User-Centered Development of an Information System in Patient's Motor Capacity Evaluation

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Abstract Many medical devices are created and rejected because of their lack of adequacy to the clinician needs and situation. The implication of a clinician in the design process may prevents the creation of solution than seems pushed to the users but on the contrary create a solution calibrated to their usages. In this paper a UCD cycle was applied to the development of an information system for patients' motor evaluation using the motion analysis sensor Kinect. The system should support the therapist in its evaluations and provide a way to improve the evaluation. The context exploration, requirements definition, solution proposition and adequacy evaluation was applied. The model allowed to emphasize the important design aspects and those who were correctly answered but also the revisions needed for a second UCD cycle to generate an acceptable device.

Keywords User-centered design · Medical device · Information system Medical population investigation

1 Introduction

Technologies are invading all aspects of our life. They help manage our task, assist the person by moderating, providing information or support etc. They can have different aims: improve the quality, generate cost economy, or provide support by given access to new information or by making a process more precise and effective.

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Medical Devices in Physiotherapy

The medical personals are led to use different types of medical devices or services to help or support their activities. In the case of physiotherapy, a category of tools exists to help them understand the movements and capacities of their patients. Those devices are from the simplest, such as an assessment manual, to the more complex such as for the gait analysis who use 3 different types of technologies: the VICON, a motion analysis tools using infrared cameras and markers, a walk structure equipped with Force plates, and EMG (electromyography) to monitor the muscle activities. Lots of technologies are developed but a lot are also rejected or abandoned for several reasons: they are too complex to use, take too much time, are too expensive or need a specific place that is not available. Most of those aspects could be prevented by having a better understanding of the factors impacting the device. The inclusion of the users and the consideration of all stakeholders in the design process may prevent the device rejection. In those case, the User-Centered Design (UCD) process, a design method putting the users in the center of the process, may be applied.

Design Process and User Centered Design

Different design processes exist to develop a product. Each process have its pro and cons: some are adapted to short-terms projects, some support prototyping, some are efficient for well-defined problem etc. In the case of a medical product there is a clear gap of knowledge between the users (clinicians) and the designer team. In our case it will be the first introduction of technologies into this type of practices which means the impacts will be difficult to define clearly in advance. Those 2 facts mean the process should emphasis the user research to define requirements and evaluate their responses and comprehension with prototypes, it needs to accommodate to an evolution of requirements. Classic systematic and linear models which used few to no prototype such as the Pahl and Beitz approach [1] or even V-model risk to deliver a product that is not in good accordance with the user's needs. An iterative process using prototypes will be needed, as with agile processes but the needs for a clear study of the users' needs make the User-Centered model more adapted even if those two approaches are not necessarily exclusive [2].

The User-Centered Design (UCD) approach is to involve the final users into the design process and was normalized by the ISO 9241-210 [3]. This process is composed of 6 steps that should be iterated until the system matches correctly the user's needs (see Fig. 1). The aim is to calibrate the product to the users. The functionalities should not be "pushed" to the users. The UCD has already be applied into a wide variety of industries. Its main advantages is its capacities to improve the qualities, effectiveness and usability of the solution. A major drawback is the difficulty to maintain the users involved during the whole process [4]. Those features are also valid for the medical device industry, as was investigated by Shah and Robinson [5], notably the difficulty to have access to the users both in terms of time and cost but the extracted knowledge about the users increase the possible success of the product [6, 7].

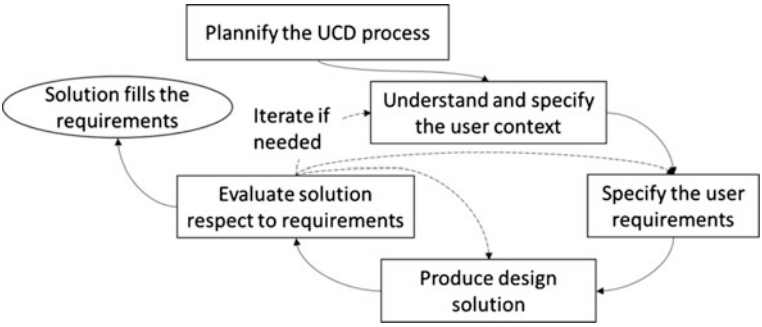

Fig. 1 UCD process [3]

Context of This Study

In physiotherapy, technologies for motion analysis is mostly used in specific and punctual analysis such as the gait analysis. Many technologies are also developed for more regular needs such as in rehabilitation [8]. The apparition of affordable motion analysis sensors, as the Kinect from Microsoft, has generated a renewed interest for assessment and rehabilitation tools and/or e-health in general [9–11]. The development of such tools should be made in close relation with clinicians to lower the risk of rejection.

This paper will present an application of the UCD model in collaboration with physiotherapists to produce a motion analysis information system using the Kinect sensor. This device has to help with the capture and analysis of the patients' movements during an assessment used to define the motor capacities of patients with progressive diseases: the Motor Function Measure (MFM) scale[1] [12, 13]. This scale, administrated once a year per patient, permits to quantify the patient's motor functions. It is composed of 32 exercises rated from 0 (fails to executes the activities) to 3 (do the activities "normally" with controlled motion, regular speed etc.).

2 Case Study: Use of the Kinect Sensor in the MFM Scale

A first UCD cycle was applied (see Fig. 2) which included one therapist to explore and manage the whole process and the punctual implication other therapists for the requirements definition and the evaluation of the solution. Three mains steps will be presented:

1. The context and requirements definition: In this step an analysis of the current context was made and an investigation with 6 therapists was realized to produce a lists of functions and criteria for the tool. The aim was to define the needs and

[1]MFM website: http://www.motor-function-measure.org/ [17/02/2017].

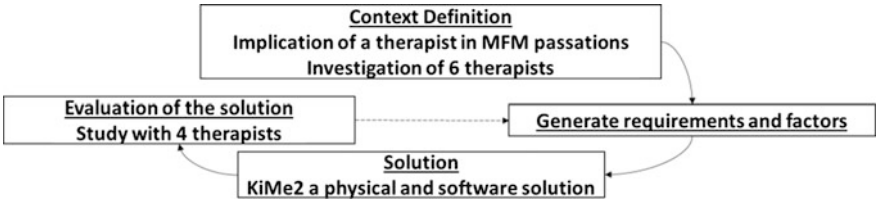

Fig. 2 Application of the UCD process in the Kinect case study

improvements needed for this tool but also to explore the changes and impacts its introduction will have on the process, and its participants (therapists, patients, hospital…).
2. A solution (in terms of physical installation, service and use) was proposed based on those functions and criteria.
3. Evaluation: The tool was then evaluated in regards to the requirