 Discussion

This project described a new method for gathering information from end users of medical devices and products. It focused on non-clinician users of medical devices, which is a group of users that may be more difficult to access in traditional ways for people in the medical device community. In addition, this is a segment of the user population that is growing as more people manage components of their health care in home settings.

This method was useful for identifying user concerns with existing product features as well as user priorities, which could be valuable for product redesign teams. It also facilitates the definition of user categories and contexts of use.

User concerns can identify areas for additional investigation. For example, one user noted that it was impossible to correctly set the time during morning hours. Further evaluation of the device and user manual are required to determine whether this is a true feature of the device, a malfunction of the device, or the user had difficulty utilizing the device correctly or interpreting instructions. This would then allow the manufacturer to explore what actions might be appropriate.

The level of frustration contained in some of the reviews suggests users may not understand why the glucometer is generating an error message. Negative sentiments related to the user guide may also point to a potential area for improvement.

Based on the reviews, users appeared to find error messages frustrating both due to the cost of using additional strips and the need to obtain a new blood sample. It is important to capture and address these user concerns due to the potential for them to reduce patient adherence to a prescribed treatment protocol. In the case of a glucometer, if patients find testing to be unacceptably burdensome due to cost, pain, frustration, or other reasons, they may be less likely to use the glucometer at the appropriate times.

There are several limitations to this method of using consumer-generated text to identify usability and safety concerns. They primarily relate to representativeness of the sample and availability of relevant information.

In previous studies, researchers have found that very satisfied and very dissatisfied customers were more likely to engage in word-of-mouth (WOM) communications [e.g., 17]. This finding was confirmed for electronic WOM in a study that found that 53% of products on Amazon had a bimodal score distribution [18]. This indicates average consumer scores may be misguiding and that information extracted from reviews may not be indicative of the experience of the average user. However, this may not be an issue for the purposes of identifying usability problems that may result in patient safety concerns, because such issues often occur at the tail ends of use conditions and the user population.

The information provided in the overall corpus of the reviews was both limited and uneven. The reviews contain few details about reviewers. Usability depends on the product, task, user, and circumstances, but not all of this contextual information was provided in every review. Therefore, even reviews that included usability information may not have enough detail for this information to be interpreted correctly.

With any anonymous reviewing system, there may be fake reviews. Our analysis was relatively insensitive to this possibility, however, because we focused on the review text rather than the star rating. In addition, we were primarily interested in specific accounts of usability and safety concerns rather than positive or negative sentiments regarding functionality.

Online reviews tend to represent some dimensions of usability and UX more prominently than others, and this may be dependent on the product category. For example, a previous study of online reviews found reviewers tended not to mention some important dimensions such as memorability and efficiency but often discussed likeability [6]. The same study found that the dimension of support is rare in video game reviews but more prevalent in software reviews.

Due to necessity, the focus of this inquiry was on qualitative rather than quantitative results. The majority of users did not supply information that would facilitate categorization, so it is not possible to determine percentages of users who self-identify with each characteristic. In addition, because the reviewers were likely not a representative sample, it was impossible to determine the number or proportion of users experiencing a certain problem. This limitation was balanced by the strength of this method at allowing efficient access to a portion of the population that might be difficult to reach using other methods.

An additional limitation of utilizing consumer reviews to identify usability and safety concerns, identified in previous studies [e.g., 14] is that reviews are only available after a product is launched. There is an ethical concern with using end users as product testers, perhaps especially in the health care domain. However, some hazards may not be discoverable during testing in controlled environments, and it is important to discover unintended consequences during actual product use. In addition, such review would fit well with the Food and Drug Administration's guidance on including post-market use error problems in the Human Factors Engineering/Usability Engineering report [19].

Due to the limitations as well as the ethical concerns, this method should be considered an addition to rather than a replacement for traditional usability testing. For example, user characteristics identified from the reviews could be used to inform the development of user personas for future usability testing.

Future work could examine product features and related consumer sentiments hierarchically. One method could be to incorporate the Hierarchical Learning process and Sentiment Ontology Tree (HL-SOT) approach described by Wei and Gulla [20]. It may also be important to consider how the language patients use may differ from professional terminologies. Techniques for extracting consumer health vocabulary were discussed by Vydiswaran and colleagues [12].

Much of the information extracted from these reviews using the method described may be useful to clinicians, manufacturers, and patient educators. Functionality concerns could suggest quality issues with the product. Alternately, if the manufacturer is unable to replicate functionality problems, there may be a usability or education issue that causes a gap between the user's expectations and the product's performance.

Reviews that describe use outside of the intended parameters may suggest a possible vulnerability or safety hazard. It may be that the interface of the device does not appropriately inform against this activity. However, such reports also present an opportunity to expand functionality in ways that users desire. Finally, they open a window into the thought processes of users, presenting evidence of risk assessment by the patient end-users.

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Preventing Chemotherapy-Induced Onycholysis with the Use of an Active Local Cooling Device

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Abstract. Chemotherapy-induced onycholysis is a severe form of nail toxicity, characterized by partial or complete detachment of the nail from the nail bed. This medical condition is caused by the presence of taxanes in the patient's blood while undergoing chemotherapy and is observed in 0 to 44% of cancer patients. The taxanes limit rapid cell reproduction, treating cancer, but also bring deterioration to the nail and nail bed structure. Cryotherapy is currently used in the form of passive cooling for the prevention of onycholysis. Ice gloves are cryotherapeutic applications that are used during chemotherapy to prevent nail toxicity. Although they are significantly effective, they cause extreme cold and pain. In this research, the effectiveness of a five-finger active cooling device was examined to control the blood flow at the distal phalanges at one hand, while increasing the patient's comfort.

Keywords: Chemotherapy · Nail toxicity · Onycholysis · Cryotherapy · Cold-Induced Vasodilation

1 Introduction

Patients treated with systemic anticancer drugs often show adverse toxic events to their nails [1]. Some nail toxicities can affect both the nail plate and bed, which causes pain and functional impairment [2]. Onycholysis is a severe form of nail toxicity where the nail partially or completely detaches from the nail bed [3]. This medical condition is reported to develop with up to 44% of the patients undergoing a systemic cancer treatment [4, 5].

Onycholysis is nearly exclusively associated with cytotoxic chemicals taxanes (principally docetaxel and paclitaxel) and anthracyclines, which are commonly used for curing prostate, breast, ovarian, lung and stomach cancer [6]. These chemicals provide a toxic effect to the bed epithelium, which will interrupt the process of melanocytes and will inroad between the structures that holds the nail on its nail bed [4].

Nail disorder categories were expanded into three grades, which were recorded in the National Cancer Institute Common Toxicity Criteria (NCI-CTC, version 3) [7, 8].

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The first grade is the least severe category with discoloration of the nails and ridging or pitting. The pitting is caused by a defect in the uppermost layer of the nail plate. These pits can vary in morphology and distribution [9]. The second grade includes partial loss of nails or pain in the nail beds, but not interfering with function. Lastly, the third category contains partial to even complete loss of the nail or having pain in the nail beds interfering with activities of daily living (ADL).

Cryotherapy – or cold therapy – is the therapeutic use of extreme cold and has been found to decrease the effects of onycholysis and other chemotherapy-induced complications [10]. Cryotherapy invokes local cold-induced vasoconstriction (CIVC), which causes a decreased blood flow and therefore limits the transport of chemotherapeutic agents towards the nail beds. After five to ten minutes of extreme cold, the vessels start to dilate again as a protection mechanism of the body to prevent cold-induced tissue damages [11]. This effect is called cold-induced vasodilation (CIVD), which has a negative impact on the usefulness of the cryotherapeutic treatment [12]. During a period of long exposure of cold, a so-called hunting reaction will take place, which is characterized by interchanging periods of vasodilation and vasoconstriction.

Examples of currently used passive cooling techniques to obtain vasoconstriction are gel-filled frozen gloves and socks and cold caps, which are refrigerated and need to be worn for a total of 90 min (15 min before the administration of the cytotoxic drug, 60 min during the drug infusion and 15 min after the infusion) [7, 13, 14]. These cryotherapeutic applications are usually frozen at a temperature of −20 to −30 °C, although Ishiguro et al. have shown that convenient preparation of frozen gloves at −10 to −20 °C is almost as effective as the standard preparation, with significantly less discomfort [15]. Since these passive cooling applications warm up during use, they have to be replaced by cold new ones. The gloves and socks are used for protecting the nails to reduce the risk of onycholysis, while the cold cap is placed on the patient's head to minimize the hair loss or alopecia. The frozen gloves and socks significantly reduce nail toxicity, with Scotté et al. reporting a drop in overall occurrence of nail toxicity from 51 to 11% [14].

Since cooling is applied passively, the temperature inside the gloves and socks does not remain constant. This problem can be addressed by implementing an active local cooling system that is capable of maintaining a low temperature. Earlier studies have evaluated active cooling devices based on Peltier elements for controlling blood flow in the fingertips. A primary prototype enabled cooling the lateral sides of the middle and distal phalanges [16, 17]. Results showed that active cooling could become an effective means to control blood flow. Cooling the lateral sides of the fingers was unfortunately not always comfortable regarding the hands pose, and the studies showed difficulties in interpreting the thermal responses at the fingertips due to local active cooling. To improve comfort and enhance control of vasoconstriction on the fingertips, it was tried to cool the palmar side of the finger with the use of a one-finger prototype [18]. Arteriovenous anastomoses (AVA's), that allow vasoconstriction, are namely found at the palmar side of the hand while the location may also allow designing a device that can be grasped more comfortably. The one-finger active cooling prototype improved controlling the blood flow towards a predefined set point as compared to the devices that provide cooling on the lateral sides of the fingers. For this study, cooling based on coolant was used as an alternative method of cooling since it provides a greater cooling capacity and does not require cooling fins enabling a compacter infrastructure compared to cooling based on Peltier elements.

The aim of this research was to examine the effectiveness of a five-finger active cooling device based on coolant to control the blood flow under the nail bed at the distal phalanges of one hand. This to enhance the effectivity of active local cooling to reduce nail toxicity during cancer treatments.

2 Methods

2.1 Participants

Twelve healthy test persons – six men and six women, aged between 18 and 40 years – participated this study. All participants had to sign an informed consent prior to the tests. People who suffer from cold intolerance, perniosis, Raynaud syndrome or other cardiovascular diseases were excluded from participating to eliminate any external factors influencing the digital blood flow. Each subject was asked not to drink any alcohol the night before the test and was not allowed to eat or drink hot beverages during the test.

2.2 Materials and Set-Up

In this study, a five-finger active cooling system was developed that allows cooling of the palmar side of the distal phalanges of one hand, as shown in Fig. 1.

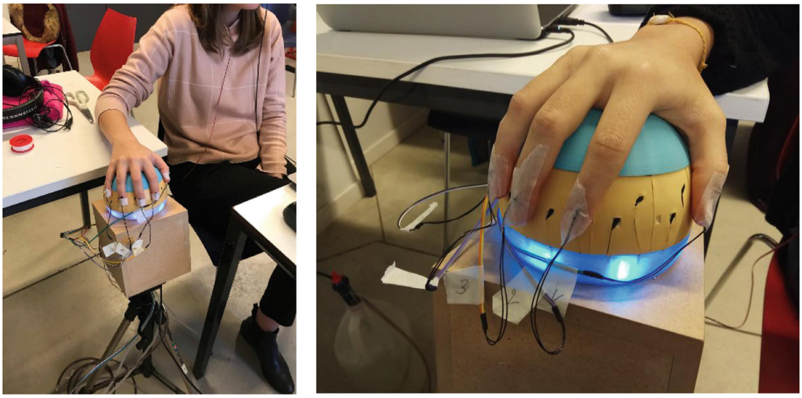

Fig. 1. Placement of the hand on the cooling device.

The cooling is induced with cooling liquid that is cooled in a freezer and circulated towards the cooling device. The cooling system of the hand was controlled by a microcontroller. A computer was connected to the microcontroller to record and monitor the data obtained during the experiments. Twenty-four NTC thermistors were placed on the Peltier elements for controlling internal temperature of the device. Finger skin temperature (and thus blood flow at the nail bed) was measured with five NTC thermistors at the dorsal side of the distal phalanges of the right hand. A last NTC thermistor was placed under the armpit as indicator for body temperature. A schematic illustration of the complete test setup is shown in Fig. 2.

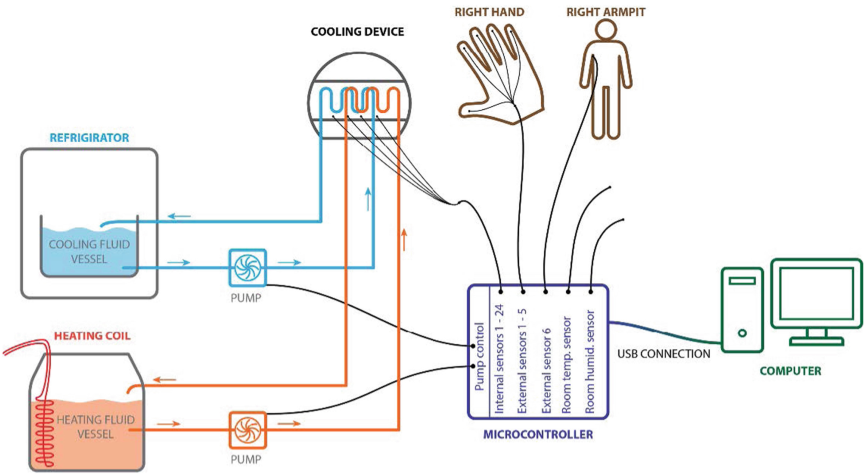

Fig. 2. Schematic representation of the experiment setup.

2.3 Protocol

The tests were conducted in November 2017. The examination room was kept at the same temperature. The participants were asked to wear similar clothes during each test: a long pair of trousers, a T-shirt and a thin sweater. They were not allowed to eat right before or during the test and not allowed to remove their finger from the device. Each person retained the right to discontinue his or her participation in the study at any time. Before being tested, each person has to acclimatise for twenty minutes at a room temperature of 21 °C. Afterwards, the cooling strategy was tested.

2.4 Cooling Strategy

The first fifteen minutes of each test were used to normalise the finger temperature of each participant, this by controlling the Peltier elements at a temperature of 20 °C. The mean temperature of the finger during this first period was calculated for each person for each test and was seen as the reference temperature. For every second after this period, the difference between the current finger temperature and the reference temperature was calculated and used as variable *delta time* (Δt). This was done to neutralise the effect of the natural body temperature of every test subject. Subsequently, it was aimed to control the palmar side of the distal phalanges at 2 °C for 60 min (independent variable). The dependent variable is blood flow at the nail bed, quantified as the finger temperature on the dorsal side of the finger. The course of the variable Δt during the test indicated the effectiveness of the cooling.

3 Results

3.1 Effectiveness of Cooling

The results showed an average temperature reduction on the dorsal side of the distal phalanges of 4.81 °C (SD 1.91 °C) during the 60 minute-trial, which indicates that the cooling strategy allowed to reduce blood flow at the fingertip.

The degree of correlation between the average reduction of device temperature and the average reduction of finger temperature is demonstrated using a scatter plot with a regression line (see Fig. 3). The results indicate a positive correlation and thus the effectiveness of the active cooling.

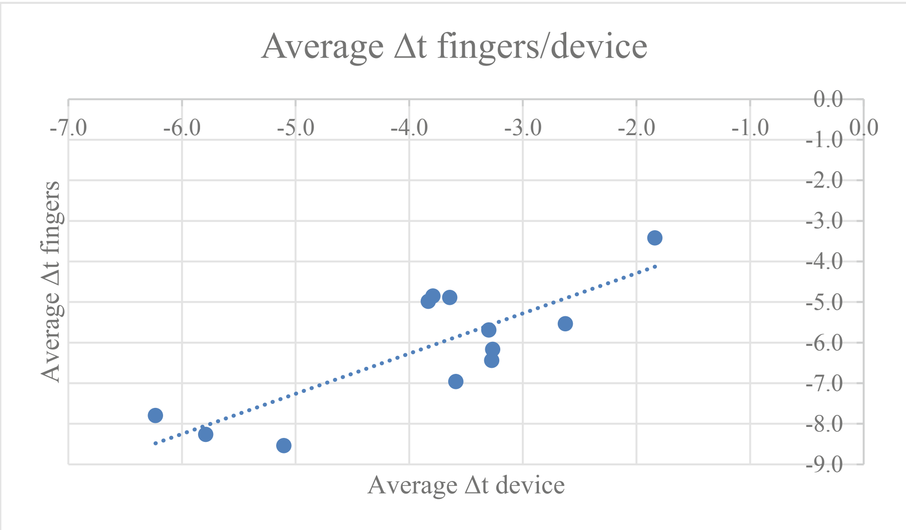

Fig. 3. Scatter plot of the average Δt fingers and the average Δt device of all twelve subjects.

3.2 Individual Differences

However, a vast variation between test persons was noticeable: a deviation in temperature reduction from 3.26 °C (SD 0.89 °C) to 7.79 °C (SD 1.55 °C) was observed between different test persons. The divergence between all test subjects is illustrated in Fig. 4.

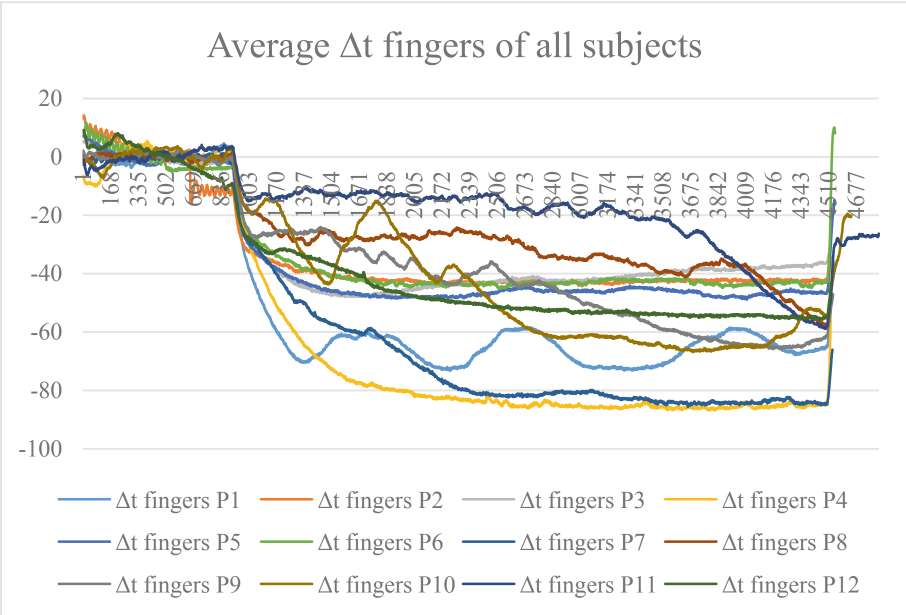

Fig. 4. Average Δt fingers of all twelve subjects

3.3 Occurrence of CIVD

The effect of CIVD was only notable at one test person. Figure 5 shows the fluctuating course of the temperature of all fingers of the subject, which might indicate the incidence of CIVD.

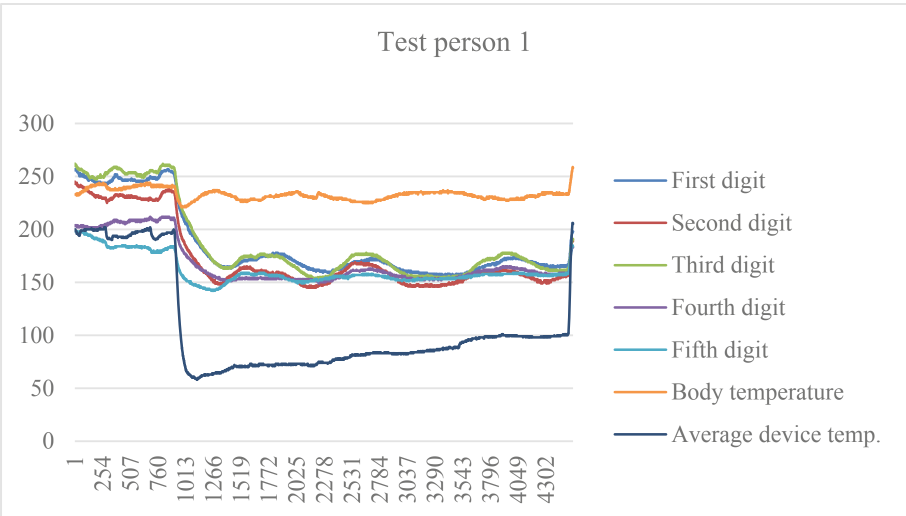

Fig. 5. Temperature graph of the fingers of a subject.

4 Conclusion

This study proposed an active local cooling device based on coolant that allowed investigating the effect of controlled cooling of palmar side of the fingertips on blood flow at the nail bed. The aim was to examine the effectiveness of the device and to gain insight in CIVD, which ultimately may conduce developing a cooling system to prevent nail toxicity during chemotherapy.

The results indicated that the cooling strategy allowed reducing blood flow at the nail bed, with an average temperature reduction of 4.81 °C (SD 1.91 °C) during a 60 minute-trial on the dorsal side of the distal phalanges. However, a vast variation between test persons was noticeable: a deviation in temperature reduction from 3.26 °C (SD 0.89 °C) to 7.79 °C (SD 1.55 °C) was observed between all test persons. Therefore, it may be considered to provide personalized treatments for every patient based on real-time measured finger temperature.

In conclusion, the five-finger prototype that induced active cooling at the distal phalanges with the use of a liquid cooling system was more challenging to control as compared to the prototypes that induced cooling with the use of Peltier elements. Furthermore, it had also been found that cooling the palmar side of the finger allowed controlling blood flow more steady as compared to cooling the lateral sides. It is therefore advised to use Peltier elements to induce local active cooling at the palmar side of the fingertips for the prevention of onycholysis at cancer patients.

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Multi-frameworks Development for the Medical Device Design Process as a Critical Factor for Innovation

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Abstract. The process of innovation in the design of medical devices is complex. The analysis of the user, the disease stage of the patient and the fact that all clinical histories are different generates a series of variables that are a challenge for any Medical Device designer. The traditional industrial design uses frameworks to control information and visualize future scenarios to understand the user experience; this allows the designer to anticipate behaviour and design the object according to the needs of the users. Industrial design framework and medical device design framework differ significantly since the design of medical devices requires the analysis of multi-frameworks for a single object. This generates a very complex brief for any designer. This theoretical work argues that prior knowledge of the multi-framework in the design process of medical devices might help the designer to visualize the spectrum of the problem and focuses its efforts on reducing frames.

Keywords: Medical device design · Engineering design · User-centered design · Design process · Design challenges · Usability · User hierarchy · Industrial design

1 Introduction

Who the user of medical devices is, or who they are, is a question that as simple as it seems, throws a massive amount of answers, but at this day these answers have not been clarified. Even so, there is previous research that states at least seven users around a medical device design [1]. Other studies speak of a large number of users, such that they are set into seven groups [2]. Therefore, a medical device must be designed considering the different needs of these users.

In traditional industrial design, the number of users is less than those considered in the design of medical devices. Typically, two types of users are considered, the direct user and the indirect user. The direct user is the one to whom the product is intended,

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whereas the indirect user is who carries out secondary activities to the primary objective, for that reason products, in general, must be designed keeping in mind the objectives of all the users.

According to the practical application manual for analyzing products, which specifies the "Scenarios to think about the product" as a fundamental tool [3], in traditional industrial design the use of scenarios is implemented during the design process to visualize possible user behaviour with the product [2].

The scenarios model to think about the product focuses on the "product" dimension. This model specifies six types of scenarios, granting a single scenario for the user's visualization and its interaction with the context, although it does not define or specify whether there are more scenarios in this same area [4].

Human Factors Engineering (HFE) involves the application of knowledge about human capabilities to the design of products to facilitate their operation by users [5]. The complexity of medical device design, based on Human Factors Engineering (HFE) in innovation, explains that it is necessary to adopt innovations if medical devices are not easy to use [6]. If we consider the case of the design of medical devices, different authors and studies talk about the importance of user-centered design. The quality control standards, such as the ones of the Federal Drug Administration (FDA), require the user's needs to be considered during the medical device design process [7].

1.1 Design Process

The industrial design process and Medical device design process seem to be equal, but they are not, because the variables are different and complex. That is why this article is based on the complexity of the system in which the medical device is used.

The objective of this paper proposal is to show the complexity of medical device design, during the design process. A focus will be made in providing a visualization of the number of possible scenarios to consider the usability of the object, before specifying the field of action of the product. This work will show how many scenarios could exist and how many frameworks the designers must consider in the medical device design process considering the following variables: (1) users, (2) stages of disease, and (3) levels of hierarchy.

The relevance of this work for designers of medical devices relies on the analysis of multi-frameworks, which seeks to facilitate the structured attempts of the designers to "anticipate experiences of use in medical devices" considering the complexity of the variables involved.

2 Scenarios and Framework/Multi-framework

What is a scenario? The scenarios are descriptions of alternative futures that can happen, thus allowing the generation of possible policies and actions to prepare us for that future [5]. How many scenarios could a medical device design process bring? How can we control all the user necessities in each scenario? How many frameworks must the designer visualize in order to understand the behaviour of the users during the medical device design process? These are all are questions that the designers must answer during the design process (Fig. 1).

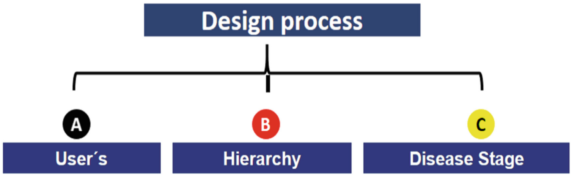

Fig. 1. Variable scheme

In this work, seven users (see Fig. 2) were selected alongside eight stages of disease (see Fig. 4) and seven levels of hierarchy (see Fig. 3).

The users were included for the analysis by their level of approach to the medical device, according to previous studies [1]. These are patient, family, doctor, nurse, specialist, maintenance, and technician as shown (Fig. 2).

Fig. 2. User table.

The hierarchy of user needs was analysed in seven priority levels ranging from high to low (Fig. 3).

Fig. 3. Priority scale, levels of hierarchy.

Eight disease stages were included for the analysis based on the model of Leavell and Clark [8]. The latter are broken down in Fig. 4 to exemplify further the stage of the disease in which the patient is.

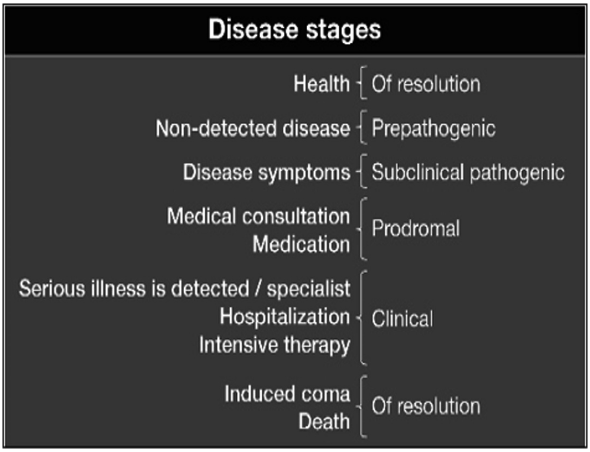

Fig. 4. Disease stages table.

The possible scenarios were analysed considering seven users with seven priority levels and eight disease stages using the Scenario-Based Design method. This design method futurizes different configurations of the possible use of a product in the idealized context. The configurations include, for example, the use of interactions and experiments based on "What if" questions? to visualize the possibilities of the product, weaknesses, risks, strengths and opportunities before the project is taken to manufacturing. These seek to reduce risks of use and generate greater use-related satisfaction [9].

The scenarios are based on observational studies and future projections with the analysis of data concluded using an investigation. A study conducted by Vincent [10] found that designers can use the scenarios to articulate differences resulting in a better understanding of how the devices will be used in the context of use. The results showed that the dialogue that was created when validating the scenarios was useful since it allowed mediation through professional perspectives and provided insight into the realities of use. The scenarios supported the acquisition of knowledge in the exchange of perspectives. It was concluded that the scenario generation method could be applied in medical and non-medical contexts [10].

The scenarios are an integral part of the international standard for medical device usability engineering (IEC 62366: 2007) and apply to health software development (IEC standard 82304-1). Standard 62366 establishes a process to mitigate risk during regular use (i.e. use according to instructions or accepted medical practice) [10].

In traditional industrial design, the term scenario is used to refer future visualizations of product usability in specific environment. However, in the software usability interfaces design, the framework term is frequently used at the same specific use. Framework is a standardized set of concepts, practices and criteria to approach a particular type of problem in specific environment that serves as a reference, to face and solve new problems of a similar nature [11].

In both cases, traditional industrial design and software interface design, the use of scenarios and frameworks respectively have the same objective. In this work, we use both terms to reduce the confusion between the designers of medical technology devices and the designers of medical devices (product or object wise) since this work can help both designers in their areas of expertise (Fig. 5).

Fig. 5. Main concepts

The scenarios seek to anticipate the user's experience before the product is brought to reality, which is why it is imperative to consider the possible user responses during the user experience. Feedback to be considered includes features such as subjective feelings, behaviour's, emotional reactions and physiological reactions since they are elements that the designer must previously visualize during the design process [12].

The user experience in an adequate and well-designed scenario will allow us to adapt the characteristics of the product to the needs of the user and this will help us reduce the risks of use and/or medical errors. In a study, Ward and Clarkson [12] presented an analysis of medical errors in US and UK hospitals, which were caused by errors in the use of medical devices. They concluded that the scale of errors in the use of the medical device is not precise since users are often blamed for misuse, before blaming the object [12]. Failure to adequately consider users in the design of medical devices dramatically increases the errors of use.

The FDA and the trials that they have carried out recognized that the medical errors correspond to the poor design of medical devices. They explain that to reduce these errors, designers need to give importance to Human Factors Engineering and understand the real needs of the users for the use of medical devices, as well as, during the design process [13].

In a study conducted by Mitchell [11], a random sample of 498 clinical incidents was reviewed, and the most severe error factor was identified as the action of the personnel as the leading cause of incidents. The errors based on the skills were strongly related to erroneous diagnoses, and the authors conclude on the importance of preventive actions [11].

Due to the high rate of errors in medical devices related to usability, the regulatory agencies have petitioned as a requirement to meet the needs of users during the design process to improve usability and reduce the risk of errors in the new medical devices. A clear example of the latter is the ISO standards that state the importance of considering the needs of users during the design process (Fig. 6). For instance, the standard: "IEC 62366-1: 2015 Medical devices – Application of usability engineering to medical devices" specifies a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to the safety of a medical device. This usability engineering process evaluates and mitigates risks caused by usability problems associated with incorrect use and use errors. This standard is as important as the "ISO 13485: 2016 - Medical devices" because the requirements can be referred to as design quality control. Good design and development processes include a systematic assessment of the outputs as an integral part of design and development. The focus is to be sure that design and development inputs, based on user needs, are met by the design and development outputs [14]. Accordingly, designers might benefit by enhanced understanding of the degree of conformance of outputs to the user and patient needs, and by improved communication and coordination among participants in the design process [14].

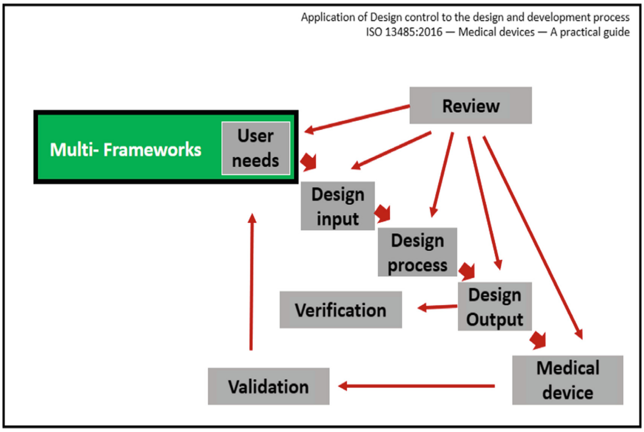

Fig. 6. ISO model in which design and development proceed in a logical sequence of phases or stages. Requirements are developed, and a medical device is created to meet those requirements. The medical device is then verified and validated, transferred to production [14].

3 Synthesis

In this paper we analysed the capacity of scenarios that can be found by combining the following variables:

1. Users: Patient, Nurse, Doctor, Specialist, Maintenance, Technician, Family (Fig. 2).
2. Disease Stages: Health, Non-detected disease, disease symptoms, Medical consultation, Medication, Serious illness is detected/specialist, Hospitalization, Intensive therapy, induced coma, Death (Fig. 4).
3. Seven Levels of Hierarchy, with 1 being the highest priority and 7 the lowest priority (Fig. 3).

A mixture of factors was calculated, looking for the possible combinations between each one of the variables concerning the seven users. From this, the outcomes were: (1) the result of combining the seven users, and the seven levels of hierarchy is equal to 1716 possibilities of scenarios (Fig. 7), and (2) the result of combining the seven users and the eight disease stages, is equal to 3432 possibilities of scenarios (Fig. 7). These large quantities of scenarios allow the concept of multi-framework. Designers must know the existence of medical device design multi-frameworks in order to understand the complexity of the user needs in each scenario.

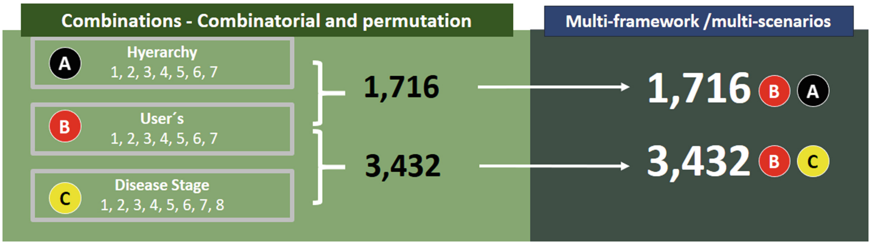

Fig. 7. Calculation of multiframework's by combinatorial.

4 Discussion and Conclusion

The difference in the process of traditional industrial design in comparison with the process of design of medical devices differs from scenarios or frameworks. The traditional design considers the development of scenarios for specific moments of usability with a single direct user and several indirect [4] but at times of stable use.

In the medical design process, the scenarios are not stable, since they depend on the stage of health in which the patient is located, and the number of variables is much higher in three aspects: a number of users [2] hierarchy of use and disease stages [8]. This indicates that the number of frameworks generates many possibilities, and it is impossible to design a single product that meets the usability of all frameworks.

We know that the disease and the users will dictate whether this number of frameworks increases or decreases. But even so, the medical device design has enough variables that hinder the design of a generalized product if we seek the satisfaction of the user and prevention of the risk of use as it explains the requirement of the ISO standard [1]. This is why the design of medical devices is intricate and challenging for any designer.

The broader the design spectrum (Multi-frameworks), the higher the risk of using a single product. It is necessary to visualize the usability spectrum of a medical device before designing to reduce risks and increase product satisfaction.

Designers should consider focusing the action of using a medical device for health states, users, hierarchy and time. They should foresee that frameworks should be reduced to visualize the future scenarios of the product, being these viable to design an efficient product that meets user's needs. These significant quantities of scenarios allow the concept of multi-framework. Designers must know the existence of medical device design multi-frameworks in order to understand the complexity of the user needs in each scenario.

5 Future Work

This work is part of a doctoral thesis that aims to generate a tool that helps designers of medical devices during the design process to improve the usability of the devices. The focus of the study is the movement in the hierarchy of users during the process of the patient's illness. The objective of this thesis is to find a pattern of movement in the group of users that surrounds a specific clinical case to generate a tool that allows knowing the needs of the users previously in order to increase the efficiency of the design process and improve user satisfaction.

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Research on Sleeping Posture Recognition Method Based on Pressure Sensor

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Abstract. Using the structure of the butterfly pillow is the most simplest identification method, combined with the pressure sensor. The resistance value of the pressure sensor is obtained by analog-to-digital converter (A/D). The change of resistance of pressure sensors under different sleeping postures is analyzed, then pattern matching system is used to realize pattern matching and sleep position recognition. The recognition rate of sleeping position in the NISS is 95.6%, and the recognition rate in ISS mode is 92.5%. The recognition method proposed in this paper does not interfere with the user's normal sleep experience. Combining the existing technology and methods to optimize the recognition of sleeping posture, the recognition rate of sleeping posture is still very high,which can help people with poor sleep to greatly optimize the sleep quality.

Keywords: Pressure sensor · Butterfly pillow · Sleeping position · Position recognition · Pattern matching

1 Introduction

One third of a person's life is spent in sleep, and poor sleep quality can cause serious damage to people's mental and physical health [1]. Sleeping posture is one of the most important factors in evaluating sleep quality (such as sleep stage and sleep difficulty) [2]. During deep sleep period (Non-Rapid Eye Movement Sleep), people will keep sleeping posture continuously and the change frequency of sleeping posture will decrease. In addition, sleeping posture is also closely related to some diseases. For example, sleep apnea symptoms can be effectively improved by changing sleeping posture, lateral posture can reduce sleep disorders in patients with mild and moderate sleep apnea [3]. There are a lot of consumer-level products to monitor sleep quality and record sleep data, such as wearable bracelets, sleep apps and other hardware and software products.

2 Overview of the Research on Sleeping Posture Recognition

Sleep posture is static for a period of time, and there is no obvious change. While the user's sleep behavior is a dynamic process [4], the duration is very short, and there is no roles to follow. Therefore, the related technologies of sleep recognition are to determine the current sleep status by identifying user's sleeping posture.

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2.1 Sleeping Posture Type

People's sleeping posture varies with their living habits and diseases [5]. Generally speaking, it can be divided into three categories: lateral sleeping (LS), supine sleeping (SS) and prone sleeping (PS). Lateral sleeping (LS) includes left lateral sleeping and right lateral sleeping. According to the actual questionnaire, 62.3% of users prefer to LS (left and right), 30.5% of SS and 7.2% of PS. PS is considered to be the worst and the least sleeping posture in the study. So this paper mainly focuses on LS and SS.

2.2 Research Status of Sleeping Posture Recognition

Sleeping posture recognition technologies mostly realize the recognition of sleeping posture based on the different pressure produced by pillow or mattress under different sleeping postures. Huang [6] and other used six pressure sensors (FSR sensor) to realize the recognition of sleeping posture. Six sensors were evenly distributed over the pillow to collect the pressure values under each sleeping posture. User models were constructed through experiments, and then pattern matching was used to identify the sleeping posture. In addition to the recognition technology based on pressure sensor, there are also recognition based on computer vision, such as Ye [7], Dong [8], which got the real-time sleeping posture images of users through cameras to recognize sleeping posture. Xu and Zhang [9] realized the recognition of sleeping posture by collecting the respiratory impedance signals of the left and right chest of users.

Based on the existing technology, the pressure value of each sleeping posture can be obtained by pressure sensor, which can realize the recognition of sleeping posture that has '0' effect on normal sleep—Non-invasive Sleeping Posture Recognition. However, the number of pressure sensors is too large for the above-mentioned pressure sensor-based recognition. In this paper, three flexible film pressure sensors are used as data acquisition module to recognize the current sleeping posture of users by detecting the pressure values of key parts of the head. The advantage of this scheme is that fewer hardware devices are used, the butterfly pillow structure is fully utilized, and the user is not affected. It has high practical value.

We would like to draw your attention to the fact that it is not possible to modify a paper in any way, once it has been published. This applies to both the printed book and the online version of the publication. Every detail, including the order of the names of the authors, should be checked before the paper is sent to the Volume Editors.

3 Construction of the Sleeping Position Recognition System

The system consists of two parts: hardware and "software". The hardware level includes sensors for detecting pressure, Arduino development board, analog-to-digital converter (ADC), SD memory card and butterfly pillow. The "software" level Including data analysis, establishing reference patterns and pattern matching and identification.

3.1 Hardware Level Construction

The pillow of the system carrying the pressure sensor is a butterfly pillow. The structure of the butterfly pillow is characterized by low middle and high sides. Hou and Shen [10] studied the design of human-computer pillows that meet the comfort of sleepIing. The suitable height for SS is 6–7 cm and the suitable height for LS is 7–8 cm, so the butterfly pillow surface is divided into three areas, the middle area (MA), the right sleeping area (RSA) and the left sleeping area (LSA), three areas correspond to supine sleeping (SS), right lateral sleeping (TLS), and left lateral sleeping (LLS), which is shown in Fig. 1. Therefore, when the pressure sensor is set in the corresponding sleeping position area, the sleeping position recognition can be performed.

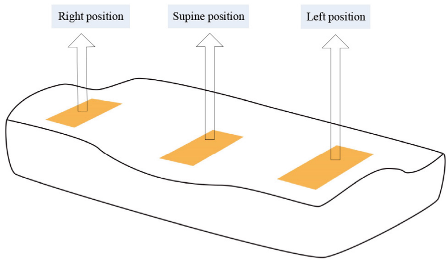

Fig. 1. Sleeping area division on Butterfly pillow

Chen Ying and others study the impact of pillow type on sleep comfort, they select three points of the head as the main pressure test points, which is shown in Fig. 2 [11]. Combined with the structure of the butterfly pillow, the system only collects the opisthion and the lateral point.

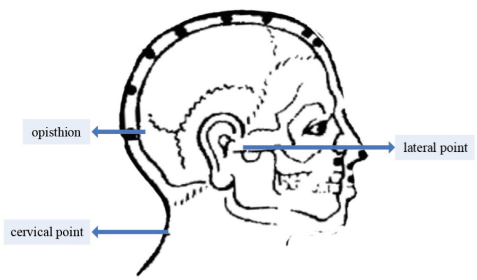

Fig. 2. Test point visual map

The pressure sensor uses a flexible membrane pressure sensor, and a pressure sensor is arranged in each of the three regions of the butterfly pillow, as shown in Fig. 3. The pressure sensor is labeled S1, S2, S3 from left to right, the opisthion of users is detected by S2 in the SS, and the lateral point of users is detected by S1, S3 in the LS.

The pressure sensor is a resistive pressure sensitive sensor, a SD memory card is used to store the corresponding value of the sensor to provide raw data for the "software" level construction.

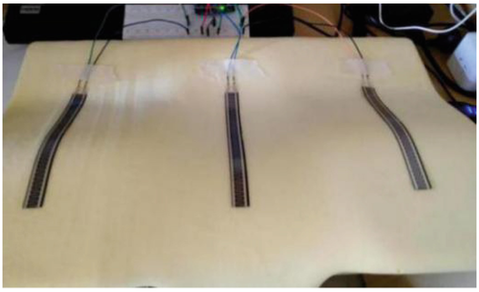

Fig. 3. Pressure sensor distribution

3.2 'Software' Level Construction

(1) Data acquisition and analysis

The analog value of pressure obtained by the Arduino is converted to resistance value. The circuit is shown in Fig. 4. The pressure sensor decreases with the increase of pressure. The formula is expressed as the nth resistance of the pressure sensor in the mth posture:

$$R_{\mathrm{i}}^{m}(n) = R_0 \times \left(\frac{1023}{p_i^m(n)} - 1\right) \tag{1}$$

$R_0 = 1\,\mathrm{K}\Omega$ is a the input resistor. $p_i^m(n)$ is the pressure simulation value of the i*th* pressure sensor in the m*th* posture.

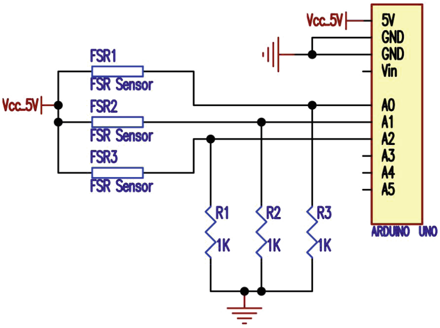

Fig. 4. Circuit diagram

In SS, the corresponding resistance distribution of pressure sensor is shown in Fig. 5. The resistance value of S1 and S3 varies from 10^6 to $2*10^5$ and that of S2 varies from 10^4 to $3*10^4$, but the value of S1 and S3 are much larger than S2. In LS, the resistance value of S1 and S3 was very high under no pressure, and the resistance value of S2 decreases under pressure, the resistance value of S2 is much smaller than S1 and S3. It shows that the interaction of S1, S2 and S3 can be neglected in the process of pressure detection, and the value can be simplified as follows:

$$R_{\mathrm{i}}^{m}(n) = \begin{cases} R_0 \times \left(\frac{1023}{p_i^m(n)} - 1\right), & p_i^m(n) \geq P_0 \\ 1 \times 10^6, & p_i^m(n) \leq P_0 \end{cases} \tag{2}$$

Threshold $P_0 = 10$ can effectively avoid the interaction between pressure sensors. The resistance value of S1, S2 and S3 in SP is simplified, which is shown in Fig. 6. It can be concluded that no pressure was detected for S1 and S3 of the RSA and the LSA during SS, but S2 of the MA has obvious pressure.

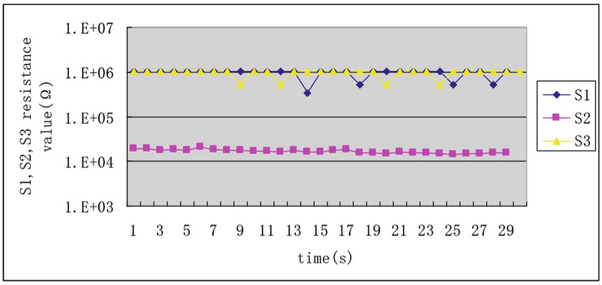

Fig. 5. Resistance of S1, S2 and S3 when lying on the supine posture

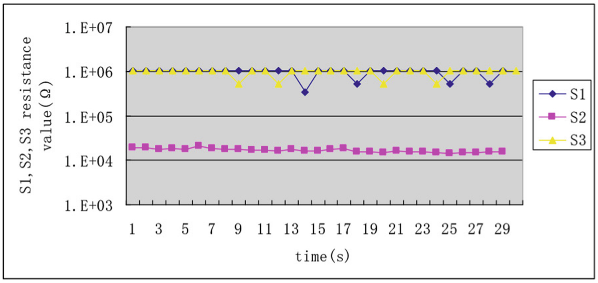

Fig. 6. S1, S2, S3 resistance after simplification

Users' sleeping posture conversion habits can be divided into two categories: in-situ switching (ISS) and Non-in-situ switching (NISS). The characteristics of in-situ conversion lie in that people are accustomed to sleeping in the middle area of the pillow, the contact area between head and pillow has not changed during the conversion of sleeping position, as shown in Fig. 7. On the contrary, in non-in-situ conversion of sleeping position, the contact area between head and pillow has changed, as shown in Fig. 8. Through online questionnaires, 30.8% of people prefer to ISS and 69.2% prefer to NISS. Next, the resistance changes of pressure sensors under these two modes are analyzed.

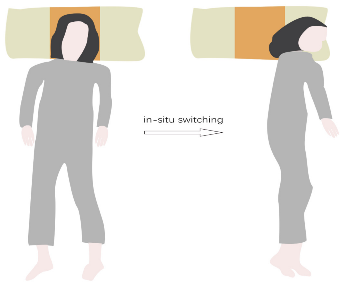

Fig. 7. In-situ conversion

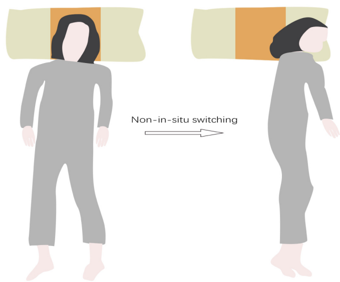

Fig. 8. Non-in situ conversion

Formula (2) can be used directly in NISS. The sensor in a certain area can detect pressure, and the corresponding resistance value of the sensor can be changed. Then the sleeping posture in the corresponding area can be identified directly. For example, the detection of pressure in S1 of the MA, the resistance value of S1 can be changed, indicating that the current sleeping posture of the user is SS.

According to formula (2), there is no change in the resistance values of S1 and S3, only S2 of the MA can detect the pressure, regardless of the sleeping position. So we can only consider the resistance change of S2, we get a resistance change chart about S2, which is shown in Fig. 9, the value of S2 in SS is obviously larger than that of S2 in LS, which can distinguish whether users' sleeping posture is SS or LS.

Pattern matching for posture recognition

Through the above analysis of the collected data, We use pattern matching system [6] to recognize sleeping posture, the system includes two programs of training and testing, training the sample gets the reference mode, then, the reference mode and the test mode use the mean square error method for pattern matching recognition.

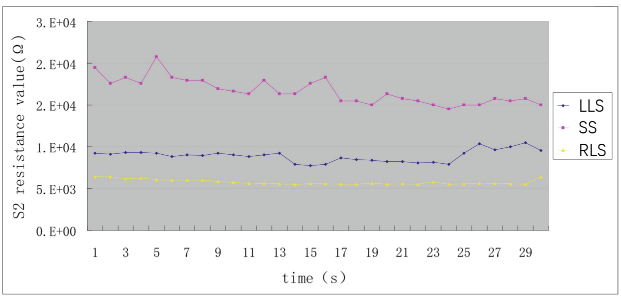

Fig. 9. Resistance of three sleeping positions S2

Signal sample: The signal sample of $\mathrm{p_i^m(n)}$ is obtained by the circuit, this is the simulated pressure value of the i*th* sensor in the m*th* position.

Feature extraction: The pressure simulation value is obtained through Arduino, and then the resistance value of the corresponding pressure sensor through the analog-to-digital converter. $\mathrm{R}_i^m(n)$ is obtained for of the m*th* posture as Formula (2).

Reference mode: The sample data of the m*th* sleeping position is obtained through experiments, and the sample mean value of the m*th* sleeping position is calculated as the reference pattern of the m*th* posture by

$$ar^m = \{ \quad ar_1^m, \quad ar_2^m, \quad ar_3^m \quad \}, \quad i = 1, 2, 3 \tag{3}$$

The sample mean of the ith pressure sensor Si can be expressed by

$$ar^m = \{ \quad ar_1^m, \quad ar_2^m, \quad ar_3^m \quad \}, \quad i = 1, 2, 3 \tag{4}$$

After the reference mode is established, the test program can begin. The signal samples and feature extractions in the test procedure are similar to the reference program acquisition, and we obtain the nth testing data $\mathrm{x(n)} = \{x_1(n), x_2(n), x_3(n)\}$, then, the testing data and the reference patterns are pattern matching by the mean square error for the mth posture as

$$MSE_m(n) = \frac{1}{3}\sum_{i=1}^{3}\left(x_i(n) - ar_i^m\right)^2 \tag{5}$$

In the test procedure, the basis of posture recognition is the minimum mean square error as

$$MMSE_m(n) = \arg\min_m MSE_m(n) \tag{6}$$

4 Experimental Process and Results Analysis

Pattern matching needs to be obtained through experiment, and the resistance value of each sample in the sleeping position is obtained, and the reference mode is constructed. The larger the sample size is, the more representative the reference pattern is in each sleeping position, and the correctness of recognition is higher. Through the sample reference mode and test mode obtained by the experiment, pattern matching and recognition can be performed to realize the determination and recognition of the sleeping position.

4.1 Experimental Environment and Parameter Construction

In this paper, user's current sleeping posture is determined by experiment and posture pattern recognition method. In the experiment, the sample data is collected when the

Table 1. Experimental related parameters.

Experimental parameters		Value	
Types of postures		SS, LLS, RLS	
Sampling rate		1 samples/second	
Sampling time per sample		30 s	
Unit of signals		Kilo Ohms	
Environment		Beyond a bed	
Measurements		3 times of each posture	
Number of samples each measurement		20 samples	
Total number of training samples	Sample number of NISS	200 samples each postures	120
	Sample number of ISS		80
Total number of test samples	Sample number of NISS	50 samples each postures	30
	Sample number of ISS		20

participant adjusts the sleeping posture to the best. Each sleeping posture was measured 3 times, the sampling rate is once per second, and the sampling duration is 30 s. The relevant parameters of the experiment are shown in Table 1.

4.2 Experimental Results and Analysis

According to the proportion of two habitual sleeping posture conversion modes, a reference mode of NISS is constructed. We select t120 people who like NISS, the reference mode can be obtained by formula (3), (4), which is shown Table 2. In the construction of the reference mode of ISS, we select 80 people who like ISS, which is shown in Table 3.

Table 2. Reference mode for non-in situ conversion sleeping position.

	Mean resistance of pressure sensor, ar_i^m (KΩ)		
Areas	S1	S2	S3
MA	7.6	1000	1000
RSA	1000	20.3	1000
LSA	1000	1000	7.8

Table 3. Reference mode for in-situ conversion sleeping position.

	Mean resistance of pressure sensor, ar_i^m (KΩ)		
Areas	S1	S2	S3
MA	1000	7.1	1000
RSA	1000	19.5	1000
LSA	1000	7.2	1000

The test sample data is obtained by formula (3), (4). The mean square deviation of the test model and the parameter model is calculated, and the minimum mean square deviation is obtained by referring to formula (5), (6). The recognition rate of each sleeping position under NISS (Table 4) and ISS (Table 5) can be calculated. Sleep recognition rate was 95.6% under Non-in-situ switching and 92.5% under ISS, and it was also possible to distinguish left side sleeping from right side sleeping under NISS.

Table 4. Non-in situ conversion sleep position for each sleeping position test recognition result.

		SS	LS		Accuracy rate	
			RLS	LLS		
SS		0	29	1	96.7%	
LS	RLS	28	2	0	93.3%	95.0%
	LLS	0	1	29	96.7%	
Recognition rate		95.9%				

Table 5. In-situ conversion sleep position for each sleeping position test recognition result

	SS	LS	Accuracy rate
SS	18	2	90.0%
LS	1	19	95.0%
Recognition rate	92.5%		

5 Conclusion

In this paper, only three pressure sensors are used to recognize the user's current sleeping posture, which greatly reduces the use of sensors. It benefits from the innovative use of the butterfly pillow's own structure and the study of the user's sleeping posture habits. A large number of experiments have been carried out to ensure the reliability of the proposed sleep posture recognition model. The method can be used in the fields of height adjustable sleeping pillow and other related products, and can greatly improve the quality of sleep.

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A Guide to Drive Medical Devices Development Through Human Factors Inclusion: Building a Value Proposition for Local Projects

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Abstract. A fundamental factor in flourishing societies is being able to provide healthcare access for every person [1]. However, the material resources such as medical equipment and infrastructure available in the public sector of developing countries impose limits to the healthcare services, directly impacting the quality of medical care provided to the population [2]. Therefore, it is crucial to provide tools that promote the development of medical equipment in a local way focused on responding to specific contextual needs. Following the hypothesis that the consideration of user requirements accompanied by socio-cultural context factors can positively impact the effectiveness of medical devices in a specific context, a methodological model based on design thinking tools is proposed to drive human factors inclusion from the conceptual stages of medical devices as the central axis of an innovation process.

Keywords: Medical equipment · Human factors · Innovation process

1 Introduction

On the development of a successful health care system, medical devices are considering as crucial factors for its importance in prevention, diagnosis, treatment, and rehabilitation. However, despite scientific and technological advances, low and middle-income countries are strongly excluded from access to appropriate and affordable health care technologies [3].

Within the quality of health care services provided in developing countries, two factors are remarkable: quick attention and waiting time. Both are related to material resources disposal to give health care attention. For this reason, it is essential to consider the availability of medical equipment because when it is not in diagnostic or treatment conditions, the services to the population are compromising, especially the most vulnerable population who does not have access to cover expenditures in the private sector.

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Some of the factors why medical equipment may be not available are: due to lack of supplies, spare parts or maintenance, this is because nowadays, most of the medical devices used on limited resources countries are imported from first world countries, and as a consequence, are not designed to satisfy local needs. For this reason, despite demonstrating its effectiveness in high-tech hospitals, it fails in these environments. According to WHO, 70% of medical equipment from developed countries does not function appropriately in countries with another economic situation.

Some of the biggest challenges that developing countries face locally producing medical equipment are human factors inclusion and technology cycle understanding.

In the specific case of Mexico, in the last decade, the sector of medical devices has been defined as a growth industry, positioning this country as a principal provider of medical products to the USA [4] and the second biggest market in Latin America. However, this growing industry produces low tech products and consumables. The small industry and the academia intend the innovative and high-tech medical equipment production; in consequence, most of the time, functional prototypes do not become final products and do not reach the market. It is necessary to add value to the production chain in the field of research and innovation to overcome the current limitation of assembly industry [5], contributing to shortening the technological gap that this country has on its public health care system.

Innovation in developing countries has a variety of benefits, not only for the people involved in the process but also for communities. One of the benefits of local innovation is that the products have greater acceptance of consumers and users, so unlike imported products, the tropicalization process is not necessary.

Following the hypothesis that the consideration of user requirements accompanied by socio-cultural context factors can positively impact the effectiveness of medical devices in a specific context, a methodological model based on design thinking tools is proposed to drive human factors inclusion from the conceptual stages of medical devices as the central axis of an innovation process. At the same time, these considerations will constitute their value proposition, positioning them over imported devices.

The model seeks to generate interdisciplinary and collaborative processes in research centers by providing methodological tools that ensure the consideration of human factors at the first six stages of medical devices development, according to the Technology Readiness Levels TRLs. This model not only affords a more precise picture to team members about the stage in which their developments are located but also helps them to exploit competitive advantages over imported devices. Finally, the model informs about the steps that must be followed to make devices and equipment viable for industrial production.

2 Human Factors on Health Care

Hand in hand of user-centered design trend, in the design of medical equipment arise a tendency where functionality is decentralized to give rise to the consideration of the complexity involved in the use of a medical device, which is focused on the interactions that the use of the product has in several subsystems including social perspective.

At the same time, the patient-centered approach stands out; its principle is that a patient is a person with unique perceptions of reality and concerns, which are the basis he uses to build relationships with all the elements involved on medical procedures [6], this includes medical devices used for detection and treatment.

The recognition of human factors in health care has been crucial for a better understanding of the patients' point of view, making this type of services more empathic. This approach allows to reformulate the interactions in medical practices; it is necessary to include all the factors involved in medical care, such as medical equipment and procedures, according to this approach. For this reason, the inclusion of human factors in the process of developing medical devices from the first steps is proposed to improve health care systems.

Human factors are a principle where very different disciplines, such as psychology and engineering, converge in the search for consideration of physical, perceptive and cognitive abilities of people in the design and performance of various devices [7].

In contrast to poorly designed devices, the actual integration of human factors into medical devices design helps to reduce errors, avoiding the exposure of the patients and staff to risks, while performing a procedure/task. Hazards associated with use increase when design problems cause human errors, risking the integrity of those involved. It is at this point where human factors engineering plays a valuable role in the identification, evaluation, and attention of those hazards. For this, it is necessary to analyze all aspects of the user, the intended use, the environment of use and the user interface of a device. In Table 1, all the considerations proposed to be addressed for each human factors aspect in each stage of the developing process of new medical devices are shown.

Table 1. Human factors to be considered at first six stages of new medical devices developing process.

Aspect to analyze	Considerations
User	Primary, secondary or third user Who will use it? (doctor, nurse, adult patient, pediatric patient, senior patient, someone external to the medical field) What are his physical characteristics? (physical strength, range of movements, anthropometrics) What are his psychological and cultural characteristics? (perception, emotional states, concerns, attitudes) What training will he receive to use it? and what is his previous knowledge with similar devices?
Intended use	What will the device be used for? (self-administration of medication, diagnosis, treatment, etc.) What is the specific task for which it is designed? (for example: monitoring the oxygen saturation level of a patient) How frequently will the device be used?

(*continued*)

Table 1. (*continued*)

Aspect to analyze	Considerations
Use environment	Where will the device be used? (In a hospital, laboratories, doctors' offices, emergency transport vehicles, patient homes or public space) What are the characteristics of this place? (lighting, noise, privacy etc.) Are other activities carried out in the same environment at the same time? (other medical devices using simultaneously or other activities where the user participates while operating the device)
User interface	Size, shape and weight of the device Elements that are displayed on the device (such as function indicators) Feedback elements (display, alarms, vibrations) How is the information placed and what is the logical sequence to perform the procedure/task? (characteristics of switches, touch screens, icons, menus, indicator lights, and alarms, but also operating instructions, and training materials)

For the correct implementation of the methodological model proposed in this paper, it is suggested that the teams (scientists, engineers and all the medical technology developers) consider all the aspects required by the guide: "Application of human factors and usability engineering to optimize the design of medical devices" proposed in 2011 by the FDA [7]. This document focuses on the use of methods to identify and mitigate the hazards associated with the use of the medical devices, including the new requirements for human factors validation tests.

3 A Methodological Model to Involve Human Factors

The development of new medical devices involves the application of some technology, for this reason measuring technological maturity is fundamental to recognize in which stage they are and assess their viability. For this measurement, Technology Readiness Levels (TRLs) are using [8], in Table 2 the characteristics and general requirements of each level are shown.

Although in most of the cases, risks mitigation carries out on the final prototype, changes and adjustments in this stage of development in minimal resources projects can represent a barrier to continue the development process. For this reason, the methodological model proposed shows some tools and considerations to allow the team members to analyze all the aspects involved in the use. In this way, their capability to identify potential risks prospectively is augmented.

At the same time, the FDA has established a Human Factors Engineering Report and a Usability Engineering Report as some of the requirements to register a new medical device [9]. For that purpose, the methodological model proposes some human factors considerations to help teams to carry out the registration of their proposal,

It has been defined for each stage of development some critical points of human factors to take into account. So that, during the first six stages of the development

Table 2. Technology readiness levels description

Stage		General requirements
TRL1	Observed and reported basic principles	Analysis of technological feasibility as a medical device Analysis of the business opportunity
TRL2	Technological concept or technological application	Classification of the device Definition of differentiators Definition of critical points
TRL3	First evaluation of functionality	Start of laboratory and analytical tests Check the effectiveness of the invention
TRL4	Laboratory verification of components	Verification of functionality at a laboratory Efficiency in a controlled environment
TRL5	Research protocol tests in a similar environment of use	Tests of a beta prototype in similar conditions to the real context
TRL6	Technological tests into a relevant environment for the system or sub-system of the healthcare model proposed	Tests of pre-production prototype in a real environment of use
TRL7	Real environment tests	Tests of the final prototype within the healthcare system proposed in a real environment
TRL8	Certification process	Registration and approval of the device by all regulatory agencies
TRL9	Market launch	Monitoring and control of use and errors of the device

process, the most relevant aspects needed to HFE (Human Factors and Ergonomics) and UE (User Experience) reports elaboration are described in Table 3.

While for professionals in the design field, talking about human factors can be daily, it should be considered the variety of professionals who works developing medical devices, for this reason, it is not certain that all teams have a member with human factors knowledge. For this reason, it is not enough to mention what are the considerations to involve human factors; it is also essential to provide these teams with some tools that allow them to include this factors even if they are not experts in this field. With this in mind, based on the bibliographic review, some design thinking tools are proposed considering the match of its outcomes with the human factors considerations previously mentioned (Table 4).

This methodological proposal, far from being an exhaustive list of tools, is focused on making it easy to identify what tool can be applied to obtain the necessary considerations at each stage.

Besides, to guide the inclusion of human factors with the implementation of design tools, the value proposition is to build the base for the user perspective understanding. The first stage of the value proposition building process is focused on identifying those attributes that users perceive as valuable, which arise from focus group application and

Table 3. Human factors considerations in each TRL stage.

TRL 1: Observed and reported basic principles	
Primary and secondary user determination	What are the roles of both users? What is the population segment to which each user belongs? What is the level of training of the primary user? What are the socio-cultural factors related to disease or condition, and the medical procedure?
The beginning of Value Proposition Building	Identify advantages of the proposal on what already exists in market
TRL 2: Technological concept or technological application	
Acceptance test	Perception analysis of the proposal (device, technique, and procedure)
Building value proposition	Benchmarketing (comparing similar products or techniques with the same purpose)
Use the environment	Where will the device be used? A detailed description of this environment With what other devices does it interact in that place? What other activities are carried out simultaneously?
TRL 3: First evaluation of functionality	
Potential risks identification	What are the risks the user is exposed to? In what situations can the risks exist?
TRL 4: Laboratory verification of components	
Aesthetic requirements	Evaluation of size, shape, materials, and color according to the user needs or preferences Anthropometric analysis to determine dimensions, particularly on portable devices or rehabilitation equipment
User interface	Function indicators and information showed on the device
Use sequence	A sequence of the use of the device. Describing in detail each step Is it optimized?
TRL 5: Research protocol tests in a similar environment of use	
Experience design	Experience design looking for acceptance and comfort of users during the medical proceeding
TRL 6: Technological tests into an environment relevant to the system or sub-system of the healthcare model proposed	
Service design	Design of all steps of medical attention within the specific real environment
Perception evaluation test	Obtain the opinion of the users to identify points of improvement

other proposed tools for TRL1 and TRL2. The no-functional prototypes test subsequently identifies the differentiators proposed in the new device. These differentiators are related to the expectations and needs that users express during the application of the “5 why’s” [13]. Finally, the value proposition involves the procedure or technique of use, so the proposed tools for the TLR6 are fundamental in the generation of the approach where the user experience is considered in medical application.

Table 4. Tools to involve human factors considerations in each stage.

Stage	Tools	Brief description	Purpose
TRL1	Mock-up prototype	Make a very rapid and simple prototype, without functionalities, just to get an overall view of the proposal	Use the mock-up to test the perception of the device and the task proposed with a specific group involving target users
	Focus group	Gather a group of people to take part in the discussion of the advantages and disadvantages of the proposal [10–13]	
	Storyboard solution	Draw the environment of use, adding a sketch for each action of the users involved in the task. Imagine hypothetical situations and stories, to understand user experiences [10, 11, 13, 14]	Recognize in a subsystem how the device interacts with users and the environment. Involving previous knowledge of team members about some perception factors
TRL2	Prototype with function simulation	Make a not detailed prototype that simulates that actually works to test with some possible users	Recognize some details that need to be considered to proper functionality
	Co-discovery	Involves two participants (primary or secondary users, in this case, can be doctors, nurses or even patients) working together to explore devices with the same or similar purpose that the device proposed [15]	Analyze functional and aesthetic qualities in sense to define what is different and valuable of the device proposed
	Focus group	Involve a group of people of your specific target to discuss similar devices or even similar medical procedures or techniques [12, 16]	
	5 Why's	Start asking a question about your main interest, and then ask "why?" as an answer to the five consecutive interrogations [13]	Recognize underlying reasons of people to perceive in a certain way something
TRL3	Role-playing	Define with your team all the roles of the users involved (primary and secondary) and make a simulation where each team member chose one role [11, 13, 14]	Identify potential errors during the use of the device imagining multiples scenarios

(*continued*)

Table 4. (*continued*)

Stage	Tools	Brief description	Purpose
TRL4/ TRL5	Think aloud protocols accord with a functional prototype	Involve two field experts or users and ask to try for the first time the device, explain that they need to say aloud what are doing, why and their opinion [15]	Explore the first impression of the product, identify difficulties of use and details that user likes or dislikes
	Co-discovery between experts or final users	Involve two field experts or users who do not know about the project, to explore the product and process for the first time. Team members need to take notes about comments and expressions of volunteers [15]	
TRL6	Blueprints	Make a visual scheme to show in detail each aspect of the procedure/task were the device proposed is involved. Considering all the users and tasks, even behind-the-scenes processes [13, 17]	Design the task to make the real user tests looking for a good experience
	Customer journey maps	Make a visual scheme to illustrate how users interact with the device during the task and how users interact between them [11–14]	

4 Discussion

Since the methodological proposal is based on the bibliographic review, the results of the next stage of the investigation are essential. Proposed tools are in development, an efficient way of presentation is also required to be designed and of course to be evaluated. For this, it is necessary to focus the attention on the problematics and deficiencies of multidisciplinary research centers while developing medical devices.

Taking into account the wide variety of devices and equipment used in health care, the tools proposed would support the development of non-invasive devices, thus excluding the devices used for surgical procedures. In these devices, although it is essential to ensure usability in the interface design, the level of depth necessary to carry out its analysis requires an expert figure in this area.

The information presented in this paper establish a precedent, which addresses the need to provide tools that contribute to the process of integrating human factors during the development of medical devices, and that at the same time allows generating on this basis the value proposition. The methodological model proposed is focused on the development of the devices that have the most significant opportunity to reach the market, through the generation of these competitive advantages, over the imported devices.

Taking into consideration the difficulties encountered in developing environments for the generation of proprietary technologies, the proposed tools seek to focus the teams' efforts on the generation of contextualized proposals that respond to specific needs. So, when applying the tools, they not only make use of their technical expertise but also capture the empirical knowledge of their social environment.

The presented methodological proposal adds to the efforts to transform the health systems of underdeveloped countries, because when generating technology in a local way the technological dependence is reduced which directly impacts the quality of the public health services in these countries. Besides, continuing with the trend of patient-centered design, the inclusion of human factors from the early stages of development of the devices will humanize the techniques and procedures of health services, in consequence, the social acceptance will be higher, by the improvement of the experiences that these entail.

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Invasive Medical Device for Cardiovascular Surgery

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Abstract. The identification of the biological requirements of the most complicated mechanism as the human body, correlated with the possibilities of the current technique, has enabled the successful achievement of an advanced material destined to be used as invasive medical device in cardiovascular surgery. In order to accomplish this type of medical device there is an increasing need for synthetic yarns characterized through: adequate ration resistance/weight, elasticity, flexibility, biocompatibility, chemical inertia etc. To design the fabrics destined for the vascular prostheses, there have been taken into account the minimal requirements for the bio functional characteristics, imposed by clinical usage field, from which there resulted the following: the product geometry imposes the use of the tubular or branched structure; impermeability imposes main parameters of fabric designing (achievement of a structure for which there are used untwisted yarns, the densities of the two systems and the product mass, etc.

The level of biomedical and bio functional performances demonstrate that the advanced product developed is suitable to be used in surgical intervention for replacement portion of vascular system with different geometry, in case of thrombosis, occlusion, aneurysm.

Keywords: Biomaterials · Blood flow · Cardiovascular surgery

1 Introduction

Woven structures' design criteria for the cardiovascular implants with variable geometry have been based on physical, hemodynamical and biological phenomena specific to the blood flow through linear and branched blood vessels, based on laminar and turbulent flow, boundary layer and membrane theories with the particularities related to: fluid incompressibility, viscosity, impermeability of the vascular wall, adherence of the blood to the vascular wall, tangential shear stresses development inside the blood and at its contact with the vascular wall, linearity relation existing between normal and tangential stress and velocity gradients.

In order to accomplish this type of medical device there is an increasing need for synthetic yarns characterized through: adequate ration resistance/weight, elasticity, flexibility, biocompatibility, chemical inertia etc.

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2 Materials and Methods

Establishment of the technological equipment as well as of the specific processing parameters in order to obtain the woven structure of the cardiovascular implant with variable geometry have been performed based on the results of ongoing complex characterization program for the biomedical yarns based on polyester, consisting of:

- spectrophotometric characterization for determination the presence of the treatment substances such as: optical bleaching, stabilizators, oxidizing agents etc.;
- physical-mechanical characterization of the biomedical yarns based on polyester having the length density of 76 den/f24 × 1/350Z and 167 den/f32 × 1 trough:
- evaluation of the tensile strength behavior in conditional, wet and after thermal treatments at different temperatures status;
- evaluation and interpretation of the tensile strength behavior under loop and knot;
- evaluation of the strength and elongation at break as a result of technological phases, specific to the weaving preparation (after warping step).

Spectrophotometric analyses (Fig. 1) allowed highlighting the special characteristics of the yarn, represented by: high structural stability, lack of the components that could affect the structural mobility of the polymer backbone and the absence of bleaching agents based of titanium dioxide (maximum white degree of 80%).

After processing the yarns within the weaving preparation phase, on the warp machine, values obtained for forces tear and elongation at break determined in conditional, wet and after heat treatment states, have not been modified due the polyethylene terephthalate low chemical creep. Following intensive warping operations (stretching, bending and abrasion), undergone for the analyzed yarns, no critical tensions in the polymeric structure associated with the deformation of the polymeric chains and with the concentration of mechanical energy on the chain segments localized in the zones with structural defects (i.e. asymmetric molecular chain) that promote cleavage of chemical bonds had not been reached. In this manner, no structural changes and hence modifications in the physical-mechanical properties of the yarn were identified.

The design and accomplishment of the woven structure used for the replacement of a portion of the cardiovascular system affected by a cardiovascular disease, in accordance with the imposed medical application requirements assumed the following aspects: - utilization of the blood hemodynamic parameters (pressure, viscosity, velocity) in order to calculate the warp and weft density; - evaluation of the influence of the cardiovascular implant safety coefficients (dynamic load coefficient, for tridimensional structural convergence, asymmetrical load and losing resistance coefficients etc.) against woven structure; - usage of the obtained results as a consequence of the physical-chemical and structural determination for the yarns.

Accomplishment of the woven structure was made under the conditions of adopting specific measures for the entire technological process and selection of the optimal processing parameters, such as: tensile of max 0,1 CN/dtex (in warping phase); shoulder kinematic advance: 1,78; implementation of the braking, tensile and guidance devices without any surface defects or rust.

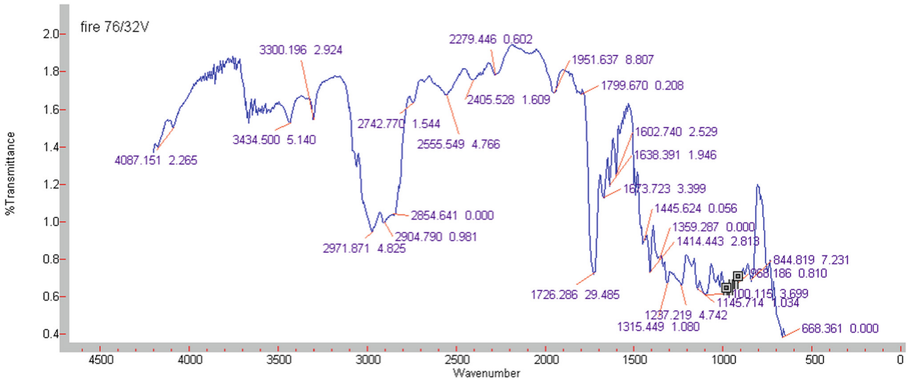

Fig. 1. IR absorption spectra for 76 den/f24 × 1/350Z yarn

The design and accomplishment of the finishing technology were based on the requirements imposed by the high- risk class of these category of invasive medical devices as well as of the clinical field of usage so that the level of physical-chemical and biological performances (i.e. sensibilization, irritability potential, genotoxicity and tolerance at implantation) to be in accordance with the international normative in force.

These requirements were secured through a sequence of stages of finishing technology represented by washing-degreasing-cleaning-disinfection in order to eliminate antistatic products as well as any oil spots or remaining glass metal filings on woven support; oligomers extraction; simple and/or double curb in order to ensure the appearance of the surface of the woven structure similar to that of the vascular wall and thermal fixing for corrugated structure stabilization.

Assurance of the biocidal effect of the implantable medical product imposed the establishment and optimal correlation of the specific parameters of the treatments with ionized radiation with the characteristics of the raw material in such a way as to achieve a 10^{-6} sterility assurance level required for invasive medical devices.

Assessment of the bio functional performance level of the cardiovascular implants imposed to conduct a rigorous and complex experimental program, represented by: the evaluation of the stress reaction in conditional, wet and after heat treatment at different temperatures status both for the linear portion of the implant and its branched area, in the crudeness and after thermo-fixing; determination of physical-chemical characteristics on aqueous extract; structural analysis of the influence of treatment with ionizing radiation to the implant by mass spectrometry RES.

"In-vitro" simulation of the phenomena that took place at the replacement of a portion from the vascular system, affected by a cardiovascular disease, has been accomplished through numerical modelling of the blood flow.

This simulation allowed exact description of the blood flow from the entrance to the exit of the linear or branched geometry of the blood vessel, through: - analyses of the evolution of the main hemodynamics parameters (velocity, pressure, density, viscosity); - highlighting the clear zones of separation flow in the form of vortex cores that are initiated from the linear area, and that are developed as they advance towards the branched area [1, 2].

Afterward these vortex are maintained as blood advance through the ramifications (Fig. 2), analyses of the Re number variations taking into consideration its dependence from specific parameters, represented by the diameter of the medical product, velocity, dynamic viscosity and the blood density; - characterization of the system diffusion, through the analysis of “the number of Reynolds of the cell”; biofluid flow study-through cardiovascular implant (in the linear area, near branched and inside the vessels) by using the lines of the current [3].

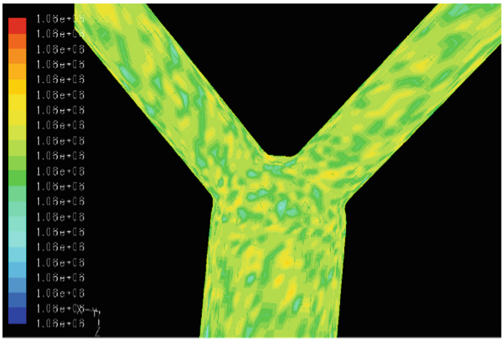

Fig. 2. Density of the blood in branched zone of the vascular system

3 Results and Discussion

Spectrophotometric analyses highlighted that the selected type of yarn will provide the biomedical required characteristics (e.g. chemical inertia, stability of the characteristics for a long period of time; good tolerance in human body; absence of irritability and sensitivity etc.), being suitable for the final application development.

RES mass spectrometry revealed that in cardiovascular implant samples (linear and bifurcated) didn’t show up free radicals both before and after sterilization by irradiation, thus validating the correctness of treatment with ionizing radiation at a dose 28 kGy, for eight hours.

It has been demonstrated that the product absorbed dose of radiation at optimal range, so there were no chemical changes of product material associated to the destruction of covalent bonds in the polyethylene terephthalate structure subjected to sterilization process were identified.

The “in-vitro” simulation allowed exact description of the blood flow from the entrance to the exit of the linear or branched geometry of the blood vessel, through: - analyses of the evolution of the main hemodynamics parameters (velocity, pressure, density, viscosity); - highlighting the clear zones of separation flow in the form of vortex cores that are initiated from the linear area, and that are developed as they advance towards the branched area.

The final product was subjected to a rigorous pharmacological experimental program in order to evaluate the following biomedical level of performances: - irritability and sensibilization potential; - genotoxicity and cytotoxicity; - inflammatory infiltration development at placement area; - edema in implantation zone and surrounding muscle fibers; - muscle tissue infiltration clearance; - reactions of the tissue in contact with the implant.

4 Conclusions

The tensile as loop and knot of the analyzed yarns showed that the breaking forces and breaking elongation increases, so the complex stress (tension and compression) that occur during the technological process can be properly supported.

The determined loop resistance predicted the workability of these types of yarns in optimal conditions, during the technological phases specific to the weaving preparation and weaving.

The selected yarn provides the biomedical and bio functional required characteristics (e.g. chemical inertia, stability of the characteristics for a long period of time; good tolerance in human body; absence of irritability and sensitivity etc.) and will suitable for the final application development.

The level of biomedical and bio functional performances demonstrate that the advanced product developed is suitable to be used in surgical intervention for replacement portion of vascular system with different geometry, in case of thrombosis, occlusion, aneurysm.

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Aging and Gerontology

Alterations in Thyroid Function Testing with Aging

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Abstract. In the present study, we investigated if there are any diurnal variations in serum thyroid stimulating hormone (TSH) levels in normal subjects and any alterations in serum TSH, free thyroxine (fT_4), and free triiodothyronine (fT_3) levels with aging. Our results showed the presence of a circadian rhythm in serum TSH levels in normal subjects (n = 11; 5 males, 6 females; age range 19–46) with no significant changes in fT_3 and fT_4, indicating that the regulation of TSH is central rather than peripheral. In addition, we examined samples from 1,571 euthyroid outpatients (513 males, 1,058 females; age range 10–90) over a 6-month period. Serum TSH levels in age groups 50–59, 60–69, 70–79, and 80–89 were found to be progressively higher than those in the age group 10–19 with no significant differences between male and female populations. These findings suggest the presence of an alteration in TSH secretion with aging.

Keywords: Age · Aging · Thyroxine · Triiodothyronine · Thyroid stimulating hormone

1 Introduction

Thyroid hormones play important roles in development, thermoregulation and metabolic homeostasis [1]. The measurement of serum thyroid stimulating hormone (TSH), using sensitive immunoradiometric assay (IRMA) and enzyme immunoassay (EIA), is an important test in the diagnosis and management of thyroid disorders [2]. As individuals age, the endocrine system and related organs including the thyroid gland undergo vital changes in both functionality and secretion patterns [3].

A considerable body of literature indicates that thyroid function decreases with age [3–9]. In euthyroid individuals with sufficient iodine intake serum TSH concentration have been found to increase with age [10]. Among the strongest evidence is data from 14, 376 euthyroid participants of the National Health and Nutrition Examination Survey III which showed a positive shift in TSH levels as individuals age. In a 13 year

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longitudinal study (n = 908) mean serum TSH was found to increase by 0.32 mU/L (95% CI 0.27–0.38) [3]. Mean fT_4 remained unchanged [3]. For each decade of life, gender-adjusted changes in TSH were found to increase by 0.08 mU/L (95% CI 0.04–0.11). Individuals with low baseline TSH values experience the largest increase in TSH as they age while individuals with higher baseline TSH values have more modest increases in TSH levels [3].

There are conflicting reports on the effect of age-related changes on the secretion of various thyroid regulatory hormones and thyroid function tests. Previous studies of euthyroid individuals have found that increased age is associated with decreased TSH secretion [11, 12]. For example, in a study of 3,346 patients, TSH was found decrease with age while fT_4 levels stayed relatively constant throughout life and fT_3 varied among ages and ethnicities [1]. We have previously shown that serum sensitive TSH assays may be used as an initial screening test for anyone suspected of thyroid disorder and for monitoring optimal thyroxine replacement therapy [2]. The presence of conflicting reports of the effects of age on thyroid function make it an important and timely endeavor to resolve such discrepancies by investigating if there are any diurnal variations in serum TSH levels in normal subjects and any alterations in serum TSH, fT_4, and fT_3 levels with aging.

The existence of circadian rhythmic patterns in the secretion of prolactin, adrenocorticotrophin (ACTH), growth hormone (GH) and luteinizing hormone (LH) have been demonstrated [13, 14]. There are reports of a circadian rhythm for serum TSH and for cortisol [14, 15]. In earlier studies, circadian variations of fT_4 were reported to be accompanied by a non-significant inverse relationship of plasma TSH level [16]. Moreover, it has also been demonstrated that concentrations of thyroxine (T_4) and triiodothyronine (T_3) fluctuate during a 24-h period [17–19]. However, in a later report, pulsatile synchronous diurnal rhythm was found for free triiodothyronine (fT_3) [17], and diurnal rhythm in serum T_3 to T_4 ratios [20]. Based on these reports, a gap in the understanding in the pattern of variation of thyroid hormones has been identified. Therefore, in this study we assess the circadian rhythm in serum T_3, T_4, fT_4 and fT_3 compared to circadian variations of serum TSH, and the relationship of TSH with the daily variation in cortisol concentration in normal adult human subjects.

2 Methods

For the portion of the study that investigated circadian rhythms and thyroid function, 11 normal hospital workers were studied. Inclusion criteria included being euthyroid (having a normally functioning thyroid gland) with TSH results within normal range and having normal levels of electrolytes liver enzymes, creatinine and urea. Exclusion criteria included taking any medication such as being on birth control. These 11 subjects were observed for their usual living and day to day habits.

Blood samples were collected every 4 h for a period of 24 h, starting at 0800 h. Various routine immunoradiometric methods, radioimmunoassay and enzyme immunoassay were employed for measurement of T_4, T_3, fT_4 fT_3, TSH, and cortisol [2, 21]. Sera were stored at −20 °C until the end of study and samples from each subject were assayed in a single batch to eliminate inter-assay variations.

For the portion of the study that investigated changes in thyroid levels and aging, samples from 1,571 ambulatory patients were sent to the laboratory over a 6-month period. Only euthyroid patients with normal levels of electrolytes, and liver enzymes were included and any participants taking medications such as birth control were excluded. The individuals in this study were grouped into decades so that comparisons of age-related changes could be made.

3 Results

Study Population. The analysis of circadian rhythm included 11 patients with a mean age of 20 ± 9.0 years, range 19–46 years. There were 54.5% (6/11) females and 45.5% (5/11) males. All subjects followed a routine of daytime work and night time sleep. The analysis of thyroid levels and aging involved 1571 patients ranging from 10 to 90 years old. Approximately 67.3% (1058/1571) of the patients were female and 32.7% (513/1571) were male.

Triiodothyronine and Thyroxine. No predictable pattern of variation was found in the levels of serum T_3 and T_4 in normal subjects over a 24-h period (Fig. 1).

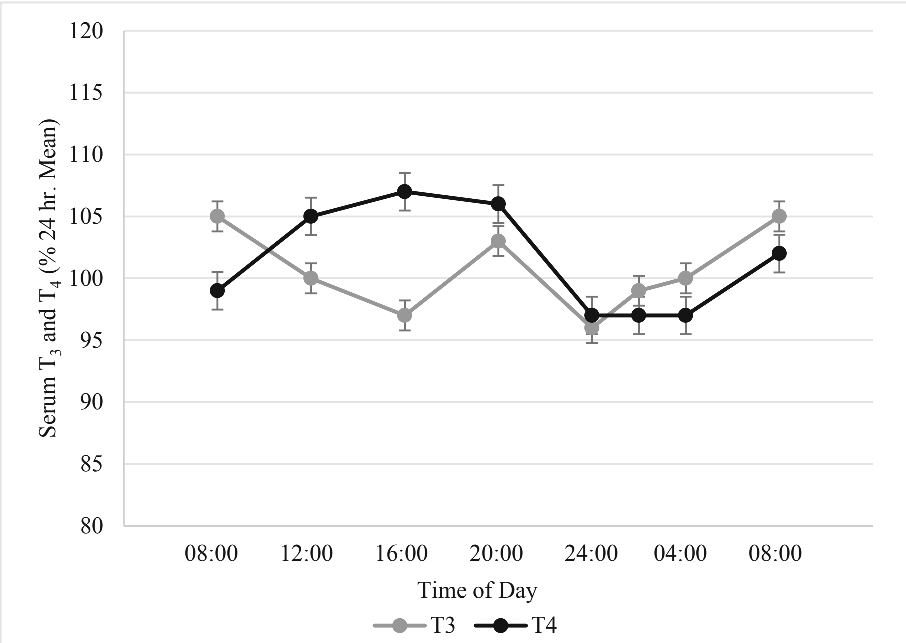

Fig. 1. Relative changes in serum triiodothyronine (T_3) and serum thyroxine (T_4) levels (% 24 h, Mean ± SEM) over a 24-h period in normal subjects.

Free Triiodothyronine and Free Thyroxine. Data showed no significant difference in the serum fT_4 and fT_3 values in normal subjects over a period of 24 h. Serum fT_4 and fT_3 levels in normal subjects over a period of 24 h are shown in Fig. 2.

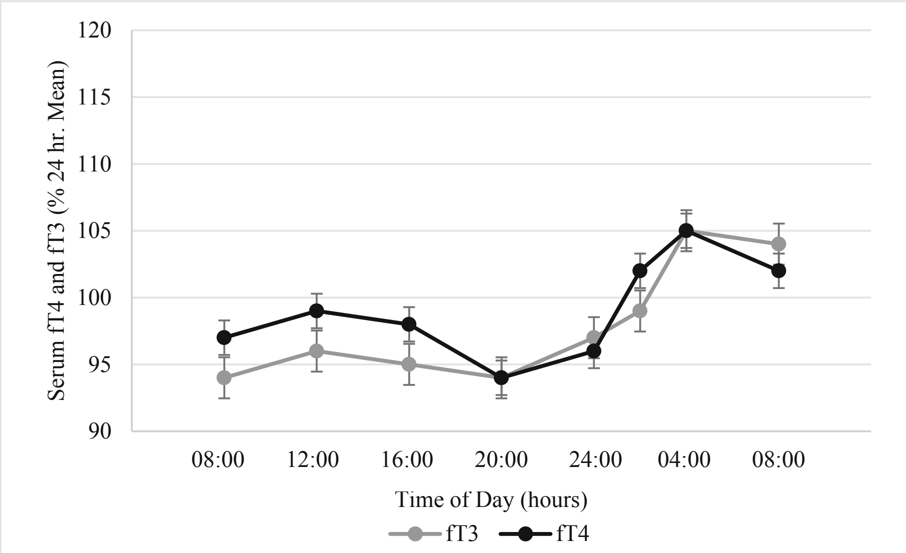

Fig. 2. Relative changes in serum free triiodothyronine (fT_3) and serum free thyroxine (fT_4) levels (% 24 h, Mean ± SEM) over a 24-h period in normal subjects.

Thyroid Stimulating Hormone and Cortisol. Mean serum TSH concentrations were found to be decreased from 0800 h to 1600 h, being lowest at 1600 h. Peak TSH levels occurred at 0200 h. Mean cortisol levels were found to be lowest at 2400 h, with a progressive rise at 0200 h, with maxima at 0800 h. A comparison of changes in TSH concentrations with that of cortisol levels is shown in Fig. 3.

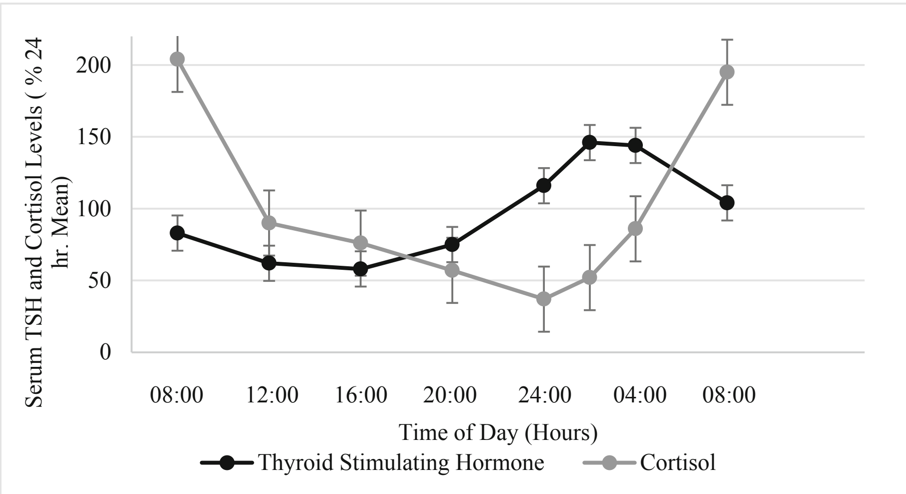

Fig. 3. Relative changes in serum thyroid stimulating hormone (TSH) levels and cortisol levels (% 24 h, Mean ± SEM) over a 24-h period in normal subjects.

There were no significant differences observed when comparing serum TSH values from the age group 10–19 to TSH values from age groups 20–29, 30–39, and 40–49. However, serum TSH levels in age groups 50–59, 60–69, 70–79, and 80–89 were found to be progressively higher than those in the age group 10–19. TSH levels in each decade of life are shown in Fig. 4.

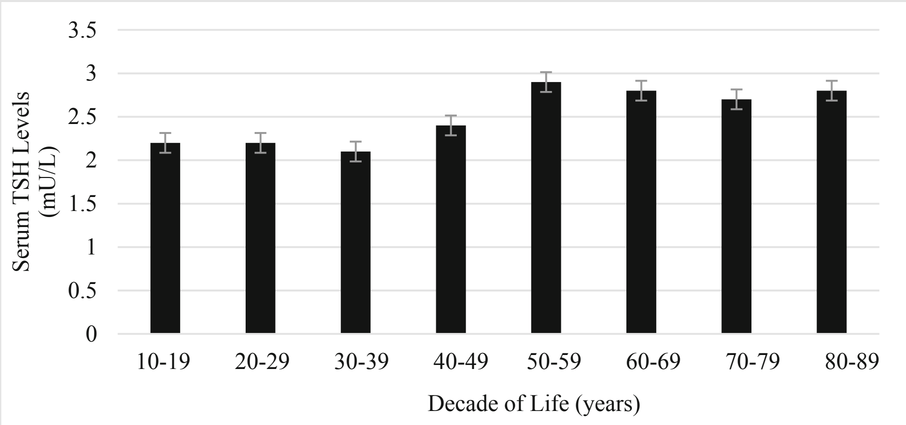

Fig. 4. Levels of serum thyroid stimulating hormone (TSH) (Mean ± SEM) in each decade of life.

When comparing TSH levels at each decade of life, no significant differences between male and female populations. TSH levels of males and females in each decade of life are shown in Fig. 5. Female TSH levels tended to be slightly greater than male TSH levels in each decade of life (Fig. 5).

Fig. 5. Comparison of thyroid stimulating hormone levels (Mean ± SEM) between males and females in each decade of life.

4 Discussion

The measurement of serum thyroid hormones has allowed us not only to study circadian rhythms of the thyroid but also to investigate how the functionality and secretion patterns of the thyroid change with age. This study has shown that there is no significant difference in the serum T_4, T_3, fT_4 and fT_3 values in normal subjects over a period of 24 h. These observations indicate that serum T_4, T_3, fT_4 and fT_3 in normal human subjects are not controlled by circadian rhythms. This finding is supported by numerous previous studies of circadian rhythms [17–20].

Our observations indicate that there exists a circadian rhythm in the secretion of serum TSH in normal subjects, as was previously reported in a similar study [22]. Mean serum TSH concentrations were found to decrease between 0800 h to 1600 h, with a minimum at 1600 h. We observed that there was a progressive increase of mean TSH concentration that began at 2000 h and reached a maximum value at 0200 h. The mean TSH concentration at 1600 h and 0200 h were significantly different ($p < 0.01$). The presence of a circadian rhythm for TSH, combined with the absence of a measurable circadian rhythm in other hormones pertaining to the thyroid suggests that there is no relationship between the release of thyroid hormones (bound or free) and fluctuating TSH values over the 24 h period. Furthermore, it suggests that the serum TSH circadian rhythm may primarily be regulated centrally rather than peripherally.

The lack of a relationship between the release of thyroid hormones and circadian rhythms of TSH values found in this study contributes to an ongoing discussion about the pattern of variation of thyroid hormones. In contrast to our findings, pulsatile release of free hormones from the thyroid gland has been reported to be controlled by pulsatile TSH secretion [23]. However, in an earlier study, no increment of plasma T_4 or T_3 followed the nocturnal TSH surge [17] suggesting that the diurnal rhythm of serum T_3 is not TSH dependent [20].

The discussion of the regulation of the thyroid is ongoing. Recently, it has been suggested that pulsatile and circadian TSH secretions are predominantly controlled by TRH [24]. Hypothalamic regulation of TSH biosynthesis and secretion has been demonstrated [25]. It has been speculated that the increase in melatonin at night leads to a dopaminergic activity, resultantly the diminished release of dopamine (DA) may lead to an increase in TSH [26]. Infusion of a DA has been found to abolish the maximal peak in TSH occurring at 2300 h while cortisol levels were unaffected by DA [27]. However, later studies have demonstrated that the neuroendocrine mechanism(s) that underlies the nocturnal increase in TSH secretion are not due to dopaminergic inhibition [28]. When interpreting the information and data provided from the combination of these studies it is apparent that the control of TSH secretion remains an ongoing debate. To contribute to the understanding of the control of TSH secretion, our data indicate that with respect to the circadian variation of serum TSH levels, the timing of sample collections plays an important role in the diagnosis of thyroid disorders. For example, in central hypothyroidism there is a deficient nocturnal surge of TSH, therefore, evaluation of circadian pattern of TSH may be useful adjunct in making the diagnosis of hypothyroidism in patients with diseases involving the pituitary or hypothalamus [29].

Cortisol was found to have diurnal variation. Mean cortisol levels were lowest at 2400 h, with a progressive rise at 0200 h, with maxima at 0800 h. As far as the relationship in diurnal variation between TSH and cortisol is concerned we our data show that the rise in serum TSH preceded the rise in cortisol (Fig. 3). Additionally, we see that during the period of maximum TSH levels, cortisol was at its lowest point suggesting an inverse correlation between the two hormones. This inverse relationship may be due to the acute suppression of TSH secretion when cortisol concentration is at a high point. These effects have been found in both man and in rats after the administration of glucocorticoids in pharmacological doses [30]. Dexamethasone administration also resulted in a prompt, sustained and significant suppression of basal TSH [30]. However, this inverse correlation between serum cortisol and TSH secretion was not consistent [31]. Therefore, the role of cortisol on the secretion pattern of TSH remains unsolved and requires further investigation. Possible factors responsible for the inconsistencies in the outcome of different investigations include variations in the adoption of methods for the determination of desired parameters, sensitivities of the procedures, sampling devices, time of sampling, lab practices, ethnicity, race, genetics, sex and the health status of the subjects under study.

In regard to the effect of aging on thyroid function, there were no significant differences in the mean serum values of fT_3 and fT_4 between age groups, as has been previously reported [3]. No significant differences were found when comparing serum TSH values from the age group 10–19 to TSH values from age groups 20–29, 30–39, and 40–49. However, serum TSH levels in age groups 50–59, 60–69, 70–79, and 80–89 were found to be progressively higher than those in the age group 10–19 with no significant differences between male and female populations. The findings of this study provide evidence that TSH levels increase with age. These results are aligned with previous studies that have reported a similar positive effect of age on TSH levels [3, 10]. The physiological processes underlying the association between aging and increased TSH levels is suspected to involve diminished TSH bioactivity or reduced responsiveness of the thyroid to TSH [3].

It has been suggested that lower reference ranges of TSH should be used in early life and that higher reference ranges should be used for elderly patients [1, 7, 32]. Although there still exists a great deal of debate around the issue [33, 34], the use of age-specific TSH levels may allow for more accurate diagnoses while minimizing overdiagnosis and overtreatment. This study has shown that aging does have a measurable and predictable effect on thyroid function and that TSH levels increase as age increases. It is therefore reasonable to support the adoption of age-specific TSH reference ranges to provide accuracy to the diagnosis of thyroid disorders. This study serves as an important step in the investigation of circadian rhythms of the thyroid and to understanding how thyroid functionality and secretion patterns change with age.

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The Design Adaptation of the Virtual Assistant Anne for Moderate Dementia Patients and Their Formal Caregivers in Protected Environment Tests

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Abstract. Dementia has become a major health problem with an equally important economic impact on our society and enabling patients with dementia and their caregivers to improve their quality of life and dignity is a great challenge. A significant solution to meet the challenge, could be the use of Personal Virtual Assistant (PVA). The aim of this paper is to share the know-how reached in the design and adaptation of the Personal Virtual Assistant "Anne" for moderate dementia patients and their formal caregivers. The paper presents the results of the first iteration of protected environment tests in Italy and Luxembourg.

Keywords: Personal Virtual Assistant · User Centred Design · Dementia

1 Introduction

Dementia has become a major health problem with an equally important economic impact on our society: approximately 47 million people have dementia worldwide and this is expected to almost triple by 2050. The cost associated with this disease is estimated to be at 818 billion dollars, and by 2030, this cost is expected to exceed one trillion dollars [1]. Enabling patients with dementia and their caregivers to improve their quality of life and dignity is a great challenge. A significant solution to meet the challenge, is the use of innovative technology. Avatars or Personal Virtual Assistant (PVA) are promising examples of technological solutions with a large potential in this field. PVAs are screen-based entities designed to stimulate human face to face

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conversation skills and thus allow for natural interaction between humans and computer [2]. The extent to which this type of innovation may be able to support people affected by dementia and their caregivers along the progressive nature of this terrible illness, represents a great challenge for the entire scientific community. The changing needs of patients and those who provide care for them force the necessity of appropriate and effective technologies at the different stages of dementia. For example, exiting systems target memory support and self-care for people in the early stage of dementia whereas in the moderate to severe stages of dementia, assistive and safety technology (i.e. motion/fall detectors, environmental sensors measuring elements such as room temperature, smoke/gas/water presence) are mostly needed [3]. Unfortunately, specific studies on the efficacy of virtual agents within the dementia context are rare. Nevertheless, some research has shown significant results: an animated conversational agent can be used as a trusted exercise adviser [4]. People with cognitive impairment seem to engage naturally with a screen agent [5]. Moreover, it is found that virtual agents provide a sense of companionship [6]. The aim of this paper is to share the know-how reached in the design and adaptation of the PVA "Anne" for moderate dementia patients and their formal caregivers, within the Living Well with Anne project.

2 The Living Well with Anne Project

The *Living well with Anne* project (http://livingwellwithanne.eu/) is co-financed under the Active Assisted Living Joint Programme of the European Commission (www.aal-europe.eu) and the National Funding Agencies of 7 partners out of 4 European countries (the Netherlands, Italy, Luxembourg and Switzerland). The project has started in June 2017 and the duration was set to 36 months. Living well with Anne is based on the AAL predecessor project *MyLifeMyWay* (http://www.mylifemyway-aal.eu/), and it operates in a promising research field based on new approaches in technical assistance systems and robotics with the focus on seniors suffering from forgetfulness, cognitive impairments and/or the early stage of dementia (Fig. 1).

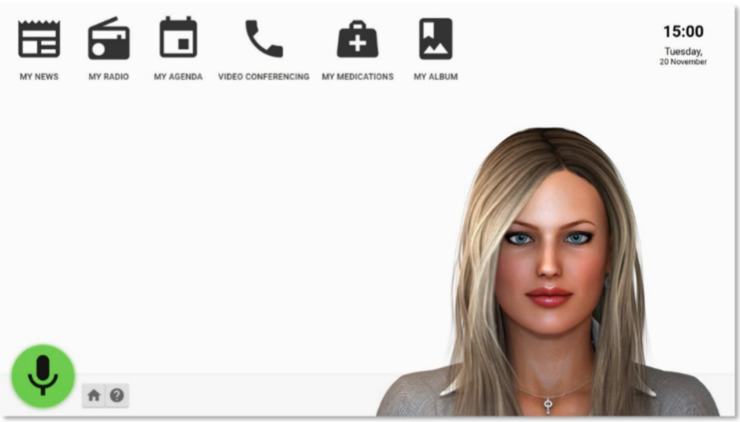

Fig. 1. The users interface. Copyright Virtask B.V.©

2.1 Component Overview of the Personal Assistant Anne

The LivingWell project features the Personal Virtual Assistant "Anne" that can support the users in all aspects of daily life: communication with the outside world, keeping track of items on the personal calendar, daily structure, medication, reading the news and re-laxation (games, music). While the technology in the background is quite complex, for the end-users the PVA is a friendly, human-looking avatar on their screen. They can interact with the PVA with their voice and touch. In this project, the personal assistant is extended with features that meet the changing needs of people with dementia (PwD). Anne will enable PwD to live independently for longer by giving them an easy-to-use, most natural way to interact with assistive technology. Anne is able to learn autonomously from its users and gets to know their personal preferences and needs. The PVA can assist and support PwD and their social environment in such a way that they can be active much longer be active and take part in social life. In addition, as end-users learn to use Anne and increase their autonomy, it is believed that it will have an unburdening effect on their informal and formal caregivers.

Anne works on a Surface Pro tablet under the Microsoft Windows 10 operating system. Currently the following languages are available: Dutch, English, German, Italian, French. Spanish and Portuguese are under development (Fig. 2).

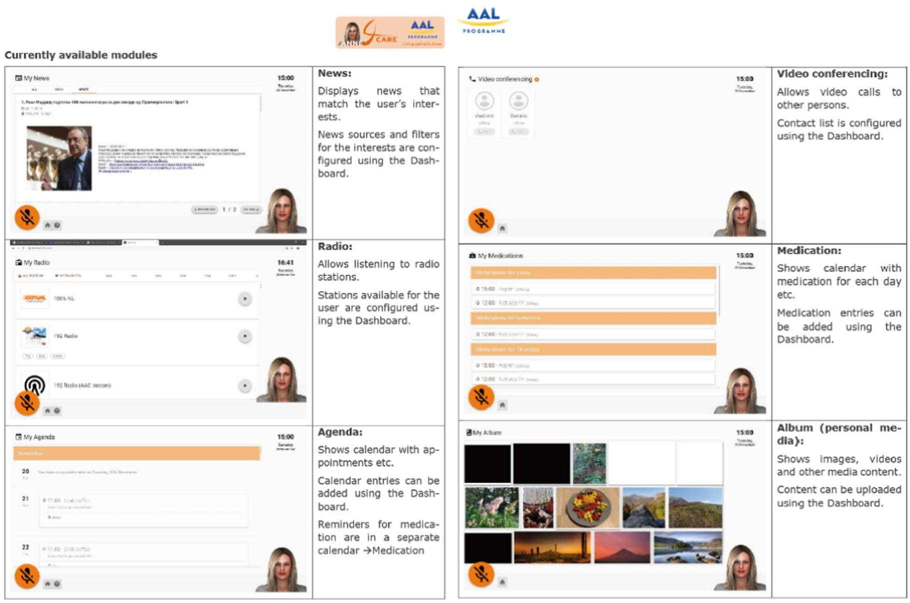

Fig. 2. Screenshots of current available modules that show an example layout. Depending on the abilities of the user, the layout can be different, or the module can be hidden or disabled. The challenges in the design development. Copyright Virtask B.V.©

In the Living Well project, we explore the following question: how Anne can be modified to the requirements of people with dementia in different stages?

Rather than to reinvent the wheel, the project uses on an already developed modular software solution and smartly combining several existing technologies such as language recognition and speech generation, 3D-rendering, adaptive decision control mechanisms etc. Building on the knowledge already attained in building the basic version of Anne, the project will go beyond the state of the art in avatar technology. The objective is to ensure that Anne will be able to adapt to the changings needs of the concerned people as the disease progresses. The new and innovative concept builds upon new functionalities of Anne advancing her in four major areas:

- **Dynamic state and progression analysis:** The avatar will be able to detect the state of the PwD living at home in order to get a close picture on what the person is still can and cannot do. This analysis continues dynamically and will get more precise while Anne learns. But Anne will also be able to detect changes in the behavior and the abilities of the PwD as the disease progresses.
- **Situational context analysis:** While in the previous area, the general abilities of the PwD living at home are analyzed on a more mid-term basis, Anne will also be able to find out more about specific situations and the typical day-to-day living patterns of a PwD.
- **Smart, context-sensitive service provision:** Once Anne knows more about the abilities of the PwD, she may choose the most suited ones among her standard and newly developed functional modules (Agenda, Radio, News, etc.) the most suited ones and decide on which level of complexity they should be provided.
- **Adaptive user interface:** Finally, Anne will be able to adapt her user interface to provide the selected services in a way that still make them accessible to the PwD.

This development requires the close involvement of end-users during the design process in conformity with the User-Centered Design (UCD) approach. A great challenge of the Living Well project is to provide a human-centered perspective that can be integrated in the main development cycles of the system [7]. The active involvement of users and a clear understanding of context of use are the key strengths to overcome the main barriers in applying technology for seniors in general and in particular for people who suffer of dementia.

In the light of this challenge, the research objectives of this particular part of the project are to obtain insights in: (i) how do patients experience the PVA in the stage of moderate dementia? (ii) how Anne can be modified to the requirements of people in the stage of moderate dementia?

3 Methodology

For this study, the method of protected environment tests was used as a phase of the UCD development process. Predefined small test sessions were performed in a safe and familiar environment where the end user met with a caregiver and a researcher for a short time (e.g. an hour or even shorter) to perform a particular activity. Each user interaction between the PwD and Anne was observed, analyzed and documented by the formal caregivers and researchers.

The protected environment tests scenarios were previously agreed between formal caregivers, researchers and technicians in order to establish the needs and requirements (pains and gains). In this way, Anne was experienced by patients with moderate dementia within a controlled setting and under the supervision of their formal caregivers and the risks of exposing PwD to the PVA (e.g. provoking paranoid reactions to the Avatar and leading to aggression behaviors) were mitigated. To supplement the observations, formal caregivers were interviewed at the end of each session of test using a semi-structured list of questions. In accordance with Preece et al. [8], our questions are conforming to the usual usability goals like effectiveness, efficiency, safety, utility and learnability. The interview included the following statements (Table 1):

Table 1. The semi-structured list of questions

Questions	
1.	Did the tool meet the predefined expectations? Why (not)? If not: what should be changed?
2.	Is this tool useful in each stage of dementia?
3.	On the basis of this experience, do you think that the system is useful in this specific stage of dementia?
4.	Do you think that this tool can be used by the patient without the caregiver's supervision?
5.	If not, what kind of changes will be necessary to adapt Anne for the needs of this stage of dementia?
6.	What kind of behaviors did you recognize in the target during the interaction with Anne?
7.	Do you think that these behaviors represent positive, negative or neutral feelings in the subjects?
8.	Do you think that Anne could have some benefits/advantages on the target?

The protected environment tests were performed in two different settings:

– In Italy, 5 female patients with moderate dementia, 2 formal caregivers and 2 researchers working at the Alzheimer Daily Center of INRCA were involved in different iterations;
– In Luxembourg 1 female patient with dementia, 2 formal caregivers and 1 researcher were involved in the requirements session. Additional patients will be involved in the testing of the consequent iteration of the protected environment tests.

4 Results

This section provides the outcomes of the participants' interactions with the PVA. The results provided are the combined notes of the formal caregivers and researchers in Italy and Luxembourg.

4.1 Protected Environment Tests in Italy

Formal caregivers, researchers and technicians agreed to develop and observe two specific requirements in the Italian setting: prayers and the quizzes. These two functionalities respond to the general need of keeping the patients calm and relax and in parallel involve them in entertainment activities that can stimulate their procedural memory. The PVA was evaluated with the PwD in a setting familiar to the participants, at the day care centers where they are frequent visitors.

From a qualitative point of view, a result of the observations was that the older adults at no point exhibited fear, misunderstanding or inconvenience when seeing the avatar on the screen or, most importantly, when the avatar spoke to them directly. Moreover, nobody withdrew from the test. Another result to underline is that PwD freely spoke to her. The sample group responded verbally to the avatar but they did not use the touch control.

The interviewed informal caregivers recognized the potential of the PVA as a tool for their daily activities. For example, for them it appeared clear that the prayer evoked the procedural memory and acted as a “mantra” and the PwD seemed to feel soon comfortable. Nevertheless, the formal caregivers were strongly convinced that the use of the PVA is only useful for this stage of dementia if controlled by the professional staff. The proactivity of the avatar emerged as the most important aspect to improve the next iterations. The users need to experience the personal assistant as a companion. Other suggestions coming from the interviews put the attention on the leisure/games functionalities and the need to maintain the residual cognitive ability of PwD fostering cognitive training by means of painting pictures, paying quizzes and puzzles, reading books and listening to stories, and music (mainly classical).

All these improvements are being implemented for the second iteration of protected environment tests.

4.2 Protected Environment Test in Luxembourg

In Luxemburg Formal caregivers, the researcher and technicians agreed to develop and observe one specific requirement of the basic Anne: the puzzle. One lady with intermittently medium dementia (temporary loss of memory and cognitive functions), together with 2 of her formal caregivers at and 1 researcher, tested the basic Anne as she is currently being used by older adults without issues of dementia. The PwD quickly focused on the games section and in particular the puzzle because she already does puzzles as a means of exercising her memory and cognitive abilities. The problem she encounters currently is that when she does puzzles in the Day care Center, there is always a member of staff at hand to help and encourage her but at home, she gets too quickly frustrated to play. As she only attends the Day Care Center twice a week, the benefits of this activity are limited. Both the PwD and her caregivers are convinced that if Anne could take on the role of supporting and encouraging the PWD at home, she would be able to play a little every day and thus maximize the benefits on her memory and other cognitive abilities and thus maybe even slow down the development of her dementia.

In the post test interview, the formal caregivers expressed the belief that within the 10 SHD Day Care Centers, a large number of their PwD patients could benefit of such a development.

The following requirements were identified:

- The Puzzle needs to be simplified (cut into simple shapes) and provide several choices of complexity in order to insure that the Puzzle can be adapted to the PwD with severe cognitive problems while still challenging those who are still more able. For example, the client tried to play the normal puzzle and failed. Client herself said that the curly complex shapes made it difficult for her. The formal caregiver said that if we oversimplify, then other clients may get bored. So they expressed the need to have a choice of difficulty to meet the needs of all their clients and help them to challenge themselves.
- The pictures used need to be relevant to the PwD's life experience (e.g. pictures of Luxembourg or their country of origin, pictures of their Day Care Center building/bus/staff, pictures of their home or their family members).
- Anne needs to actively invite and encourage the PwD to play and provide choices on the level of difficulty.
- Anne needs to notice when the PwD has difficulties completing the Puzzle and offer appropriate help and/or offer to reduce the level of difficulty.
- Anne has to actively encourage and complement the PwD throughout the session and after each game.

These and other specifically designed features are being implemented to be tested in the 2^{nd} iteration in the protected environment tests which will include other PwDs attending the SHD Day Care Centers.

5 Discussion

The goals of this study were to find answers to the research objectives introduced in Sect. 2.1.

5.1 How Do Patients in the Stage of Moderate Dementia Experience the PVA?

PwD and their formal caregivers enrolled in this study were positive regarding the PVA. All the participants interacted with Anne playing games, quizzes or praying with her. No problem behaviors (i.e., verbal, physical, and overall agitation), were observed, neither patients withdrew from the tests. This data suggested that people with moderate dementia can be engaged in interactions with a PVA. This results confirm the state of the art in the field [9–13].

However, patients experienced difficulties in using a touchscreen and navigating the different applications of Anne. This convinced the formal caregivers in Italy that Anne could be a useful tool for their daily working activities but that their patients could not use it independently. The caregivers in Luxembourg agreed that the daily living activities of the current Anne (e.g. Agenda, medication, video call…) were too difficult for PwD to use independently at home. This is in line with recent researches that shown how the PwD needed permanent help and prompting while using natural user interfaces [14, 15]. However, the staff thought that once adapted appropriately, the Day Care Centre attendees with mild to moderate dementia could continue to play the games (e.g. puzzles) independently at home with Anne mimicking the support given by the formal caregivers.

The results showed very clearly the importance of personalized solutions: the design adaptation was conducted in close collaboration with the care organizations which provide daily assistance to the patients both in Italy and Luxembourg. This participatory strategy allows for easy adaptation and consequently helps to match the needs of future beneficiaries with the proposed technology [16, 17].

5.2 How Anne Can Be Modified to the Requirements of People in the Stage of Moderate Dementia?

In software design for PwD, user centeredness is crucial. User-centric design (UCD) implies developing in small steps, iteratively testing new versions with the end-users. This is only possible in a software environment where it is very easy to implement changes to the look-and-feel, without having to adapt many back-end functions, databases etc. We therefore decided to use a simplified version of the Anne software on stand-alone systems without backend integration, where we could provide software versions tailored very specifically for each protected environment test, without having to adapt many back-end functions not directly visible for the user. For each protected environment test, the researchers, carers and developers collaborated closely to design the test, to install and perform it. The development cycles were shortened further by creation of mockup images before implementing software. For installation and support of the test computers, direct remote access for the developers proved very useful. From the results of all these very specific tests and software versions, the following general results can be extracted for an Anne version suitable for PwD:

- Encouragement: Anne should encourage the user to continue if he/she has succeeded in doing something, has finished a subtask or done a step towards a goal.
- Immediate feedback: Whenever the user interacts with Anne, immediate feedback should be given, e.g. a visual effect when touching an active element on the screen, or an audible feedback when Anne has heard a speech command. This is a common truth for all user interfaces, but for PwD it is crucial.
- Give hints: When the user is stuck in a task, Anne should give hints or make suggestions what to try or what next step could be possible.
- Simplify screens to the absolute minimum: The PwD should not be confused with visual elements that are not important for the current task.
- Personalization: Anne should be personalizable very easily by the carers, not only to the overall wishes of the PwD (e.g. what modules should be visible in general), but also depending on current strength of the PwD, as this can vary from day to day. As the Anne software knows the interaction patterns of the user, it should support

the carers in this configuration process by recommending simplification possibilities. The associated machine-learning capability of Anne opens many research questions and, if proved feasible, even possibilities that future versions of Anne could self-adapt their user interface, based on the current condition of the PwD.

5.3 Limitations, Conclusion and Future Steps

While this study was limited by its small sample size, gender homogeneity (only females were included in the group) and very low ICT skills, its intent was to develop some specific features for the use of people with different stages of dementia and associated cognitive problems and pave the way for future studies of how PVAs can be adapted to fit the different stages of dementia. It is to underline that current PwDs had generally little experience with mobile technology before they became affected by dementia.

Nevertheless, future steps are needed. The first step is to conduct methodologically sound scientific researches in the community dementia care and support. This could lead to the urgent proof of the cost-effectiveness of such devices. The second step is to study in depth what are the factors that can influence the deployment of these technologies. In this respect, it could be very interesting to know if a participatory design strategy is the key to sell products to PwD but also to the caregivers (informal and formal) who will recommend or even buy the product for the PwD asking themselves "what is the added value for me?". In the future, interaction with technology may become less of a problem for PwDs. This increased IT literacy will open the way for broader application of ICT with PwD in a more severe stage.

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Design and Implementation of Bed-Exit Alarm System for Preventing Elderly Falling

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Abstract. In recent years, with the aging of the population, the increase in the elderly population has brought a greater burden on medical institutions. Therefore, how to reduce the incidence of hospitalization through medical technology will become an important issue for hospitals. In many hospitalization accidents, the greatest threat to the elderly due to falls. Besides immediate dangers, the sequelae will also increase the burden on caregivers and health care. In order to reduce the second-degree injury caused by falls, hospitals or nursing homes often use the bed-exit alarm system to actively inform the nurse or caregiver to help when the patient gets out of bed. However, the false alarm of related products on the market are too frequent, which not only causes the caregivers to be exhausted, but also delay critical rescue opportunities.

Based on the above issues, this study will propose two new types of bed-exit alarm systems, one of which is based on the nurse's clinical care experience, setting up multiple sensing such as infrared, ultrasonic and triaxial accelerometers on the route that patients pass by most often. Another set of bed-exit alarm system uses the infrared array sensor mounted on the headboard of the bed to capture the patient's thermal imaging, and then uses the support vector machine to analyze the position of the patient on the bed to determine whether the behavior is about to leave the bed. Unlike traditional image processing, this method eliminates the need for edge detection and motion tracking and is immune to ambient light sources.

Keywords: Bed-exit alarm system · Elderly · Falling

1 Introduction

1.1 Background

According to the report of the Statistics Department of the Ministry of the Interior, the number of elderly people over the age of 65 in Taiwan has increased from 1.39 million to 3.31 million (+122.16%) at the end of March 2018, that is to say, Taiwan has entered the "ageing society" from the "aged society" in 25 years. According to the National Development Committee, it is estimated that the elderly population will exceed 20% of the total population after eight years. It is listed as a "super-age society" with Japan, South Korea, Singapore and some European countries (Fig. 1). The year-on-year

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increase in the elderly population has brought greater pressure on medical care. To this end, the relevant units of the medical institution must propose appropriate programs to respond to this problem, and the safety of patients will therefore become the primary concern and input project.

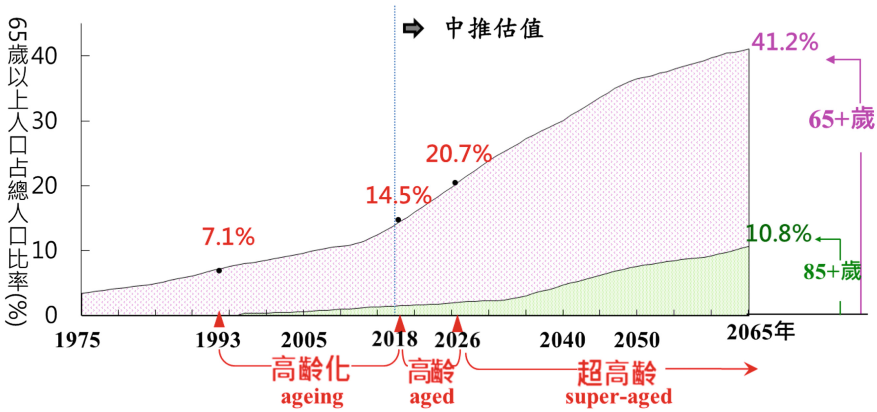

Fig. 1. Estimated figure of senior population ratio

The injury incidents that cause patient safety hazards include: drugs, falls, medical care, injury behaviors and surgical accidents, etc. Among them, the fall problem is one of the most important issues of global public health, in the 107 years of the patient safety notification system of the Ministry of Health and Welfare Among the number of notifications in the first quarter (Fig. 2), a total of 8531 cases (35.2%) occurred in the drug incident, followed by a fall event, which occurred 5899 cases (24.3%) (Ministry of Health and Welfare of the Republic of China 2018). However, the Hospital Assessment and Medical Quality Policy Council noted (Table 1) that the impact of a fall event on a patient's health is much greater than a drug event compared to a drug event. Nearly half of all falls have occurred in the elderly, and the improvement and implementation of medical care for fall prevention has become a top priority.

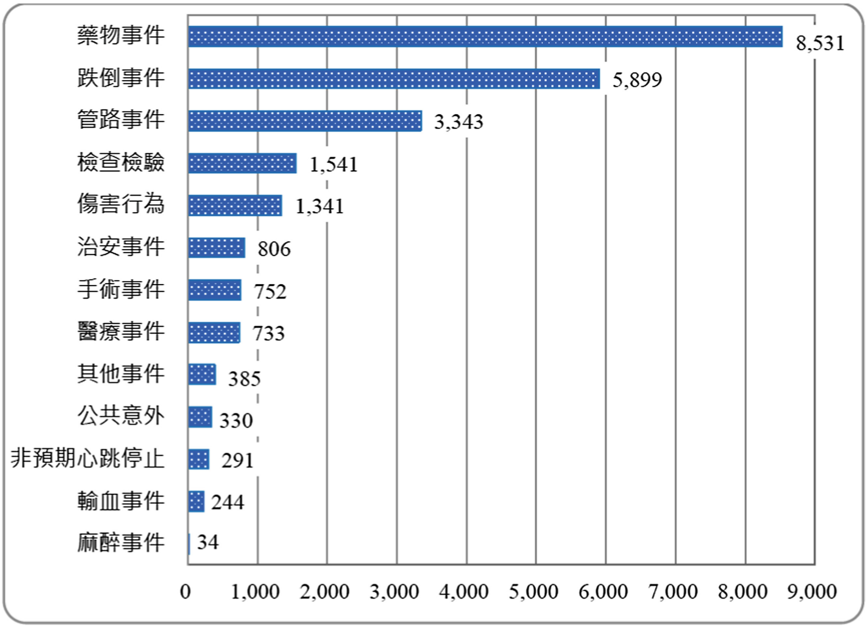

Fig. 2. Medical notification of various types of incidents

1.2 Research Purposes

In summary, in order to reduce the accident rate of hospitalized patients falling in hospitals, they began to cooperate with hospitals more than half a year ago, trying to make effective preventive measures against this problem. In general, since falls often occur when elderly people go to bed, the major hospitals often use the "bed-off alarm" to monitor the movement of the elderly to get out of bed, thereby preventing the elderly from getting out of bed and preventing falls purpose.

However, the goal of this research is not only to stop the "bed-off alarm" used in the hospital, but to develop a "bed-off alarm" that is common in hospitals, nursing homes and even homes. The non-contact design of the bed-off alarm system is designed to reduce the fall rate caused by the elderly to get out of bed, so that the nursing staff can relieve the physical and mental burden of the nursing staff with the help of smart instruments.

2 Related Work

Falling is quite common accident in the elderly, and it is also a very important health issue. There are many factors in the falling of the elderly, including cognitive function, sensory dysfunction and gait instability (Tinetti et al. 1995). Falling problems are also common among older people in care settings, such as nursing homes, rehabilitation facilities, and chronic wards.

2.1 Analysis of the Falling Factor of the Elderly

The falling of the elderly is usually not caused by a single cause. Among them, aging leads to poor balance, gait instability and decline of cardiopulmonary function. Common causes include chronic diseases (such as infection, dehydration, etc.), the new medical treatment and environmental stress (in the face of unfamiliar environments) are also among the risk factors for the falling of the elderly (Inouye 2000).

Risk factors for falling include past medical history of falling, lower limb weakness, advanced age, female, cognitive dysfunction, abnormal balance, use of psychiatric use, past history of stroke, anemia, and postural hypotension (Bischoff-Ferrari et al. 2009). Many different falling risk factors also have been found in different studies. These shows that the cause of falling is inherently multi-independent and can only be explained by a single cause. However, many studies have consistently found that risk factors in many falls. Among them, the problem of gait instability and balance is the most common.

The location of the fall, whether inside or outside, is considered to be the focus of an analysis of the cause of the falling, because people who falling indoors tend to be weaker, usually accompanied by physical disability and mean health. Poorer and more static lifestyles; outdoor falls are more common in younger and more active populations (Verma et al. 2016).

In general, the more risk factors fall, the greater the chance of falling. The following is a detailed breakdown of the risk factors for falls, which are summarized in Table 1.

Table 1. Elderly falling factors

Internal factors	External factors
Aging-related posture control degradation	Multiple medicine use
Muscle tension changes	Footwear selection
Blood pressure regulation problem	Environmental factor
Chronic disease	
Cognitive dysfunction	

Internal Factors

1. Aging-related posture control degradation

Maintaining an upright posture relies on the input and integration of several sensations, including vision, proprioception, and vestibular nerve coordination, all of which function with age. In addition, aging can also affect the central nervous system. For example, loss of neurons in the basal ganglia and loss of neurotransmitters (such as dopamine) can further cause difficulty in posture control (Bekkers et al. 2015).

2. Muscle tension changes

Aging can cause muscle loss, and the fat cells in the muscle will increase, which will affect the decline in activity and loss of function of the elderly. In addition, when the balance is lost, the reaction speed of the muscles and joints will also slow down, resulting in easy fall. Situation (Woollacott and Shumway-Cook 1990).

3. Blood pressure regulation problem

The regulation of systolic blood pressure is an important key to maintaining an upright posture. Postural hypotension can cause insufficient blood perfusion in the brain, which increases the risk of falls. The causes, including the reduction in sensitization reflexes associated with aging, do not compensate for increased heart rate when blood pressure is lowered. Another cause of low blood pressure in the elderly is that the total body water content decreases with age. Therefore, the elderly population is prone to hypotension volume due to acute diseases, diuretic use, or hot climate. Low blood pressure and falls.

4. Chronic disease

Certain chronic conditions may increase the risk of falls, including Parkinson's disease, chronic musculoskeletal pain, skeletal degenerative arthritis, and diabetes spasms. Parkinson's disease causes falls, including stiffness of the lower limbs, difficulty in starting the movement, postures that cannot correct the body's swing, and side effects of hypotension caused by treatments (Kempster et al. 2007). Knee degenerative arthritis affects the mobility and posture stability of the elderly, as older people tend to avoid joints that are heavier than pain, and chronic pain may also affect their attention and cognitive function. Can reduce the occurrence of falls. In addition, the study found that people with diabetes have a higher chance of falling (Berlie and Garwood 2010). The more elderly people with chronic diseases, the higher the chance of falling.

5. Cognitive dysfunction

Mild to moderate cognitive dysfunction is associated with higher risk of falls and hip fractures (Guo et al. 1998), and other studies have found some anatomical changes associated with cognitive dysfunction. It is also related to the risk of falling, for example, the volume of white matter in the cerebral cortex is related to the risk of falling.

External Factors

1. Multiple medicine use

The problem of drug use is one of the most likely factors to change among the causes of falls. In addition to special types of drugs, the use of multiple drugs and changes in drug dosages will increase the trend of falls, and it is also worth noting that drug compliance is poor. The patient has a higher risk of falling. There are two common types of drugs that are associated with falls risk: drugs that act on the central nervous system and cardiovascular drugs. Drugs that act on the central nervous system include psychotropic drugs, benzodiazepines, and antidepressants. The use of these drugs is significantly associated with the risk of falls, but it is easier to use at the beginning or chronic use. There has been no conclusion that a fall has occurred. In addition, long-acting or short-acting benzodiazepines, which are more likely to cause falls, have no clear evidence (Ray et al. 2000). There are not many studies on the association between antidepressant drugs and fall risk in selective serotonin reuptake inhibitor

(SSRI), but a few studies have found that this is used by older generations older than 50 years. The drug may increase the risk of fracture by twice. In the cardiovascular component, vasodilators in blood pressure lowering drugs increase the risk of falls, but a recent integrated study showed that beta-blockers and diuretics are associated with falls. Sex is not significant (Woolcott et al. 2009).

2. Footwear selection
The choice of footwear is also related to the risk of falling. According to a small study, thinner and harder can provide a better balance, but these shoes are generally less comfortable (Robbins et al. 1992). In addition, studies have shown that sneakers have a lower risk of falling than other footwear, but such research has many potential interference factors, because the healthy elderly may wear sneakers more often, so the risk of falling is lower.

3. Environmental factor
Safety measures such as poor lighting, uneven floor or slippery floors, sliding of the carpet, and the absence of armrests and non-slip floors in the bathroom are among the many risky environments that may cause the fall of the elderly. Environmental factors often interact with internal factors, so their importance is often not clearly defined. For example, functional therapists visit elderly homes to improve the risk of falling in the home environment, but because the therapist may It is recommended that older people have better behavior and gait, thus reducing the risk of falls, so it is difficult to study.

2.2 Existing Product Analysis

In recent years, in order to improve the safety and management convenience of elderly people, there are many products on the market that prevent the fall of elderly people. The most common of these is the bed lift alarm. Since the fall of the elderly is mostly caused by the shift of the upper and lower beds, if the elderly can be prevented from getting out of bed, the chances of the elderly falling due to lack of muscle strength can be reduced (Tzeng and Yin 2014).

The representative bed lift alarm product is Smartcaregiver's Falling Monitor, as shown in Fig. 3. Its appearance is the only cushion with a matrix shock detection pressure change. Put it under the cover, the elderly will change from the lying position to the sitting position in order to get out of bed. When the pressure applied to the matrix electric shock disappears, the bed alarm can detect the change and judge the elderly to get out of bed. Actions. However, the matrix electrode may not be able to distinguish the pressure changes of the elderly who are underweight, and the movement of the elderly in the bed often causes the device to misjudge. Table 2 is a statistical table of the research of Kaohsiung Veterans General Hospital. The research shows that the report rate of Fall Monitor is as high as 30%. Frequent false alarms not only make the caregivers exhausted, but also delay the key rescue opportunities in hospitals where every second counts.

Fig. 3. Fall Monitor product image

Table 2. Elderly falling factors

Bed-Exit Alarm	Bed-Exit	No Bed-Exit	Total
Trigger alarm	3717	1687	5395
Untriggered alarm	222	4648	4870
Total	3939	6329	10235

In 2016, in order to reduce the high false positive rate of pressure-type bed-away alarms, the team of Hao Liu of Wuhan University published a related paper (Liu et al. 2016) proposed combining pressure sensor and infrared sensing. The bed-out alarm structure of the device uses the Finite State Machine Method to identify the patient's status based on the sensor data, and then determine whether the elderly person gets out of bed by the transition between states, and sends out the bed alarm through the ZigBee network. In this paper, the influence of sensors installed at different positions on the measurement results is compared. The ideal configuration of pressure sensors and infrared sensors is proposed, and good results are obtained in internal experiments. However, this study did not actually conduct a large number of tests in the hospital, so its accuracy is still open to question. And because the pressure sensor will directly contact the elderly, there are concerns about health problems.

In addition to the traditional pressure is the bed sensor, the team of the University of Adelaide DCRanasinghe proposed in 2014 to remove the bed based on the wearable RFID (Radio Frequency Identification) triaxial accelerometer and RSSI (Received Signal Strength Indication). Alarm system (Ranasinghe et al. 2014). This system detects the current action by detecting the RSS of the mobile home speed and the surrounding antenna by the sensor fixed to the elderly. When it is detected that the posture is changed from sitting to standing, the elderly are getting out of bed, and an alarm is issued, as shown in Fig. 4. Since the sensor uses RFID technology, it can be hunted by the signal of the receiving end (antenna), so no battery is needed. In addition, the system has the advantages of light weight, simple maintenance, low cost, and no inconvenience to activities. However, since the algorithm of the system cuts the sensor data in units of 20 s, it may cause a delay of 20 s in the worst case, and cannot respond to the action of the elderly getting out of bed in time, so it is not suitable for leaving the bed. The application context of the alarm.

In order to improve the above shortcomings, the same team introduced the support vector machine (SVM) into the above system in 2017. The new system classifies the actions of senior citizens by the labels "in bed" and "out bed". The well-trained SVM will determine which tag the elderly person's current action belongs to based on the acceleration and RSSI data collected by the sensor. If the current label is out bed and the previous label is in bed, then it is considered that the elderly person gets out of bed and issues an alarm. Since the improved algorithm processes the sensor data in units of 2 s, the alarm can be issued more instantaneously than in the past. However, the experimental data shows that the system still has room for improvement. The reason is that RFID communication is vulnerable to environmental influences. If obstacles (such as human bodies) are blocked, once the antenna signal strength of the RFID can be inefficient, it will cause the device to fail. working normally. In addition, the two out-of-bed alarm systems proposed by the University of Adelaide require an antenna as the receiving end. Compared to the RFID sensor, the antenna cost is not cheap, and since the RSSI signal is subject to environmental changes, Therefore, if the environment changes, the RSSI data must be re-collected to train the SVM model, so there are still many restrictions on its use.

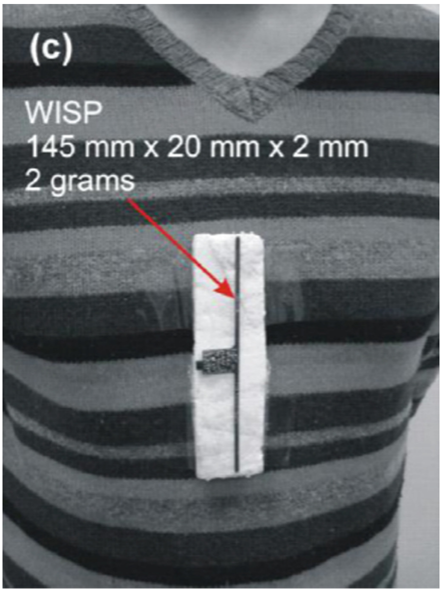

Fig. 4. RFID-based indoor fall detection system

In addition, in 2014, the team of Keio University's Shota Mashiyama proposed an indoor fall detection system based on the low-resolution thermal imager Panasonic Grid-Eye and Arduino. In order to reduce the risk of falling alone and the inconvenience of the current wearable device, the study installed the thermal imager on the ceiling. By extracting the temperature pixel changes, input KNN so that the person directly below is standing or It has already fallen. As shown in Fig. 4, this system has the advantages of small size and low cost compared with the above-mentioned pressure type and wearable type. The appearance of the device is shown in Fig. 4. However, since the device needs to be mounted on the ceiling, it is not easy to use. It can only be done after the fall has occurred, and it is impossible to prevent accidents, so there is still much room for improvement.

In the context of this study, the study aimed at the safety of elderly hospitalization and the burden of reducing caregivers; combined with multiple modules, as well as infrared sensing, ultrasonic sensing and thermal imaging technologies, developed two new models. The bed-off alert system hopes to create a care environment that is friendly to seniors and caregivers. ent will be used by the nurses to do subjective questionnaires and interview evaluation.

3 Research Method

This study will be targeted at elderly or hospitalized patients, and will be divided into observation analysis, design criteria, device design and design evaluation, as shown in Fig. 3. Firstly, through observation and analysis, we can understand the risk factors of falling down caused by the living and living in the ward, and also discuss the living behavior pattern of the patients by cooperating with the nursing teacher. It is aimed at the elderly or patients. The specific behavior of the bed is studied and combined with the literature to propose design parameters and criteria, and the design of the next stage of the device will be carried out. The design assessm

3.1 Observation and Analysis

Observing the behavior of elderly and inpatients is divided into two parts, one is to directly observe the behavior, process or situation of the elderly and inpatients, and the other is to use the semi-structured interview nurses to care for the elderly. For the former to observe the daily living problems, such as: elderly or inpatients want to get out of bed to go to the toilet or get up and walk, the latter through the interview with the nurse to understand the existing hospital care situation, in-depth discussion of elderly or hospitalized The distress and needs of the patient during their stay in hospital. During the process, the effects of different types of devices on training motivation and the social behavior of older patients were observed. In addition, the existing tracking methods were interviewed with the therapist, and the above observations were used for analysis and discussion as design parameters.

3.2 Semi-structural Interviews

Semi-structural Interviews, using the same sentence but in other words, the schema is unchanged, and can be used to guide respondents according to different interviews with different open-ended questions. An in-depth presentation of the topic. For all the questions of the subjects, the words do not need to be the same, only the pre-set questions have the same meaning. If the respondents cannot understand the questions, the visitors can ask the questions again to make the respondents clarify. For sensations that are not easily detectable, such as human feelings and emotions, this method can obtain information simply, effectively and practically, and the data is less likely to be biased and neglected.

4 Expected Results

The expected result of this study is: through the system 1 training system 2, to achieve the prediction of elderly people to leave the bed, rather than the alarm system after the elderly leaving the bed.

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A Grip Force Training and Testing Device for Old People

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Abstract. Grip force is an important physiological index to reflect people's healthy status. In this article, we tried to design a grip strength training and testing device for elderly. Through competitive analysis, we found that products in market are not able to record data, show grip force trend, draw users' attention nor socialize with others. We established old people's persona and investigated their needs, determined product orientation and main functions. Besides, by portraying their daily activity scenes, we found out several service design touchpoint and discussed solutions according to the touchpoint. The devices were eventually used in three communities and get over 100 people's data. We have obtained improvement advice to the equipment, and communities has also increased the fitness activities of residents and the monitoring of the health of the elderly.

Keywords: Grip force · Gamification · Design for old people · Service design touchpoint

1 Background

1.1 Grip Force

Hand, which is composed of joint bones and muscles, is the most flexible organ of human beings. People have to do a lot of work by hand everyday so that the flexibility and grip strength of hands are significant. Grip force is an important physiological index to indicate hand health and work capacity [1]. In addition, grip force has relationship with other diseases, including pneumonia, cardiovascular disease and so on [2, 3]. Therefore, detecting and exercising grip force are necessary for people especially elders.

Nowadays research of grip force includes hand strength and finger strength. The study of the grip strength concentrates on grip force's relationship with population difference, and the strength of hand in different sports states [4]. The study of finger force aims to find out the relationship between different finger force and overall strength [5].

Grip force devices including dynamometers and grip training devices. Dynamometers are mainly used in clinical medicine, professional grip test, post-injury grip recovery test, which need highly testing accuracy. Some studies have engaged to

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improved the accuracy of the grip tester to obtain accurate data at different atmospheric pressures [6]. Besides, comfort is also in designers' consideration. Grip training devices are mainly used for the recovery of the grip of injured people, and the flexibility and grip of hands are practiced through small games. The training devices that can be used at home are shown in Fig. 1.

Fig. 1. Grip force training devices and dynamometers

1.2 Gamification

Games with appropriate difficulty can make player generate a flow of heart, invest in the game, and get happiness. Gamification refers to transformation of systems, services, organizations and activities to obtain similar experiences, motivation and skills as games [7]. Gamification has been widely used in education, healthcare, management, software engineering and so on [8–11].

McGonigal [12] in her book thought that goal, rules, feedback system and voluntary participation were four major components of game. Real time feedback serves to players as a promise that the goal is definitely achievable. In the following research, we use gamification method to design our competitive mode, in which the goal is to get higher rank and the feedback is visual display of strength that appears in real time during griping.

1.3 Design for Old People

There was analysis of apps for old people on Google Play and iTunes. It showed that health and fitness category got the highest rank with a following of medical [13].

Study shows that aging and non-visual feedback will bring decline in grip strength and strength stability control. Besides, elders show difference in dominated hand and non- dominated hand while young people don't have this difference [14]. We can infer that visual feedback and grip exercise can help older people improve their grip force.

Old people are not that good at cell phones as young. At the same time, cell phone use impairs standing postural balance of elderly and young adults. For old people, dialing function causes the largest mobility deterioration [15]. Turning to community has been introduced as a way of thinking about and doing HCI research and design with older people [16]. In community, elders' social isolation is reduced and they will concentrate more about technology appropriation. So in this study, we encourage old people to use grip training and testing devices in community and they can get others' help in phone using.

2 Investigation

2.1 Interview

Interview was chosen as the investigation method. Seven old people in three communities in Hangzhou were interviewed and the question includes subjects' health of hands, whether they have used a grip training device, the evaluation of existing grip exercisers, and the need for a grip training and testing device. At the same time, in order to construct user behavior scenarios, we also asked about the main activity areas and activities of the elderly.

Only one of them have used a grip training device which is very simple and unattractive. Most subjects feel it important to train the grip force of hands and would like to try a new product.

2.2 Community Environment

We investigated three communities in Hangzhou and found that they all had community activities centers, where there were rooms for residents especially retired people to dance, draw and do handwork.

Moreover, community have its own health examination room, including blood pressure test device, grip test device and so on. In addition, doctors and nurses from hospital come to check the physical status of old people regularly. There are also staff and volunteers in every community to help residents in their life and activities.

2.3 Competitive Products Analysis

Shortcomings

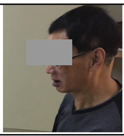
1. There's no device that combines training and testing.
2. Dynamometers are not portable.
3. Dynamometers can not storage data and analysis data.
4. Grip force index is too simple.
5. Grip force training devices are not attractive enough for users to use them long time.

3 Product Orientation and Main Functions

3.1 Persona

According to the investigation, we establish the persona of a typical user. Persona always includes user's basic information and actions from interview and can combine with several interviews' characteristics. This typical image can help designers understand user's mental model and behavior, and better design for the them (Table 1).

Table 1. Typical user's persona

	Basic information			
	Name	Xing Lin	Gender	Male
	Age	67	Occupation	Retired, used to be a driver
Goals	Interesting grip training and testing device; easy for people not good at smartphone to use; offer data simple to understand			
Using Area	Home, community, areas near community			
Social circle	Other old people in community, community workers &their children			

3.2 Product Orientation

Non-professional products, mainly used for daily grip training and simple testing. Target users are middle-aged and older people in the community. After discussion, the name of the product is 'grip ball'.

3.3 Main Functions

1. The grip ball is put in the fixed location of the community, smartphone users can download the app and register by phone number to use the grip ball. Non-smartphone users can use community's public phones to register and practice.
2. Three modes are available: free practice mode, test mode and competitive mode.

In free practice mode, we record user's practicing time, number of griping and average grip force value.

Test mode record user's maximum *grip force value (GF)* of each hand. To insure that users have played their best level, they are forced to grip three times and maximum is used as eventual grade.

The *competitive mode* including grip explosive strength competition and grip endurance competition. *Grip explosive strength (EF)* records grip force value (GF) and the length of time to reach the value(t1).

$$\mathrm{EF} = \mathrm{GF}/\mathrm{t1}. \quad (\mathrm{N/s}) \tag{1}$$

Grip endurance (TF) records the length of time grip force value decaying from F to $F/\sqrt{2}$. (defined according to the characteristics of electronic components) We define t2 as the time *when force value is* $F/\sqrt{2}$.

$$\mathrm{TF} = \mathrm{t2} - \mathrm{t1}. \quad (\mathrm{s}) \tag{2}$$

Competitive mode has ranking lists. And it ranks according to the data. To ensure the timeliness and freshness of the game, the rankings are updated weekly.

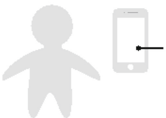
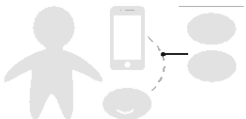
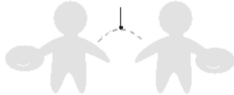
3. The user data and grip strength data are stored by phone and some data is uploaded to the sever. The data is visualized and show in trend graph or other form.

4 Service Design Touchpoints and Interaction Design

Touchpoint is a common concept in service design, especially in commercial scenes [17]. It means the during service, customer's behavior interaction with human, machine, Internet and so on.

After determining the main functions of the grip ball, we established using scenes and found out the service design touchpoints to finish interaction design (Table 2).

Table 2. Using scenes and service design touchpoints

Scene	Register	Connection	Learn to Use
Picture			
Touch-point	Old people are not good at smartphone.	In community, there might be more than 1grip ball ready to connect the phones. And during using, grip ball may disconnect with phone	Old people need easy guide.
Solution	One account to quick switch user	Clear matching way; Detect the connection status in real time and reconnect automatically	Simple and clear UI with voice guide
Scene	Go Outside	Feedback	Social
picture			
Touch-point	Grip ball may discon-nect with phone	Users would like to know the testing result	Users would like to interact with others
Solution	Data storage and recon-nect	Data visualization and the standard grip force under different age, gender, height and weight	Competition is neces-sary

Scene 1. Register. The regular registration is registering with phone number, which is easy to remember and retrieve password through verification code. With a phone number, users can quickly finish the registration by completing their nickname, age, gender and physical information. However, old people may not have a smartphone or they are not good at it. So that we use a *quick registration mode*, in which old people can use the community's phone or their children's phone to register without logging out nor a new phone number. At home, family members can quickly switch the account to use grip ball and Check each other's healthy data (Fig. 2).

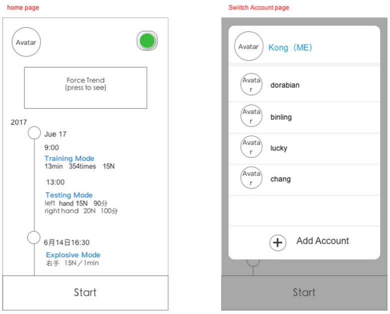


Fig. 2. Simple interaction design pictures of quick switch account. When clicking on the avatar at home page, there will appear a pop-up with account list. User can quickly switch the account by clicking on the aim avatar. If user wants to add new account without logging out, just press the '+' button and finish the information.

Scene2. Connection. Grip ball and phone are connected by Bluetooth and every grip ball has its own code on the body. When there are several phones ready to connect grip balls simultaneously, there is grip ball list for user to choose.

When users prepare to practice or test, they click on the 'start' button and app get to check whether phone's Bluetooth have already turned on. If not, there's an instruction to turn on the Bluetooth and next step is to connect grip ball. If already connected grip ball, the steps are skipped.

During using, grip ball may disconnect with phone and affect the testing or competition. Therefore, during practice, test mode and competition, connection is detected in real time. Once disconnected, there is pop-up to alert the user and for them to choose to reconnect or quit to home page.

Moreover, a small button is set to indicate the connection status. Green means connection, red means disconnection from a connection status when using the grip ball, and grey means grip ball haven't connected or is disconnected by user.

Scene 3. Learn to Use. In testing and competitive modes, users have to test each hand three times according to different test objective. And they have to switch hand after testing one hand. Considering that most users are old people, voice prompts are imported with text instructions. When one step finished, another voice instruction starts.

Scene 4. Go Outside. Users may go outside with the grip ball without phone connection, therefore in the disconnection period, chip inside the grip ball temporarily stores the data. And when users go back to home and reconnect phone and grip ball, data will be transmitted from chip to phone.

Scene 5. Feedback. During or after using grip ball for a while, uses would like to know their training effect and healthy status. So that we record every training, testing and competitive data including time and force value.

During training, testing and competitive modes, data displays in graph according to their value of their force in real time.

After griping, data is shown on the home page. Users can also get their grip force trend by clicking on 'trend' button at the homepage, and they will see grip force trend pictures with time as horizontal axis and force value as vertical axis. Of course, only the best results of the day are showed on the trend picture.

In addition, it's hard for users to know their healthy status only from data. So standard grip force value range under user's age, gender height and weight are offered and a score will be given based on it. Grip endurance and grip explosive strength standards can be formed after getting enough data.

Scene 6. Social. Users' requirements of competition and socialization are realized through competitive mode. After testing their grip explosive strength or grip endurance, the rank list is shown after the data displaying. Only the top 20 scores are shown on the mixed left and right hand ranking. To keep the attraction of the game, rank is cleared every week. If the user is on the list, his or her score is highlighted.

5 Hardware Design

5.1 Product Appearance

The grip device is designed to fit users' hands, so that we used sludge to try different shapes. At last, considering the internal component layout and product proofing, we choose the 'egg' shape (Fig. 3).

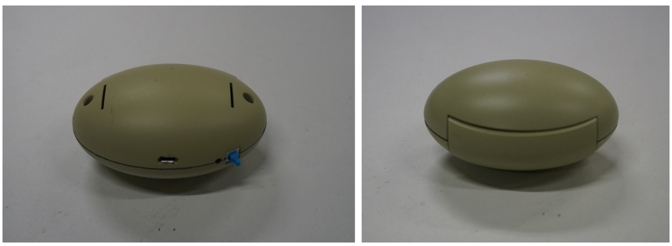


Fig. 3. Grip ball's product appearance

5.2 Structural Design

As shown in Fig. 4, the grip ball includes a left outer casing 8, a right outer casing 6, a force receiving plate 1, a light emitting unit 3, a power switch 4, a battery 7, a development plate 5, and a pressure sensor 2.

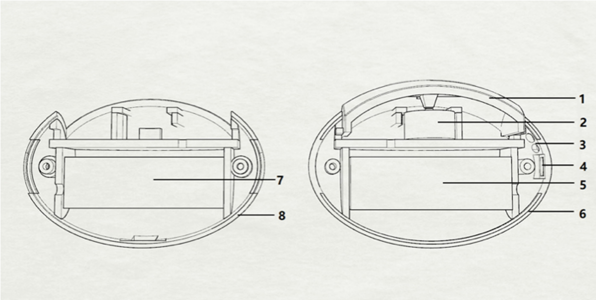


Fig. 4. Grip ball's structural design

The left outer casing 8 is connected to the right outer casing 6. Between 8 and 6, there are force plate 1, light-emitting unit 3 and power switch 4. The force plate 1 is in close contact with the pressure sensor 2.

Pressure sensor 2 is used for detecting the grip strength. And light unit 3 is used for displaying the battery power and the Bluetooth connection status. Besides, pressure sensor 2 and light unit 3 are connected to the single chip 5 through the data line. Meanwhile, battery 7 connected to the power supply terminal of the single chip 5 to supply power for it. The built-in Bluetooth module can communicate wirelessly with the mobile phone. The light-emitting unit 3 includes a three-color LED light 3-1, different colors indicate different power levels. And there is a green LED light 3-2 indicates whether the Bluetooth connection is successful.

The working principle of the grip ball system is that when the user uses the grip ball, the mobile phone sends a signal to the grip ball through Bluetooth, and single-chip microcomputer 5 in the grip ball starts to select the working mode after receiving the Bluetooth signal. When user presses force plate 1, pressure sensor 2 detects the pressure signal and transmits it to the single-chip microcomputer 5 through the data line. The single-chip microcomputer 5 transmits the signal to the mobile phone app through the Bluetooth after the signal processing, and stores the data in the sever for competitive ranking.

As shown in Fig. 5, it is a working principle diagram of the circuit of the present invention. As can be seen from Fig. 4, the circuit of grip ball is mainly composed of four parts: a power switch 4, a light-emitting unit 3, a single-chip microcomputer 5, and a pressure sensor 2. The pressure sensor 2 detects the pressure signal, the lighting unit 3 displays the working state of the grip ball including battery remaining amount and Bluetooth connection. Single chip microcomputer 7 controls the data running of all components and performs data interaction with the mobile phone app.

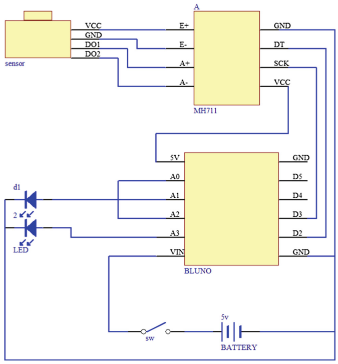


Fig. 5. Working principle of single chip circuit

6 User Interface Design

The user interface design style is defined as simple and clear. Dark blue is chosen to be the background color which can fit the sedate style of elderly. According to the interaction design, user interface design is accomplished (Fig. 6).

Fig. 6. Three user interfaces of grip ball

7 Application

The devices were eventually used in three communities in Hangzhou, Zhejiang for three weeks and we got 294 people's data. 39% of them are female and 61% are male. Figure 7 shows user data interface of explosive strength in server, which stores user's id, time and grip force value. In Fig. 8, it's obvious that residents between 60–70 are our main users. Through average using times figure, we can see that users seem to prefer to use competitive mode and testing mode. However, the average using time is low. This may because for management, the staff required that grip balls were only used in the communities and were not allowed to be taken away.

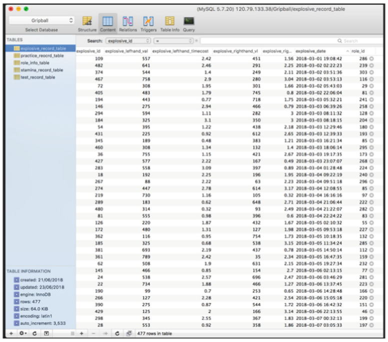


Fig. 7. User data interface of explosive strength in server, including user's id, time and grip force value

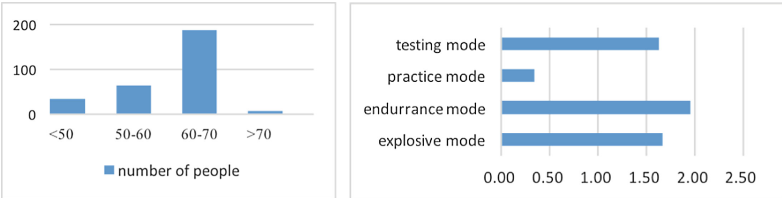


Fig. 8. User age distribution and average using times during different modes

In addition, we have obtained improvement advice to the grip ball, and the communities have also increased the fitness activities of residents and monitoring of the health of the elderly.

Advice. (1) The material of grip ball can change from plastic to silicone, which is more comfortable to grip, and shape change will give better feedback to users. (2) Besides competition of explosive strength and endurance, designer can add more interesting games.

8 Conclusion

By investigating the residents and environment of the community, researchers established persona and using scene. And accomplished interaction design, hardware design and UI design for old people. The grip balls were eventually used in communities and got user's data.

In the next study, we are ready to improve from three aspects. Firstly, the material of the grip ball will be improved, which is more comfortable for users. Secondly, after obtaining more grip data, the relationship model between user's physiological information and the grip strength value will be established. Thus users will be provided with reference and scoring results in testing and competition mode to infer their health status. Finally, we will develop more interesting gameplay to attract users.

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Optimized Design of Accompanying Smart Car for the Elderly Based on Humanization Design Methods

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Abstract. The aim of this paper is to design accompanying smart car for elderly people, it is not just a tool to assist them more appropriate to travel but also reducing their psychological burden. This paper uses the method of user-friendly theory and human factor engineering theory. Through observation, interviews and literature analysis, this paper analysis the travel needs and characteristics of studied group deeply. Through market research, the advantages and disadvantages of related product is obtained. As result, considering the design orientation mainly from four aspects of shape, structure, color and ergonomics. In conclusion, this paper introduces the design of companion intelligent vehicle of short distance, and discusses the connotation of elderly-friendliness in product design and its relationship.

Keywords: The elderly · Smart car · Humanization design · Psychological burden

1 Introduction

At present, intelligent travel tools for the elderly are mainly intelligent wheelchairs, and wheelchairs generally cause psychological discomfort to them. In order to solve this problem and ensure elderly users' travel demands, the smart car and the smart wheelchair are combined and designed to provide a stylish, easy-to-use accompanying smart car for the elderly as viable solution. It will not only be a mode of transportation, but more importantly, the elderly users can use the smart car to carry out physical exercise and participate in social activities, which can help the elderly to communicate with the people better and reduce the burden of psychological inconvenience.

Through literature analysis, it has been found that there are many related researches on smart wheelchairs. The structure and composition module have mature technologies. However, research aimed at the elderly segment is less frequent, and even less frequent is the investigation about the needs in term of shape for those products. Discover through market research, the old scooter products are numerous, and the brand competition is fierce. There are also aesthetic problems, with unsmooth or unappealing shapes, and functional ones, with diverse deficiencies. There are vacancies of assisted walking, short-distance travel in the product market for the elderly and older people.

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1.1 Analysis of Travel Needs of the Elderly

The study shows that the purpose of the elderly travel is mainly leisure and entertainment, accounting for 53.1%; the travel mode is mainly based on taking public transport and walking, 48.4% and 43.1% respectively; the travel destination is mainly open public places such as parks, squares, roadsides, community supporting fitness areas, accounting for 55.3%; travel distance is 0.5–1.5 km away from home, accounting for 24.2%; activity duration is mainly 60–120 min, accounting for 27.9% [1]. With the increase of age, the decline of physical condition, the reduction of motorization level, the dependence of the elderly on walking tools is increasing, but electric cars and motorcycles are no longer suitable for the elderly.

According to the survey, the types of injuries suffered by the elderly mainly include abuse, age discrimination and accidental injuries. Among them, falls accounted for the largest number of accidental injuries. The main causes of falls were physiological dysfunction, disease, physical environment and other factors [2]. In order to prevent such situations, there is a functional need for protection, hazard warning and post-injury alarms.

The causes of death in the elderly are mainly malignant tumors, cerebrovascular diseases, respiratory diseases, heart disease and various physical diseases. Therefore, it is particularly important to strengthen the monitoring of physiological parameters of the elderly in daily life.

The mechanical memory of the elderly is obviously reduced, and they tend have bad memory effect on numbers and names. However, the elderly's recognition of images and cognitive memory decline is not obvious [3]. Therefore, in the interface design of the elderly mobility aids, existing knowledge and experience should be incorporated to improve the recognition and understanding of information.

1.2 Definition of Accompanying Smart Car for the Elderly

Older walkers refer to tools that maintain balance, support muscle strength, and assist walking in older people with limited limb movement [4]. Mainly divided into three categories: one-arm operation walker, two-arm operation walker and wheelchair.

The Intelligent car is a result of the combination of the latest technological achievements such as electronic computers and the modern automobile industry, and thus "comprehensive". It usually has automatic driving, automatic shifting, and even has the function of automatically recognizing the road [5].

The elderly accompanied by smart cars is one tool that combines the latest scientific and technological achievements to improve the basic functions of assisting the elderly to walk, and try to reduce psychological burden to the elderly.

1.3 Related Work

The early development of smart wheelchair for the elderly has been given low-level controls such as simple motion, speed control and obstacle avoidance. With the development of technology, smart cars incorporate modern robot control technology and robotic mobile technology on the basic requirements. Intelligent electric tool which helps users and the disabled have better interactivity, adaptability and autonomy.

In 1996, the intelligent wheelchair developed by the French VAHM project had three operating modes: automatic, manual and semi-automatic. When the user selects the automatic mode, the computer on the wheelchair can realize path planning and navigation, and control the autonomous movement of the wheelchair to the target position selected by the user; when the manual mode is selected, the wheelchair moves according to the operation instruction of the user; in the semi-automatic mode, the user can Choose between intelligent control and manual control [6].

In 1998, the smart wheelchair called WHEELESLEY, researched by the MIT Intelligence Lab, have three controls of menus, joysticks, and user interfaces. In the menu mode and joystick mode, the wheelchair user can make use of the joystick to issue a direction command to avoid obstacles. In the user interface mode, the user can use the eagle eye system to control the wheelchair only by eye movement [7].

The multi-functional intelligent wheelchair system developed by the SIAMO project in Spain adopts the modular design principle. According to the difference of the user's degree of disability, the intelligent operation bar, voice and head motion recognition, respiratory control and electro-optical signal drive are designed [8].

In 2007, Scewo is an electrical wheelchair able to climb stairs. Moving on the ground is accomplished with a Segway-like system by balancing on the two main wheels. The stairs are climbed using two rubber tracks mounted on the bottom of the chair [9].

The TAO Aicle intelligent wheelchair developed by AISIN Seiki and Fujitsu in Japan can automatically avoid obstacles and move to the destination. In outdoor environments, data can be collected through acquisition equipment on smart wheelchairs. To transfer and monitor wheelchair movement status, provide traffic information for users and provide path management functions [10].

In 2016, Whill is another revolutionary design of new electrical chairs with new specifications and better innovations, such as the inclusion of a mouse controller, instead of a joystick. The front wheels are multi-directional, giving the advantage of a 4-wheel driving chair that can go through grass, snow and rough surfaces [11].

Although the research on intelligent wheelchairs in China started late, it has achieved certain research results in recent years. For example, the multi-modal intelligent wheelchair prototype developed by the Institute of Automation of the Chinese Academy of Sciences; the intelligent wheelchair Luoson-III researched by the Chung Cheng University of Taiwan; the intelligent wheelchair designed and developed by Shanghai Jiaotong University [12].

2 Design and Demonstrate

2.1 Existing Product Analysis

According to the research and analysis of the walker market of the aged, it is found that smart cars are mainly divided into wheelchairs and electric bicycles. According to the number of rounds, they can be divided into three-wheel, four-wheel and crawler styles.

Analysis shows that the style of the smart car can be divided into stable, portable, fashionable, public. Red as the mainstream color, accounting for about 63%, and less common colors like white, blue, yellow, green, in descending order.

Through card method and inductive analysis of some existing products in markets, the four styles of stable, portable, fashionable and popular are obtained, and the vertical axis and the horizontal axis are marked; the color of the color area indicates the main color of the product, and the size of the color area represents the representative proportion (Fig. 1).

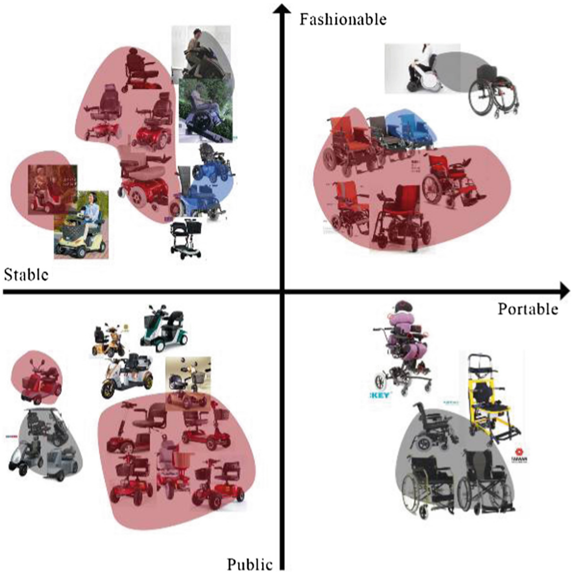

Fig. 1. Positioning map of existing elderly scooter.

Analysis of the existing products in terms of categories, styles and colors found that wheelchairs can be operated with one hand, have simple and comfortable operation, can up and down stairs, and generally no shopping baskets; electric scooters generally have shopping baskets and can travel long distances, but inconvenient to store, not suitable for the elderly.

Stable style is wide and thick overall, and has a sense of security and a large volume. Portable style is light and small, generally it has a folding function, which can save space; the fashionable style has a smooth and beautiful body line, and the visual impact and interaction are strong; The public function is clear and easy to understand.

The three-wheeled scooter is lighter overall, and the four-wheel type is more secure. The crawler type is convenient for up and down stairs, divided into a push type and an electric type. The former has a long back and requires extra assistance. The electric type can be operated by a single person and outdoor activities are easier.

2.2 Ergonomics Analysis

The human body parameters required to accompany smart car for the elderly are mainly divided into two parts: standing and sitting size data. The basic size of the elderly is obtained by consulting the literature [13], and according to the application method of the human-machine size, the 95th percentile and the first 5th percentile is used as the basis for the upper and lower limits of the size to obtain the standing and sitting dimensions of the elderly, as shown in Table 1. Since the above data is generally measured naked or in a single coat, it is necessary to increase the amount of function correction, that is, the human-machine size of the elderly accompanied by the smart car = the old man's percentile + function correction amount, and the final size data is shown in Table 2.

Table 1. The elderly standing position and sitting position size percentile.

Size measurement project	Female(5th)	Male(95th)
Height	1425 mm	1761 mm
Shoulder height	1157 mm	1481 mm
Elbow height	845 mm	1118 mm
High hand function	544 mm	789 mm
Hand width	245 mm	361 mm
Sitting height	753 mm	929 mm
Sitting deep	406 mm	492 mm
Sitting shoulder height	489 mm	660 mm
Sitting knee height	395 mm	528 mm
Sitting elbow height	194 mm	301 mm
Sitting hip width	332 mm	418 mm

2.3 Design Strategy

After research, the older scooter products are abundant in the market, and the brand competition is fierce. There are also problems about the product shape is not being smooth and appealing, and its function being still insufficient.

In view of these problems, through the humanized design concept, according to the behavior habits, physiological structure and thinking mode of the elderly, on the basis of the basic functions accompanied the smart car of the elderly, Rethinking and optimizing design in terms of function, shape, man-machine, material, usage, color, etc. To achieve the convenience and comfort of the elderly, to meet the travel and aesthetic needs of the elderly.

In the end, the product positioning of this article is safe, environmentally friendly, fashionable and beautiful, convenient and easy to use. Use of modern technology to provide quality travel services for the elderly with the smart car optimization design. The population is located between the ages of 65 and 85, and elderly people who need short-distance or longer-distance travel activities, and those with mild mobility disorder who need assistance. The function is positioned as manned storage, walking assistance,

Table 2. Man-machine size of accompanying smart car for seniors.

Size project	Man-machine size
Body length	1300 mm–1500 mm
Body width	500 mm–700 mm
Body height	900 mm–1100 mm
Pedal height	160 mm–200 mm
Handle height	780 mm–820 mm
Handle diameter	25 mm
Sitting height	360 mm–420 mm
Sitting deep	394 mm–509 mm
Sitting width	361 mm–450 mm
Handrail height	254 mm–284 mm
Dashboard tilt	30°

up and down stairs through electricity, voice timing reminder, alarm help, physiological monitoring, voice interaction and so on.

2.4 Design Scheme and Comparison

The drawing of creative sketches is an important and basic part of product design. According to the design and positioning of the smart cars as defined above, use modern design methods of brainstorming, mind mapping, reverse thinking, learning creative flexibility to fully expand and divergent thinking, and display it on paper through design tools (Fig. 2).

According to the man-machine size obtained above, the four sketch schemes were modeled with modeling software, and the functions, modeling, materials, color, sizes of sketches were compared and analyzed.

The first sketch has rich functions, such as up and down stairs by electric, physiological monitoring, alarm for help, etc. Arc curve support structure and Orange chair, simple and smooth. The red-light band is at the same time a warning and a recognition. Large volume is inconvenient in pass the public field or go out shopping; Lockers are small and have limited capacity.

The second sketch has fewer functions, such as manned storage, long-distance travel. Adopts the seat form of small car and the modelling is concise. The red body gives a warm feeling of happiness. It is also inconvenient in pass the public field or go out shopping. Large storage compartment for more items.

Sketch 3 has less functions, like manned and placing items, up and down stairs by electric. Orange seats with blue lattice design have more fashion sense. Small size access to public field, go out shopping is more convenient.

Sketch 4 has fewer functions, storage, electric up and down stairs, handrail assistance. Using traditional Chinese patterns, there is both a sense of style and nostalgia.

According to the study, some key words of the elderly companying smart car were extracted, and the user survey and statistical analysis were conducted to obtain the results, as shown in Table 3. Final sketch 1 was selected as the final option (Fig. 3).

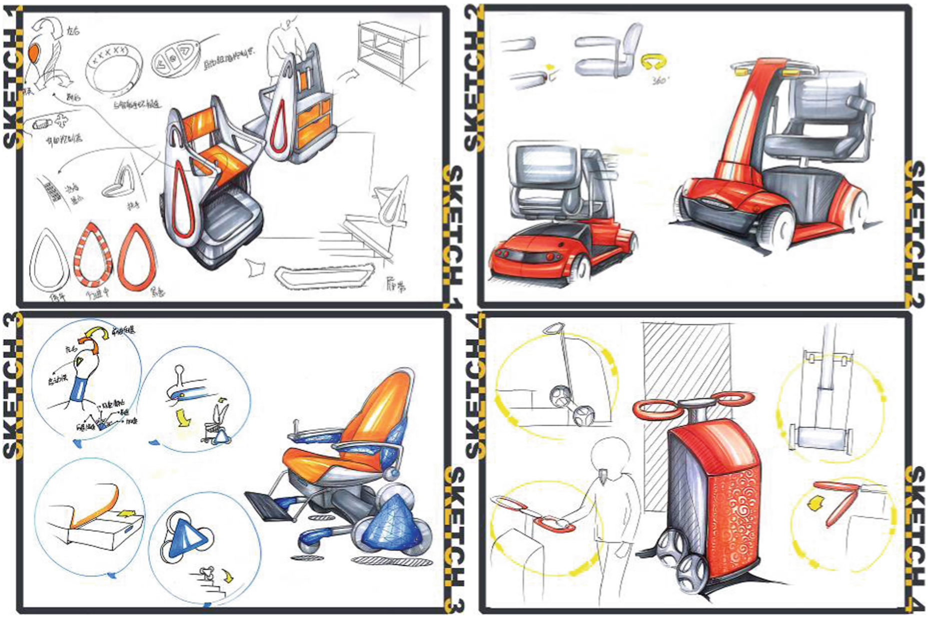

Fig. 2. Four design sketches selected and deepened from creative ideas.

3 Results

3.1 Modeling and Color Analysis

Considering that the elderly lack long-lasting endurance, standing up requires the upper limbs and leg strength. Therefore, it is necessary to reduce the physical exhaustion during use. It is also essential to meet the aesthetic needs of the elderly, and to keep the shape beautiful and concise.

The final scheme design renderings show that the final scheme has three modeling elements: “fashion”, “simple” and “smooth”. On the whole, its basic modeling semantics is a circular support structure. This styling concept is derived from the tumbler. Characteristics of the tumbler swinging around bring about the left and right rotation in the design, so that the elderly can ride or stand on the accompanying smart car, and become the supporting structure in the scheme.

The body line has a simple curved structure, and the lines at the track pass through the smooth curve and the tough line, which makes the whole look sporty. At the same time, the orange decorative line runs through the whole body, which is a more harmonious and stable model (Fig. 4).

3.2 Function Analysis

According to the investigation and analysis, under the premise of satisfying the basic functions of manned storage and electric climbing, physiological monitoring, voice

Table 3. Function analysis of the accompanying smart car of the elderly.

Function	Figure	Function analysis
Manned and placed		As the basic function of accompanying by smart car of the elderly, manned storage not only meets the needs of the elderly to assist in rest, but also meets the needs of the elderly to carry goods with them. The main placement position is shown in the figure, the space formed on the left side and the backrest armrest; the drawer under the seat; the footrest.
Electric climber		The crawler type is safer and gentler, saving the physical strength of the elderly to carry objects and climbing stairs.
Cloud transmission service		Through the association of app, the physiological monitoring data of the elderly can be transmitted to the electronic device to understand the long-term changes of the body; besides, with the relevant equipment, the function of alarm help and voice reminder can be achieved.
Travel assistance		To raise the seat to a suitable angle so that the upper limbs and legs are less stressed to assist standing. The elderly is also allowed to walk through the design of the side armrests.

timing reminder, alarm help and other functions are added according to the design positioning. Specific function analysis is shown in Table 3.

3.3 Detail Analysis

The control handle is a square mouse shape, which fits the curve of the hand of the elderly, so that the upper limbs of the elderly naturally fall on the handrail. Simple swing operation makes the elderly operate more comfortable. It is decorated with orange lines and is consistent with the overall shape.

The seat is dominated by orange vertical stripes, contrasting with the blue, adding a sense of stability to the bright. The seat surface can be lifted upwards to provide the necessary assistance for the elderly to stand up. When the maximum angle is reached, a space is formed with the backrest and the armrest for storage. There is a drawer at the seat that can also be used to place items.

The compartment and the seat surface are designed as a whole, the shape of the arc is coordinated with the whole, and the edge of the drawer panel is decorated with decorative lines to enhance the recognition.

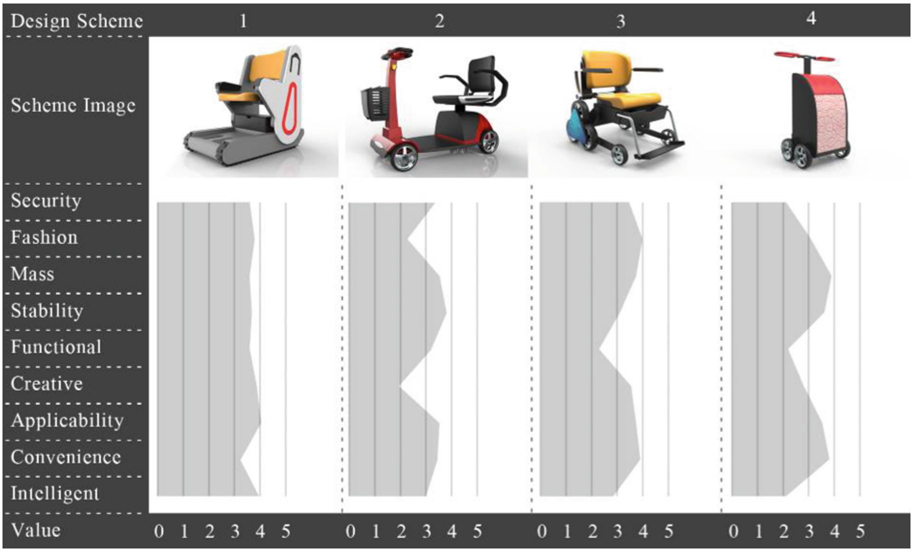

Fig. 3. Extract some keywords of the elderly accompanied by smart cars, conduct user surveys in a certain community and analyze the statistical results (point value is 0-5, a plus sign indicates a point).

Fig. 4. Final scheme's design rendering.

The arc-shaped support structure can be rotated left and right to balance it when going up and down the stairs, and to provide a more comfortable seat and standing angle for the elderly. The side of the arc is decorated with decorative lines to make the sides have a layered feel, and different materials also make the shape more abundant.

The side light strip is a transparent engineering plastic shell with LED light-emitting material embedded in it. The red light is bright and conspicuous, and there are two kinds of light display states. The red light is slightly bright - driving, red light flashing - warning.

The U-shaped handrail on the side stretches the side curve to make the overall shape harmonious. The rounded armrest on the back can be fully turned up to provide support. Signs and decorative lines are printed on the back of the chair.

The taillights are sturdy and eye-catching, and are divided into red and yellow lights to provide warnings during parking and foggy weather.

3.4 Ergonomics Analysis

According to the human body size parameters, the front seat width of the seat is determined to be more than 390 mm, and the sitting depth is 380 mm–440 mm.

The back length is larger than 280 mm, the anticline angle is between 90°–97°, and the seat angle is between 0°–2°. In addition, according to the elderly body size parameters and corrections. Calculating the height of the seat, it should be between 429 mm–450 mm.

In order to maintain the stability and safety of the accompanying smart car, the angle of rotation of the arc is from −32° to 55°. Generally, the slope of the stairs ranges from 23° to 45°, and the suitable slope is about 30°. The rotation angle of 32° increases the stability when climbing stairs. In general, the height of the step is 15–17 cm, and the pedal height is inconvenient in the elderly, so the pedal height should not be greater than 15 cm.

3.5 Environment Analysis

When you are outdoors, there are two main driving conditions. One is that user sits on the smart car and carry out one-handed driving. The armrests on both sides provide walking assistance for senior partners and increase communication between the elderly. The second is that the elderly stand on the accompanying smart car. By manual operation, the speed of accompanying the smart car is faster, which can help the elderly reach the destination more quickly (Fig. 5).

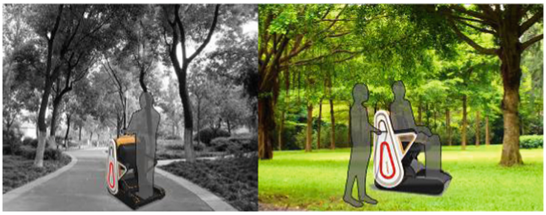

Fig. 5. Two main driving conditions. One is standing on the smart car with faster speed, other is sit on the smart car and perhaps with senior panters.

4 Discussion

The accompanying smart cars of the elderly as a means of transportation for the elderly and one of the bridges to increase communication between the elderly. It is helpful for the elderly to maintain their physical and mental health. The characteristics and research results of this topic are summarized as follows:

Based on the humanized design, this paper proposes the design of the accompanying smart car to meet the actual needs and psychological needs of the elderly to the greatest extent, based on the requirements of user needs, sensibility engineering, ease of use, safety and health, to achieve human emotional care to the aged.

Through the analysis of travel demand for the elderly and market research of related products, the existing products are optimized and designed to produce a safe, environmentally friendly, fashionable, convenient and multi-functional elderly car.

This thesis is an exploration based on the trend of aging and humanized design. This paper still has many shortcomings. First of all, the design works of this proposal do not in-deep understand the needs of the elderly, the characteristics of materials and the processing technology, and the structure of the products. Secondly, the ease of use and safety of this work are not perfect. In addition, the elderly population in different regions and the use of products in different environments are not well understood.

In the future research, we can design a more reasonable product by deepening the understanding of the attributes of the elderly and elderly products, deepening the understanding of the product material and structure processing technology, the elderly groups in different regions, and the use environment.

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Design and Strategy of Senior Tourism Under the Background of Population Aging

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Abstract. The world is facing a serious problem of population aging. The research of senior tourism not only can effectively alleviate the urban population expansion, but also can promote the development of the economy in small and medium-sized cities. The main problem of current senior tourism is that single function cannot meet the cultural, medical, life and production needs of old people. A new strategy of senior tourism is proposed with actual design case. The new strategy of senior tourism would put tourism, culture, entertainment, medical, and other functions together. It will extend the elderly industrial chain and integrate different resources.

Keywords: Population aging · Senior tourism · Strategy design

1 Introduction

1.1 Background

With the development of medical technology, people can live a healthy and long life. But the world is facing population aging. According to the latest demographic statistics, China is in the process of population aging with the largest scale in the world. The number of people over 60 years old exceeded 212 million in China in 2015, accounting for more than 15% of the total population.

According to the Market and Population Analysis of Peking University, by 2025, the potential market purchasing power of the aging population will reach 1.4 trillion respectively due to the rapid economic development and continuous expansion of the aging population. However, as the elderly demands change, and the tourism market develops further, new problems gradually emerge. For example, one of the new trends in senior tourism is that old people start to try slow-moving. But the current senior tourism industry does not design products and travel routes according to the physical needs and characteristics of the elderly.

1.2 Research Objective

Based on the analysis of the development situation of the existing senior tourism bases, this paper puts forward the development ideas of senior tourism strategy. The construction of senior tourism strategy can avoid the problems in the existing senior tourism bases and promote the development of the elderly-care industry and tourism industry.

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1.3 Research Significance

The significance of senior tourism can be divided into social and economic aspects. From the perspective of society, the aging population makes the elderly care in cities increasingly serious, especially the safety of some empty-nest elderly. In particular, for the normal elderly, due to the implementation of birth control, a couple generally must take care of and support four parents, but many children do not have much time to accompany the elderly because of their jobs. Therefore, the elderly need to walk out of the house and adopt a new lifestyle to make up for the lack of family companionship.

From the perspective of economy, changes in the elderly-care concept make senior tourism develop faster, which makes the elderly economic industry in cities occupy a huge market space, and the elderly economic industry will play an important value and gain huge economic benefits [1]. The senior tourism mode is also an important opportunity for the development of tourism industry.

1.4 Research Scope

Some conditions shall be met for the elderly to choose senior tourism as their way of elderly care. First, the main target group is the elderly who are young and healthy. Secondly, people who choose senior tourism are mostly the elderly with relatively rich material conditions and high requirements for retirement life. Finally, the elderly will live in the area for at least half a month. Having time and no burden of taking care of grandchildren are also the important conditions for choosing senior tourism. In general, our main target population shall have good health, a certain amount of savings, enough time and a little travel experience.

In terms of selecting the residence for senior tourism, the place with characteristic conditions and customs shall be selected. This paper takes Lijiang, Yunnan with the Naxi nationality characteristics as a research example.

2 Literature Review

In the studies on senior tourism, the mainly-used theories include Continuity Theory, Intergeneration Theory, Life Cycle Theory, Motivation Theory, Theory of Planned Behavior and Leisure Constraint Theory. Continuity Theory is mainly used to explain that senior tourists' tourism characteristics and behavior patterns change less after growing older and tend to maintain consistency. However, according to the Life Cycle Theory, although the behaviors of the elderly tend to maintain consistency, their psychology and behaviors change due to the changes in their life cycle, which brings different travel behaviors. Leisure Constraint Theory is mainly used to explain the influence factors which restrict the travel of senior tourists, but the Motivation Theory is mainly used to explain why the senior tourists travel, which is the most widely-used theory by researchers. At present, there are few applications of Life Cycle Theory and Intergeneration Theory.

2.1 Perspective of Age

After applying the Continuity Theory to the senior tourism, Nimrod pointed out that the tourism characteristics and behavior patterns of senior sojourners in the same intergeneration tend to maintain consistent with the previous ones as they grow older [2]. According to the Intergeneration Theory, Chen and Shoemaker analyzed that the elderly who are at the same life stage but belong to different generations will have different tourism behaviors and characteristics because their psychological and behavioral characteristics formed by the unique social and historical environment of each generation are different [3]. After applying the Life Cycle Theory, Chen and Shoemaker also point out that aging will change a person's physical condition and hinder the elderly from engaging in some travel activities that they used to like when they were young, such as high-risk activities, which will lead to psychological and behavioral changes.

2.2 Perspective of Motivation

Alen et al. applied the theory of motivation, which usually includes push and pull motivation. Push factors mainly refer to the internal tourism demand of individuals, while pull factors mainly explain the attraction of destination [4]. Gardine et al. applied the Theory of Planned Behavior to explore the behavioral intentions of senior tourists [5]. After analyzing the factors influencing the motivations of older people's senior tourism in Taiwan, SooCheong (Shawn) Jang, Chi-Mei Emily Wu and other scholars believed that knowledge acquisition, safety and health are the most important [6]. After comparing the user portraits of the needs of elderly sojourners in Taiwan and the mainland, Wang and other scholars concluded that the elderly in Taiwan pay more attention to the contents of tour guide, accommodation, meals, transportation and scenic spots while the elderly in the mainland pay more attention to introduction materials, catering and tourism programs [7].

2.3 Perspective of Senior Tourism in China

China's theoretical research is still in the initial stage, the concept and division are still in the discussion stage. Li pointed out that in the process of population aging with the largest scale in the world, China's elderly-care mode is developing toward the diversified direction of mainstream elderly care, institution elderly care, senior tourism and so on, and believed that the lifestyle of the elderly in China will definitely become more diversified [8]. Li pointed out that the social background for the development of senior tourism in China is the demographic structure, family structure and class structure at the current stage [9]. Under this circumstance, the elderly are provided with feasible plan for the senior tourism in different places. Through the field investigation on the elderly in two communities in Beijing, Jiang Xiangqun et al. analyzed the differences in the needs of the elderly with different age structures, cultural structures and economic conditions for the senior tourist. Zhou argued that the main lifestyles of the elderly include migratory birds, ecological health, elderly living groups, elder-care tribes, rural elderly care, and chain replacement of different places [10].

Therefore, a new senior tourism mode is an important way for the transformation and upgrading of senior tourism. The new senior tourism mode integrates tourism, elderly care, culture, leisure and entertainment, medical treatment and other functions. Senior tourism enterprises gather horizontally, integrate vertically and extend the elderly industry chain with multiple subjects.

3 Method

First, searching the theoretical and basis of senior tourism. Second, comparing the cases and finding out deficiencies. Then, the hypothesis of the new mode of residence is proposed. And the interview method is used to verify the hypothesis. Finally, applying the new model of senior tourism through a practice.

3.1 Research Tools

Literature Research. Theoretical research mainly summarizes the literature and books to clarify the progress of relevant research on senior tourism and also provides theoretical support for the research.

Interview. The in-depth interviews are used to further understand the user needs and verify the hypothesis of new mode.

Practical Application. Taking the transformation of the senior tourism base in Yunan as an example, the empirical study analyzes the specific ideas for the construction of new senior tourism mode.

3.2 Hypotheses

Combine Residence with Tourism. Different from ordinary tourists, the elderly who choose senior tourism usually live here for more than 20 days. Therefore, the long-term living needs of the elderly shall be taken into account in the planning.

Social Contact and Love. According to the activity theory in Psychology, people's self-consciousness comes from social activities, and they can achieve self-satisfaction through the roles in these activities. However, after retirement, most of the elderly suddenly lose their important working roles in the society, which makes their social scope reduce rapidly. In order to make up for the loss of these activities, the elderly definitely will try some recovery activities, so as to create some new roles to supplement themselves and improve the satisfaction of elderly life. Therefore, senior tourism can create an effective way for the elderly to actively participate in social activities, establish new roles and improve their life satisfaction.

Personalized Development. The personalized needs of the elderly have become the characteristics and commercial power of senior tourism. Therefore, the place for senior tourism shall be designed for meeting the hobbies of the elderly and promoting social activities.

3.3 Interview Verification

Interview Design. This paper selects four elderly people in Shanghai loving tourism for interview, and the questions are mainly divided into the user's basic information (age, gender, degree of education, marital status, living status, occupation before retirement), family members and the relationship (number of children, whether do they live together, how often do they contact their children, occupation and income of their children), physical condition, pattern of consumption, traveling preference, (tourism frequency, selection of tourist destination) and so on (Table 1).

Table 1. Basic information of interviewee

Age	Gender	Educational level	Economic status	Physical condition	Child status
82	Male	Bachelor	Medium	Well	Independent
75	Female	High school	Medium	Well	Independent
64	Male	Bachelor	Medium	Well	Independent
58	Female	Bachelor	Medium	Well	Independent

Needs Summary. From the interview, the key factors which the elderly pay attention to when choosing senior tourism are summarized. It reflects their demand for the residential area, such as basic eating and sleeping needs, water and electricity security needs, etc. According to Maslow's Needs Pyramid, it can be analyzed that residence for senior tourism shall meet the following needs: 1. Basic physiological needs of users such as meals, toilet, shower and bed. 2. Security needs such as water and electrical safety and anti-skid floor in the guest room, medical examination for the elderly, first aid and so on. 3. Social needs of elderly users such as companionship and a sense of belonging. 4. Self-esteem needs such as personalized service for users; 5. Self-actualization needs such as cultivation and development of their hobbies. These requirements from the interview can be used as a basis for later practical application.

Needs Classification. At the present stage, some elderly people who like traveling have a relatively low demand for residence because the sojourn residence especially for middle-aged and elderly users has not been popularized in China. At this stage, the ordinary senior tourism mode mainly meets the physiological needs and security needs of the elderly users. The new senior tourism strategy shall meet their social needs, self-esteem needs and self-actualization needs, help users adapt to the elderly life, establish new social roles and improve life satisfaction, which works in connect with the hypothesis put forward in the beginning of preamble.

The needs of the elderly can be divided into two categories. One category is basic needs: including physiological needs and security needs. The other category is high-level needs, including social, self-esteem and self-actualization. The basic needs are reflected in the residential area and must be met as the most basic norm. The satisfaction of high-level needs has become the source of the service characteristics of each residential area.

4 Construction and Exploration of New Strategy

4.1 Living Mode of Courtyard Style

The living space is planned reasonably according to the needs of the elderly, and the concepts of inner courtyard and outer courtyard are put forward. Inner courtyard is mainly for two pairs of elderly people who know each other, or the elderly people who live with their families. Outer courtyard is mainly for old tourists who do not know each other.

Inner Courtyard. The suites of inner courtyard are mainly designed for two pairs of elderly people whose relationship is the relatives by marriage or the colleagues before retirement. This type of travelers wants to live together under the same roof but have their own private space.

The inner courtyard is divided into two separate bedrooms, bathrooms and a public living room and kitchen. Therefore, the inner courtyard is suitable for a long-term residence (Fig. 1).

Fig. 1. Schematic diagram of suites in inner courtyard

Outer Courtyard. Due to the reduction of social scope caused by retirement, the elderly need to increase the opportunities to interact with people in daily life. In the planning and design of the residence, it is necessary to create many opportunities to contact and communicate with others for the elderly, so that they can meet new friends.

The suites in the outer courtyard are mainly designed for 3 or 4 pairs of elderly people who do not know each other. The spatial structure like the quadrangle courtyard in Beijing is more conducive to the communication among people, and the four families can live here like a big family. In Lijiang, the architectural form of the Naxi nationality is also very similar to that of the quadrangle courtyard, which mainly includes three rooms and a screen wall. The revolution is made according to these two forms, so, the form of outer courtyard is proposed.

The suites in outer courtyard integrate the concept of neighbors and patios in the traditional residence into the design. A living space which can provide elderly tourists with opportunities to make friends and socialize is designed. The elderly can enter public patio from a corridor corner, and 3 or 4 guest rooms enclosure the patio (Fig. 2).

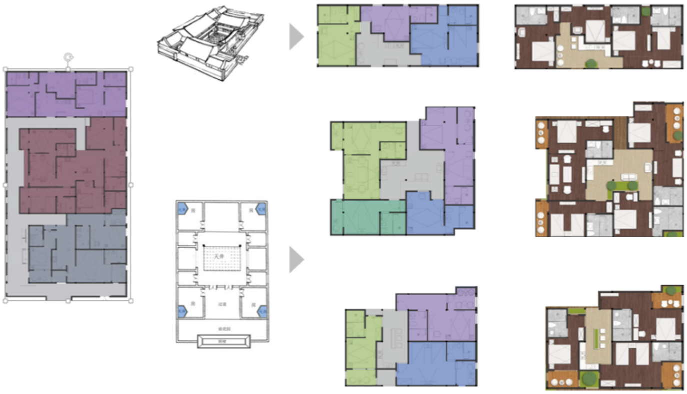

Fig. 2. Schematic diagram of suites in outer courtyard

Accessorial Function of the Residence. When some elderly people go out for travel, children will often come to visit and accompany them, so beds for children are set in some rooms. Besides, some old people hope to set a living room for inviting friends, so a few guest rooms are equipped with a separate living room.

The elderly all love being close to nature. Some space is reserved for indoor green plants, so that there are green plants at every corner, ends of every aisle and every public space. Tourists can feel natural greenery at any time during the process of walking indoors.

4.2 Interactive Development of Interests and Hobbies

In the literature review, it was found that the elderly pay attention to the exploration of their spiritual world after retirement and usually stick to their own interests and hobbies, which shall be considered in the new senior tourism mode. Therefore, a multifunctional activity room, leisure tearoom and other public space are set in the residence.

In the multifunctional activity room, calligraphy, Beijing Opera, movies and other activities are held regularly. Besides, the multifunctional room can be used as the activity room for Tai Chi, square dance and so on after moving the chair into the storage room according to the needs of elderly tourists.

The leisure tearoom is equipped with a skylight on the top, and two indoor green plants are planted at the corner. The leisure area mainly provides a natural and comfortable place for the elderly tourists to read books and newspapers, chat and drink tea, which is a semi-enclosed space and separates the relatively noisy reception area from the dining area.

4.3 Self-service Safety and Health System

Full Safety Precautions for the Residence. Safety is the most basic requirement for the living environment of the elderly. Therefore, Full safety precautions for the residence can minimize the occurrence of safety accidents. For example, gas stoves and other kitchen wares with an open fire are replaced by induction cookers in the kitchen. Emergency call box system is installed in every guest room, so that the elderly can get help through emergency call in case of danger. In terms of easing the burden on the actions of the elderly, horizontal armrests are set in the corridor and at the corner, and the skid-proof materials are used for floor tiles or floors of the toilet to meet the requirements of skid resistance. The armrests are set beside the toilet for the elderly to save a lot of strength while standing up.

Simple Instructions. The elderly who are not familiar with the environment also can understand how to escape quickly by seeing simple instructions. The clouding patterns are put on the armrests of the residence, and the elderly can find the safety exit and entrance by following the direction of clouding pattern in case of danger (Fig. 3).

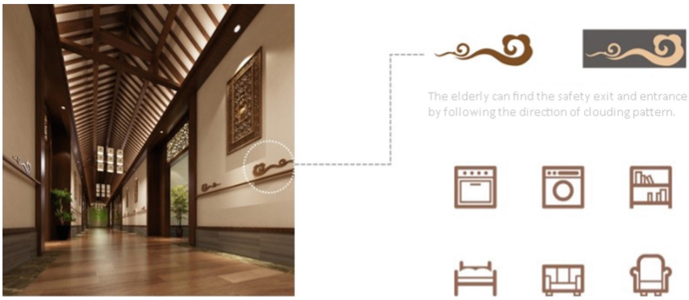

Fig. 3. Signs for the elderly

Health Care Center. The Health Care Center is emphasized in the design because several bases for the elderly in China cannot retain users due to the lack of medical facilities. Compared with the young people, with the original intention to cultivate body and spirit, the elderly pay more attention to their own physical health. Therefore, the Health Care Center is an important guarantee for the health and safety of the elderly.

4.4 Regional Culture Edification

Three Levels of Decorative Style. The decorative style of the residence is divided into three levels. The first level emphasizes standardization for the old people with weak adaptability. The second level introduces local materials and decorations for the elderly who like characteristic styles. The third level is to make the elderly fully experience the local lifestyle of the Naxi nationality (Fig. 4).

Fig. 4. Effect figure of residences at the first level, second level and third level

Local Entertainment. Local folk custom experience activities are held regularly. Teachers of handicraft, gardening, tea ceremony and so on are invited to conduct on-site teaching, so that tourists can experience local culture and the regional economic development can be revitalized.

4.5 Operation Concept of 'Independent Self-esteem, Cultural Sunset'

Because senior tourism is a complicated systematic project involving tourism, accommodation, life and a large number of people and institutions, so the operation management shall be emphasized specially. The operations management system is the guarantee for the normal operation of the senior tourism complex. The report of the 19th National Congress of CPC directly pointed out that "the aging population shall be dealt with actively, and the policy system for elderly care and the social environment shall be created" and put forward the theory of 'active population ageing'. In addition to the investment, the investor shall also be responsible for the training of staffs, brand publicity, market development and so on. At present, there are few professional staffs for elderly care, which requires investors to specially train the staffs in the senior tourism complex. At the same time, the senior tourism is not accepted widely, so the investment group needs to change the elderly-care concepts of people through various publicity activities, make more elderly people choose senior tourism, explore the market for senior tourism, increase brand awareness, advocate the concept of 'independent self-esteem, culture sunset' and promote the prosperity of elderly industry.

5 Conclusion

There are many problems in the existing senior tourism which must be transformed and upgraded. The existing problems mainly include single function, failure to meet the needs of culture, medical care and leisure, disunity of resources and high construction cost.

A new senior tourism strategy is an important way for the transformation and upgrading of senior tourism. It integrates tourism, elderly care, culture, leisure and entertainment, medical treatment and other functions. Senior tourism enterprises gather horizontally, integrate vertically and extend the elderly industry chain with multiple subjects. The integration of tourism resources and elderly-care resources require the cooperation among many parties. The new senior tourism strategy shall be planned and constructed from sightseeing, health care, residence, culture, operation management and security guarantee.

Although a series of progress has been made in the study of residential care for the past ten years, compared with other groups, the academic community has not paid enough attention to the study of senior tourism, especially in China.

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Design of Waist Wear Products for Warm-Up Training for the Elderly

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Abstract. With the increase of the elderly population, the health status of the elderly is widely concerned. This paper takes the safety of the elderly during the exercise as the main research content. Through field interviews, the demand during exercise and living conditions of the elderly were investigated, and the effect of point massage on prevention and treatment of exercise fatigue was studied by studying a large amount of literature. Finally considering the physiological characteristics of the elderly, the sports needs and the potential safety hazards during the exercise process, the corresponding product design and interface design are proposed.

Keywords: Elderly population · Sports injury · Acupoint stimulation · Product design

1 Research Background

As early as 1999, China has entered the ranks of an aging country. The advent of an aging society puts forward higher requirements for the universal design of various products [1]. However, product design and interface design related to the elderly population are still relatively rare in China [2]. How to maximize the satisfaction of the needs of the entire public and enable the elderly to use the products equally as ordinary people is a question worthy of our serious consideration. For the elderly, if they exercise in an inappropriate way, it is prone to sports injuries such as joints, ligaments, muscle strains and even fractures [3], On the one hand, we should pay attention to the sports needs of the elderly, encourage them to actively participate in physical exercise, and also try to prevent possible safety hazards during the exercise.

2 Research Content

2.1 Field Research

In order to understand the causes of sports injuries in the elderly, field observations and interviews were conducted. The survey location is in Shun feng Mountain Park, Foshan

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City, Guangdong Province. The main research object is the middle-aged and elderly people involved in exercise. Their age range is between 45 and 75 years old. And the survey line is the north entrance to the west entrance of Shun feng Mountain Park. The research methods used are observation, recording and interviewing. The investigation took a total of five weeks, during which three days were not investigated due to weather. We divide the research work into three phases, as shown in Fig. 1.

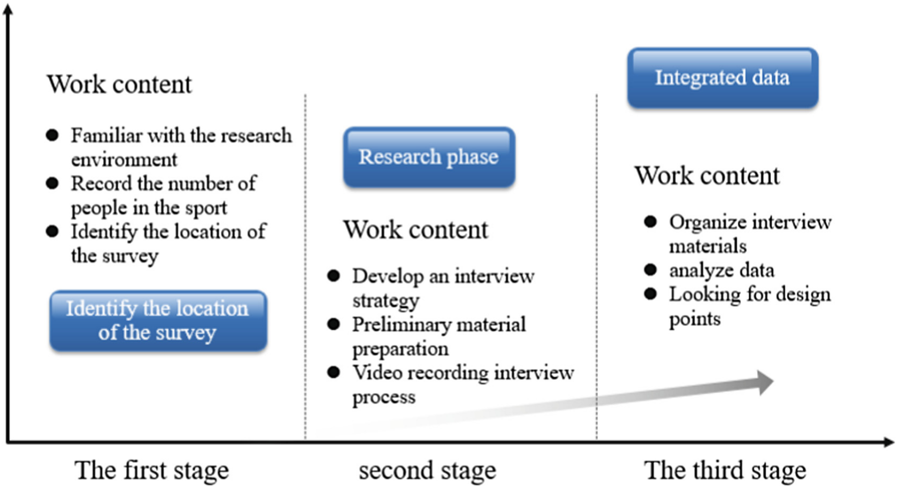


Fig. 1. Field research arrangements and progress

The first phase took four days. We mainly did the following work, familiarized with the park environment, observed and recorded the main locations, narrowed the scope of investigation, and finally determined the China's first archway and Qing long Pavilion. West Entrance Station and Taiping Mountain are the follow-up observation interview sites, as shown in Fig. 2.

The second phase is the core part of field research and takes 25 days. We conduct observations and interviews at identified research sites. The most important task at this stage is to record the interview process by video and audio recording. Get valid data related to sports injuries in the elderly. In order to get more effective and real information from the respondents we sorted out the interview questions before the survey, as shown in Table 1.

The summary of the second stage observations is shown in Table 2. From this, we found that there are the following eight types of fitness methods for the elderly in the park.

Then, relevant interviews on the research of this topic were started, and the results are summarized in Table 3.

The third stage team members spent two days to integrate the data obtained from the previous research, analyze the needs of the elderly during the exercise, in order to provide direction for the subsequent product design. And the main exercise parts as shown in Table 4. It can be found that the most involved part of the exercise is the lumbar vertebrae, knees and ankles.

Fig. 2. Location of the investigation in Shunfeng Mountain Park

Table 1. Summary of interview questions

	Early problem preparation
1.	Basic conditions such as age, occupation, physical condition, and living conditions
2.	What are the difficulties in the movement?
3.	Whether the sports location is a fixed sports venue？
4.	What are the daily ways of participating in sports?
5.	Which type of exercise is preferred ？
6.	What measures have been taken to prevent sports injuries?
7.	Are you taking measures to relieve muscles after exercise?

In further interviews, the following five points were found to cause sports injuries. (1) Lack of adequate or correct preparation activities. (2) The wrong way of exercising. (3) Poor physical condition. (4) High-intensity exercise. (5) Other reasons, including sports venues, weather conditions, sports equipment and so on. The corresponding preventive measures are proposed. (1) Pay attention to warm-up preparation before exercise. (2) Arrange training intensity reasonably. (3) Perform muscle stretching after exercise.

Table 2. Average number of participants in various sports modes

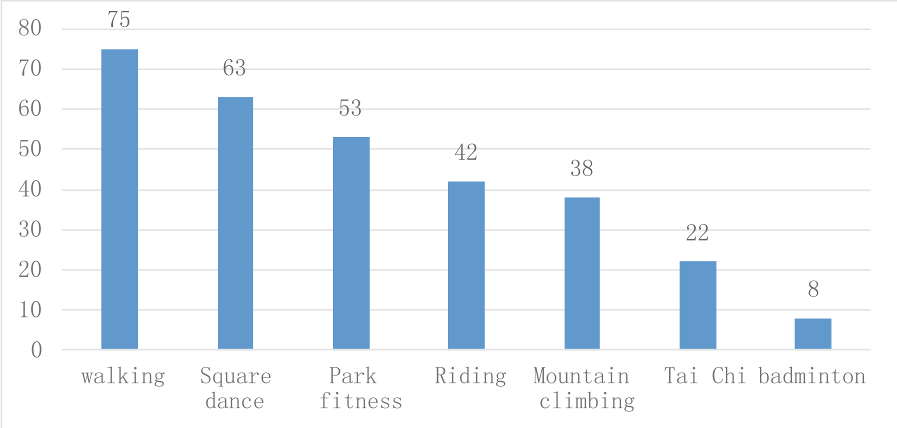


Table 3. In-depth interview results

Content	Question	Interview situation
Physical conditions Sports condition	Physical condition, living condition	High blood pressure, overall health
		Suffering from rheumatic joints, slow movements, unfavorable legs and legs
		Weak and sometimes feel dizzy
	Difficulties encountered during exercise	It's hard to stick to it when I start learning square dance
		My family is a little worried when I go out alone
		I can't keep exercising for a long time
	Have there been any sports injuries?	I am a retired athlete, and I have lots of physical problems
		I have fallen because of the slippery ground, it is quite serious, I lived in the hospital for a few days
		There are dizziness and heat stroke in summer
Psychological needs	What kind of experience do you hope to have during the exercise?	Improve the safety of sports
		Let family don't worry too much
		Guided instruction in sports

Based on the results of field observations and interviews, three types of representative elderly groups were integrated. The character card was created as shown in Table 5.

List of functional requirements (as shown in Table 6)

Table 4. Analysis of the most engaged fitness methods

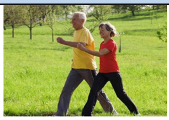
Fitness method	Sports characteristics	Main exercise site
 Walking	The action is simple, it will not cause serious damage to the bones.	Back muscles, buttocks muscles, lower limb muscles, slow muscle fibers, arm muscles
 Square dance	It can be carried out in parks, squares and other open spaces at any time. And the rhythm is strong.	Waist, leg, arms, wrist Knee joint, ankle joint
 Outdoor fitness path	Use the low threshold to exercise to all parts of the body, effectively strengthen the muscles	Leg muscles, arm muscles, waist muscles, back muscles
 Riding	Need to prepare for riding equipment, there are certain requirements for physical strength and endurance.	Arms, shoulders, buttocks, waist and abdomen, leg muscles

Table 5. Analysis of Persona Cards

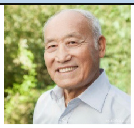
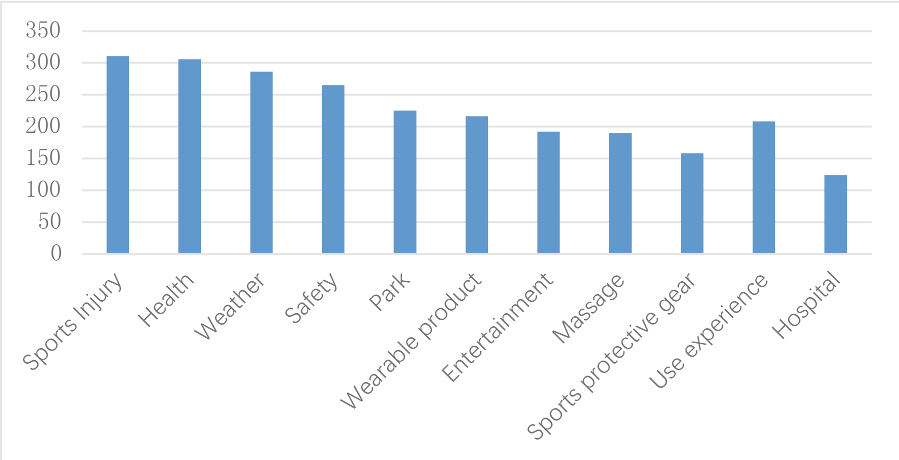
User role	Characteristic	User behavior	User goal
 living alone	The physical condition and safety of the elderly living alone are the most important issues to be concerned	After breakfast, go for a walk in the park. Go fishing in the farm when you are free	Passing time and maintain good health through exercise,
 living with family	Cheerful, like to go to the elderly activity room usually need to pick up and drop off children to go to school	take granddaughter k to fly kites. go to the orchard to pick fresh fruit.	Exercise body and enrich life while caring for the family's daily life.
 physical inconvenience	Life can't be completely self-care, and it needs help from going out.	Go to the park after dinner	Restore physical function

Table 6. List of different user role requirements

	Elderly living alone	Elderly living with family	Elderly with poor health
Safety requirements	1. Weather reminder 2. Health tips 3. One-click help		1. Care needs 2. Accompanying needs
Other demands	1. Social needs 2. Contact with neighbors and juniors	1. Time schedule 2. Matter management	1. Physical function recovery 2. Rehabilitation training

Table 7. High frequency topics in interviews



According to the preliminary research data, the high-frequency words and topics in the interview process are shown in Table 7.

3 Product Concept (As Shown in Fig. 3)

3.1 Function Definition

It has been found from the previous research that lumbar muscle strain is the most common type of body injury at present, It is preliminarily supposed that the hardware products are smart wear products for the waist, the waist wear product needs to meet the following four functions. (1) Prepare for exercise. (2) Display the user's physical condition during exercise. (3) Emergency help. (4) Point massage.

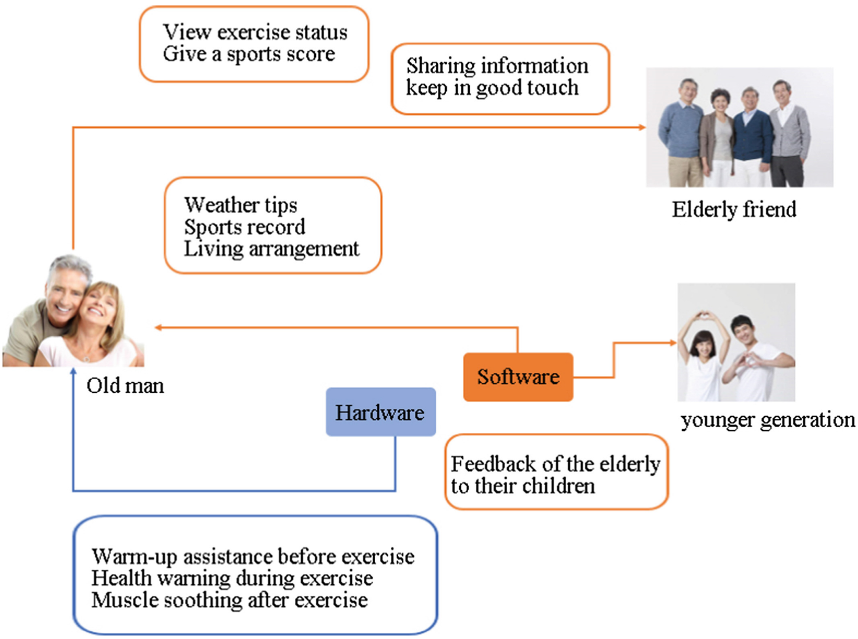


Fig. 3. Product composition and function concept

A larger proportion of older people's expectations for smart wearable products are not limited to security features, so further analysis of user needs is listed below. (1) Weather forecast (2) Social function (3) Time planning, (4) Sports health assessment.

4 Design Points

Older people prefer "lightweight, minimalist, soft" wearable products [10], so the products need to bring more intimacy to the users in terms of shape and material. At the same time, the control and feedback methods should be as simple as possible to minimize the learning cost of the elderly.

In the design process, it is necessary to take the elderly as the center of research and follow the principle of easy learning. Elderly have difficulty in identifying small fonts and buttons. Word No. 8-12 is more suitable for older users' font size [4].

5 Design Presentation

Product three view is drawn as shown in Fig. 4. The two sides of the product used highly flexible silicone material, It can be adjusted within a certain range according to the size of the elderly's waist.

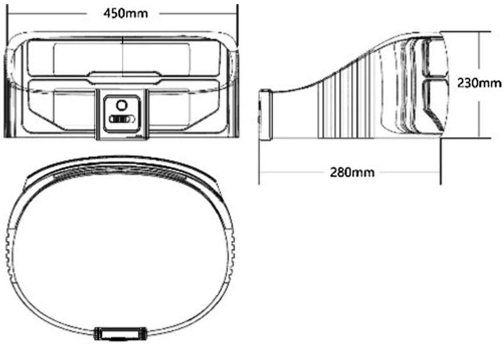


Fig. 4. Hardware product three views

The product is connected to a magnetic material, as shown in Fig. 5. The principle of heterosexual attraction can be used to fix the product to the user's waist. The user usage scenario is shown in Fig. 6.

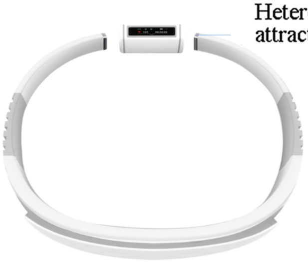


Fig. 5. Hardware product wearing principle

Fig. 6. Hardware product usage scenarios

The side of the product that comes into contact with the skin is a soft, grainy material, as shown in Fig. 7. In addition, the product is equipped with a massage ball and an electric induction plate. As shown in Fig. 8, when the electric heating module detects the position of the acupuncture point, the massage ball at the corresponding position will be massaged. Design the switch of the product into a red button that is easy to find.as shown in Fig. 9.

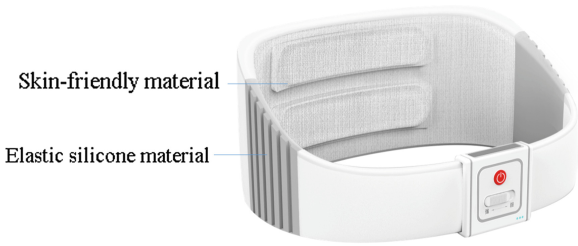


Fig. 7. Application of product materials

Fig. 8. Product internal structure

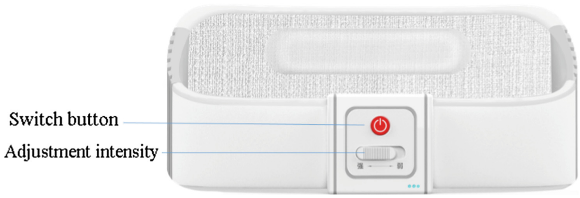


Fig. 9. Product control method

The white part of the back of the product is a certain hardness ABS material, as shown in Fig. 10. It can give the spine a certain support to avoid the amplitude of the overload of the lumbar spine during exercise. And the gap left in the middle ensures the flexibility of the user when using the product.

The product displays the detected body parameters on the electronic screen. As shown in Fig. 11, the user can look at the motion data when he looks down, which can better ensure the safety of the exercise.

According to the concept of products and services and the needs of the elderly, the content map of the mobile APP is drawn, as shown in Fig. 12. The visual effect of the interface is shown in Fig. 13.

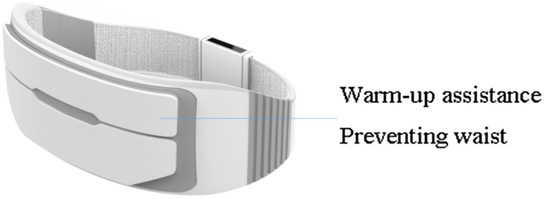


Fig. 10. Product details display

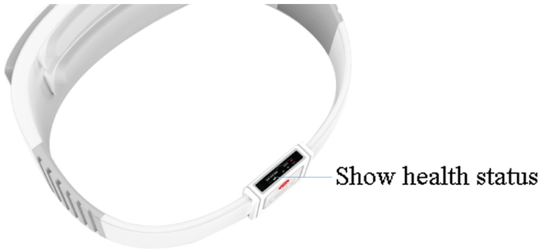


Fig. 11. Product details display

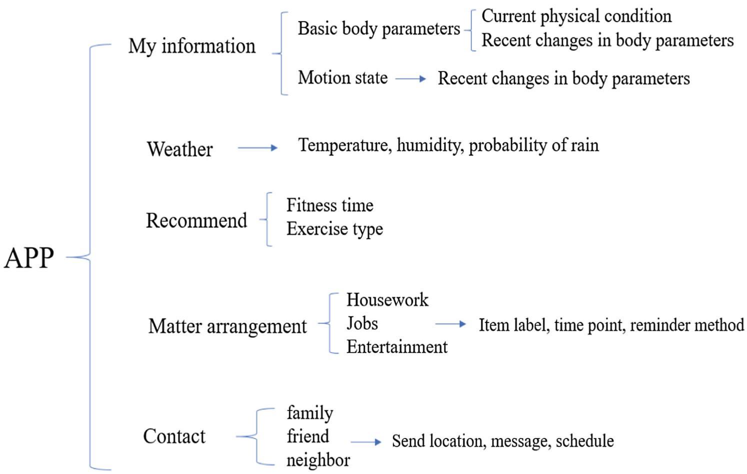


Fig. 12. Mobile APP content architecture

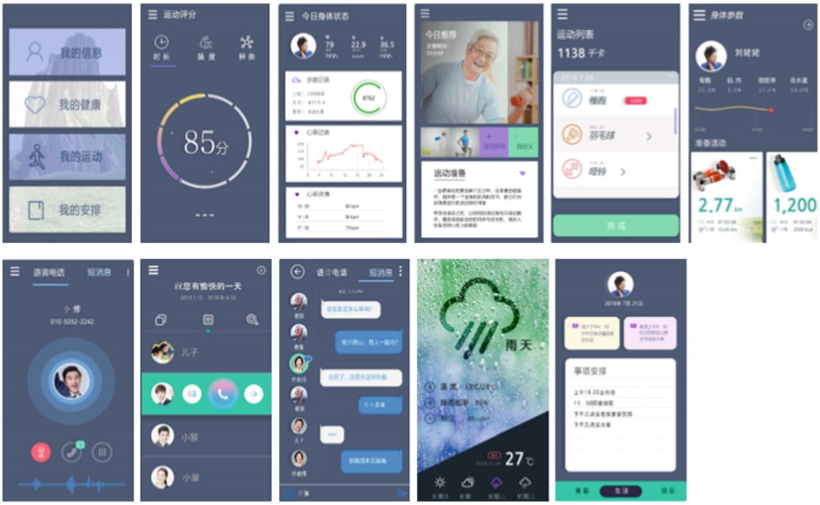


Fig. 13. Mobile APP visual display

6 Conclusions and Recommendations

The elderly is still very weak in the prevention of sports injuries, which is one of the important reasons for the frequent sports injuries of the elderly. In the process of product design, we comprehensively consider the safety hazards that may occur before, during and after sports. We hope that the combination of hardware and software can provide better services for the elderly's fitness and entertainment.

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Measuring Ways Research on Public Facilities of the Elderly's Physical Flexibility

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Abstract. This research took the old people aged over 60 in southern China as the example, first discussed the physical conditions of the elderly and the problem raising in fitness test, Then make an overview according to the research status and the classification and the problems of the measurement ways for elders' physical flexibility. The physical conditions of the elderly were learned by tracking their living behaviors. By analyzing the corresponding conditions of outdoor living behaviors and body conditions, the needs of the elderly for measurement of physical flexibility were extracted, which were qualitatively analyzed by combining with Kano model. Finally, the design direction of the public facilities of physical flexibility of the elderly is obtained.

Keywords: The elderly · Physical flexibility · Kano model · Behavioral analysis · Measurement way

1 Introduction

According to statistics, at the end of 2017, there were 240.9 million people aged 60 and over in mainland China, representing 17.3% of the total population. China's aging population has a large elderly population base, China's economic development, social stability has brought great challenges.

The maintenance of the body softness of the elderly to the elderly exercise and daily life ability to bring some benefits, good soft quality can enable the elderly to maintain good muscle elasticity, to prevent muscle stiffness and muscle strain, reduce sports injury has a good role. However, there are very few studies on the body softness of the elderly over 60 years old in China. Since the tools for measurement have not been improved, the improved method based on the flexibility measurement of adolescents is not particularly suitable for the elderly. According to the characteristics of the activities of the elderly, older people will have more spare time to outdoor activities after retirement, while socializing, which can bring positive psychological mood and improvement of physical conditions to the elderly at the same time.

According to the outdoor activities and physical condition of the elderly, this study hopes to provide some soft measurement of the body to meet the physical and psychological needs of the elderly design direction of public facilities.

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2 Literature Review

2.1 Health-Related Physical Fitness and Physical Flexibility

The concept of Health-related Physical Fitness derives from Physical Fitness. The WHO (World Health Organization) defines physical fitness as an individual who, in addition to coping with daily work, does not feel overly tired and has the ability to enjoy leisure and emergency response. In the 1970s, the ACSM (American College of sports Medicine) suggested that fitness includes 'Health-related Physical Fitness' and 'Sport-Related Physical Fitness' [1].

Health-related physical fitness is an essential physical health quality in daily life work for the general public, healthy physical fitness refers to the quality that has a special effect on improving health and preventing certain diseases, including human composition, muscle strength endurance, cardiopulmonary endurance, flexibility; maintaining a good level of health-related physical fitness, and prevent accidental falls, etc., in reducing the incidence of disease in the elderly, improve the quality of life of the elderly, and reduce the cost of health care to bring effective help. Therefore, we should pay more attention to the health fitness project for the elderly [2].

Among them, physical flexibility refers to the range of human joint activity and the elasticity and stretching of joint ligaments, tendons, muscles, skin and other tissues, that is, the area of activity of joint and joint systems.

2.2 Influencing Factors of Physical Flexibility

Liu [3] from the anatomical point of view, the physiological factors that affect the flexibility of the body include: the microstructure of the joint surface, the size of the activity depends on the structure of the joint itself [3]. On the one hand, affected by innate genetic factors, on the other hand, also affected by acquired training factors, such as muscle size, fat accumulation and other factors will affect the development of physical flexibility.

Yu [4] and other scholars believe that muscle work during exercise produces a lot of calories, which can reduce the rubbing force and viscosity of muscle and ligament tissue in exercise, and strengthen the ductility and improve the flexibility of the body [4].

According to the above research, physical flexibility can be cultivated through physical exercise and gradually raised to a certain level.

2.3 Measurement of Physical Flexibility

According to the NHC (National Health Commission of the People's Republic of China) issued, <2017 China Health and Health cause Development Statistics Bulletin>, life expectancy per capita in mainland China reached 76.7 years in 2017. At the same time, China has only begun to pay attention to the study of the physique of the elderly for more than 1998 years, and has now carried out 3 large-scale physical fitness testing work, but the implementation of the test is mainly 60–69 of the elderly [5]. Because of the lack of indicators and evaluation criteria for physical fitness testing over 70 years of age, there is little research on the physical fitness of this group and even the measurement of physical flexibility, and it focuses on the flexibility of the lower extremities.

The measurement of physical flexibility shows more of the ability of the human joints to exercise in different directions, as well as the ability of muscles and ligaments to stretch. Up to now, the measurement methods of physical flexibility are: sit-and-reach and its improvements, back hook of both hands, shoulder-raising test, prone back extension.

The measurement and evaluation of physical flexibility applicable to the elderly in China is a single-legged sitting front flexor, which is proposed by Cailliet (1988) [6].

However, this test method still characterizes the angle index by length index, and the data obtained represents the overall physical flexibility, but it does not completely overcome the influence of body shape factors such as upper limb length, sitting leg length, sitting shoulder peak and so on to measure the effectiveness of physical flexibility.

Wang (2017) believes that the physical flexibility of the elderly over 70 years of age should be collected in front of the seat of the physical flexor muscle, hand hook two measurement data [2]. Two data can indirectly reflect the range of activity of the whole physical muscles, ligaments, torso and lower extremity joints, as well as evaluate the flexibility of the shoulder joint, indirectly reflecting the elasticity of the entire physical muscle, ligaments and the range of activity of the upper limb joints.

The flexibility of the waist, domestic and foreign scholars often use the posterior flexor bridge method, prostrate tilt method, the position of the anterior flexor method, the above several methods have the participation of waist movement, can be used to measure the flexibility of the waist. But the range of action is too large for the average elderly, and there is a risk of falling, so generally will not appear in the elderly physical flexibility test.

ADL (Activities of Daily Living) is an important complement to the study of physical flexibility in the elderly, and the results of this evaluation system are particularly important for older or frail elderly people [7]. In the ADL-centric interview questionnaire, the SF-36 scale (the Medical Outcomes Study 36-Item Short Form Health Survey) is currently a healthy survey tool for multi-country translation and application. The survey covered daily activities that require physical fitness, lower limb muscle strength, endurance, flexibility and so on in daily life, including even the investigation of heavy physical activity. In China, SF-36 is mainly used in the field of clinical medicine to evaluate the health status and quality of life of patients, but also for the health status of specific groups of social surveys. Liu (2001) have shown that the SF-36 scale is basically applicable to the evaluation of the health status of the elderly population in our community [8].

3 Investigation of Physical Condition and Behavioral Activity of the Elderly

This paper selects the Huanghuagang People's Park in Guangzhou Yuexiu District as the research site of the behavior activities of the elderly. Huanghuagang People's Park belongs to the large memorial Park, the surrounding residential quarters, near the configuration of a number of large general hospitals, family structure is mostly trunk families, resident elderly more, and the surrounding no other large public leisure areas, so the nearby residents are mostly concentrated in Huanghuagang Park for leisure activities and physical exercise.

Video statistics were conducted to track the behavior of older persons and to conduct indiscriminate random interviews with people aged 60 who were willing to be surveyed. The observed subjects themselves have independent self-care ability, good health status, with the ability to engage in general physical activity, good quality of life. The selection of location is itself a place for social leisure activities, so most of the elderly have strong social interest, good social skills and good mental health.

The physiological function is the main reason that affects the quality of life, such as the elderly relatively slow response to the elderly, more need to assist travel tools, and the aging of the age caused by the decline of the physical function related. The above situation is similar to that of Zhou [7] using SF-36 Scale to investigate the quality of life of the elderly in Guangzhou area [9].

Video is set up at the main entrances, trunk roads and activity gathering points of Huanghuagang Park to observe the types, intensity and characteristics of outdoor activities in the elderly. A total of 902 elderly people, including 489 men and 413 women, were observed, and the overall gender distribution of the elderly in the park was balanced. Specific categories are shown in Table 1.

Walking is the most basic and highest frequency activity for the elderly. Most of them need to go to the market to buy food, and the use of small trailers and other tools to reduce the weight of women is the majority, which is related to women's physical strength is lower than that of men.

Walking stops at any time standing and chatting is more of a woman's favorite thing to do, but there is some stretching during walking, regardless of male or female sex.

To carry out high intensity of jogging activities and strength training, to the younger age of the elderly mainly, and the majority of men. Participation in ballroom dancing, square dance crowd is mostly middle and low age elderly, for the aggregation of group activities, basically women, the action is mostly gentle tilt, swing, reflexive and rotational action, moderate activity intensity. The elderly involved in Tai Chi sports are old age, mainly by acting alone, this slow and uniform circle movement with a waist-centered speed is low, and can exercise the ability to coordinate the whole body well.

Men are more found of individual activities, women are more involved in gathering activities, but they all like desktop chess games.

Table 1. Activities of the elderly in Huanghuagang Park

Activity type	Men	Women	Total
Walking with its classification			
Normal walking	297	223	520
Pestle crutches	4	12	16
Load (buy food)	63	55	118
Load (back the baby)	3	1	4
Load (backpack)	14	13	27
Push wheelchair	2	1	3
Push the pram.	27	22	49
Drag Shopping Cart	2	9	11
Stretch while walking	11	13	24
Jogging	21	5	26
Watering the flower	1	0	1
Weeding	1	0	1
Driving an automatic wheelchair	1	0	1
Standing and chatting	0	8	8
Sitting and chatting	4	3	7
Half-body push-ups	1	0	1
Tai chi	2	6	8
Square dancing	0	17	17
Ballroom dancing	2	6	8
Sketch	0	1	1
Desktop chess games	19	14	33
Stand and watch the board game	10	4	14
Bird watching	4	0	4

4 Analysis of the Needs of the Elderly in the Measurement of Physical Flexibility

4.1 The Requirements for Measurement

The user's needs are determined by the user's behavior [10]. Combining Dai (2007), description of motivation and action in life: the user's internal motivation is hidden in the external behavior [11], if the user's internal needs are satisfied, then they show a positive evaluation of the surrounding products, services, etc., and vice versa to obtain a negative evaluation.

The elderly character is conservative and introverted, the expression of their own invisible needs is not clear enough, so from the elderly explicit life behavior and physical condition as the starting point, with the researcher's experience, sensitivity and relevant technology, from the user behavior to excavate, can be the elderly on the physical flexibility measurement of the demand factors to subdivide (Table 2).

Table 2. Requirements form for measurement for the elderly

NO.	Requirement	NO.	Meaning
1	Ease of Use	7	Record and Compare Results
2	Timely Feedback	8	Accurate Results
3	Multi-Person Testing	9	Easy to Identify Results
4	Safety	10	Encourage
5	Clean	11	Easy to Share
6	Close to Residential Area	12	Privacy

4.2 Demand Analysis in Combination with Kano Model

Kano model is a classification method based on user demand, and it is also a useful tool for the classification and prioritization of user needs, based on the analysis of the influence of user demand on user satisfaction, which embodies the nonlinear relationship between product performance and user satisfaction [12].

According to the relationship between different types of quality characteristics and customer satisfaction, Noriaki Kano divides the quality characteristics of product services into five categories: Attractive Requirement, One-Dimensional Requirement, Must-Be Requirement, Indifference Requirement, and Reverse Requirement.

Attractive requirement, when it is satisfied, will make the user's satisfaction with the product increased, but if not, it will not affect the user's satisfaction with the product. One-dimensional requirement, when such needs are met, the user's satisfaction with the product increases, and conversely, the level of dissatisfaction increases, so care should be taken about such needs. Must-be requirement, to meet such needs can make the user's dissatisfaction with the product to a certain extent reduced, but to increase satisfaction does not have much impact, so the design of such needs do not consider. Indifference requirement, whether provided in the product or not, have no impact on the user's operational experience, so such requirements will be eliminated. Reverse requirement refers to the need to provide in the product instead will reduce user satisfaction.

For the study of the measurement of physical flexibility in the elderly, this layered method of demand also applies. The purpose of this model is to distinguish the different needs of users, so as to propose an entry point that can improve user satisfaction, can help designers understand different levels of user needs, is a typical qualitative analysis model.

The Kano model questionnaire is mainly analyzed from three parts: Kano questionnaire, Kano evaluation form and Kano survey results table. According to the problem template provided by Kano theory, a problem is set for each requirement item of the physical flexibility measurement of the elderly, and the problem is divided into two parts: forward and reverse, each with five options, which is 'not like, can be endured, does not matter, rightly, like', the score is 1, 2, 3, 4, 5, the design of the Kano questionnaire.

A sample of the topic of the Kano questionnaire is shown in Table 3.

Table 3. Kano model questionnaire sample

NO.	Requirement	Not Like	Can Be Endured	Does Not Matter	Rightly	Like
1	If It Is Clean	1	2	3	4	5
	If It Is Not Clean	1	2	3	4	5

For the elderly, the understanding of the questionnaire options is different, some elderly people read and fill out the questionnaire is difficult, so it will be completed by the unified training of investigators. The data obtained from the questionnaire are collated, and the results of the Kano evaluation table shown in Table 4 are counted, and the Kano categories belonging to each customer demand item in the questionnaire can be obtained.

Table 4. Kano evaluation form

Positive Issues	Reverse problem				
	Not Like	Can Be Endured	Does Not Matter	Rightly	Like
Not Like	Q	R	R	R	R
Can Be Endured	M	I	I	I	R
Does Not Matter	M	I	I	I	R
Rightly	M	I	I	I	R
Like	O	A	A	A	Q

Corresponds to: A - Attractive Requirement, O - One-Dimensional Requirement, M - Must-Be Requirement, I - Indifference Requirement, R - Reverse Requirement, Q - contradictory, that is, respondents in the positive and negative two questions in the answer to the contradiction.

The survey collected a total of 19 questionnaires and screened 17 valid questionnaires. By summing up the recycled Kano questionnaire and analyzing each user's requirements, you can get the Kano category to which the requirements belong, as the Table 5 shows.

In order to make the results obtained by the Kano model refined in the design practice, Berger and other researchers suggested that the ratio of increasing the satisfaction coefficient to the elimination of the dissatisfaction coefficient, that is, Customer Satisfaction Coefficient (CS, Coefficient), should be used to deal with the category more finely. Customer satisfaction factor consists of two aspects, that is, the extent to which a requirement increases customer satisfaction (Better), or increases the level of dissatisfaction (Worse), which is calculated as follows:

$$\text{Better} = (A + O) \,/\, (A + O + M + I) \tag{1}$$

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

Table 5. Kano survey results form

NO.	Requirement	A	O	M	I	R	Q	Type
1	Ease of Use	11	1	2	1	1	1	A
2	Timely Feedback	2	4	3	6	2	0	I
3	Multi-Person Testing	2	0	1	7	5	2	I
4	Safety	6	7	0	1	3	0	O
5	Clean	6	7	0	4	0	0	O
6	Close to Residential Area	8	3	0	4	1	1	A
7	Record and Compare Results	6	0	0	8	2	1	I
8	Accurate Results	6	0	0	7	3	1	I
9	Easy to Identify Results	14	2	0	1	0	0	A
10	Encourage	7	0	0	9	0	1	I
11	Easy to Share	8	0	0	7	1	1	A
12	Privacy	2	1	0	6	7	1	R

Better, can be interpreted as an increased satisfaction coefficient, generally a positive number, representing if the requirements are provided in the design of the measurement tool, will increase the user's satisfaction, the larger the number of positive numbers and the closer to 1, indicating the greater effect on improving user satisfaction, can improve the design quality faster. Worse, can be called the lack of supply requirements when the user's dissatisfaction coefficient, expressed as a negative number, the closer the value-1, indicating that the impact of lower satisfaction effect is stronger, the faster the design quality drops. Therefore, according to the "Better-Worse" coefficient, the requirement item with high absolute score of coefficient should be given priority. The demand is recalculated, the "Attractive" attribute ">1.1", the "One-Dimensional" attribute "0.9–1.1", the "Must-Be" attribute "<0.9". According to the concept of "Better-Worse" satisfaction coefficient and the calculation formula, the data are analyzed and processed, and the results shown in Table 6 are obtained.

Table 6. Customer satisfaction coefficient form

NO.	Requirement	Better	Worse	Better-Worse
1	Ease of Use	0.80	−0.23	1.03
2	Timely Feedback	0.40	−0.58	0.98
3	Multi-Person Testing	0.20	−0.11	0.31
4	Safety	0.93	−0.50	1.43
5	Clean	0.76	−0.41	1.18
6	Close to Residential Area	0.73	−0.20	0.93
7	Record and Compare Results	0.43	0.00	0.43
8	Accurate Results	0.46	0.00	0.46
9	Easy to Identify Results	0.94	−0.12	1.06
10	Encourage	0.44	0.00	0.44
11	Easy to Share	0.53	0.00	0.53
12	Privacy	0.33	−0.11	0.44

5 Conclusion and Future Studies

According to the screening principle of Kano demand, it is more necessary to pay attention to attributes as "Attractive" and "One-Dimensional" demand in the design of the measurement of physical flexibility in the elderly. Based on the above calculation results, the following conclusions are drawn:

1. Safety
   Safety is the basic requirement of product design, but also is the physical decline, easy to hurt the elderly most value the design quality. Older people want flexibility measurement tools in line with device safety specifications, there are obvious use of prompt information and safety warning information, and hope that in the event of danger can produce a stop, rescue role supporting the design.
2. Clean
   Most old people can accept that in public places, measuring tools inevitably carry a trace of wipes that can be erased with a bit of wet paper towels. Older people want the physical flexibility measurement tool to be easy to keep clean, using a material design that is not easy to dirty, in case of bacterial infection accidentally damaged skin.
3. Easy to Identify Results
   Older people care more about whether the results can be easily read than the results of precise physical flexibility tests. A simple numeric value or rank to indicate that the result is their appeal. The process of reading at the same time is simple and quick, such as being able to hear directly, or being able to see your test results between head-up and bow.
4. Ease of Use
   The learning speed of the elderly is generally lower than that of young adults, the use of machines requires low learning costs, less operating procedures, low operational difficulties.
5. Timely Feedback
   When measuring equipment is designed, it is necessary to match the speed and intensity of the action response of the elderly, and the reaction is too fast and may frighten them.
6. Close to Residential Area
   Because the elderly show that their physical strength is low, tool placement close to the residential area, convenient daily shuttle in the process of different places of life can be measured at any time flexibility. At the same time increase their motivation to test, so as to pay more attention to exercise.

   In the process of qualitative study of the physical condition and life behavior of the elderly, it is often only the behavior that is observed and interviewed, and the need of depth can be dug up after a certain model analysis. Although the study of some elderly people's physical flexibility measurement needs, but China's vast territory, the living conditions of the elderly are very different, so the actual interview survey has a certain impact.

   In the next study, there is a need to overcome geographical and site constraints, expand the number of participants in the survey, and find better needs for the measurement of physical flexibility in older adults. This study extracts the design factors of physical flexibility measurement entity tools suitable for the elderly according to the behavior demand, and also needs ergonomics, user psychology and so on as the starting point to carry out more comprehensive research. It is hoped that physical tools suitable for older people to measure physical flexibility will be designed in the future.

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Correction to: Advances in Human Factors and Ergonomics in Healthcare and Medical Devices

Nancy J. Lightner and Jay Kalra

Correction to:
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In the original version of the book, the following corrections have been made:

Chapter 1:

Double quotes have been inserted over some of the terms; commas have been inserted after some of the terms in Sections 2.1 and 3.1; "s" has been deleted in one of the term in Fig. 2 caption; some of the words have been deleted in Sections 2.1 and 3.2; reference has been inserted in the reference list; and reference citation has been renumbered in the text.

Chapter 14:

Author name has been changed from "M. S. Lanners" to "M. Squillaci Lanners" in the page header. In section 5, "46 studies" has been changed to 45 "studies".

Chapter 20:

The author name has been changed from "Helen Fuller" to "Helen J.A. Fuller"; "University of Michigan, College of Pharmacy, Ann Arbor, MI, USA" has been added to the affiliation of the second author "Timothy Arnold"; Vertical space has been added between the paragraphs in Section 1.1. In Section 3.1, one of the words "Cooccurrence" has been changed to "Co-occurrence".

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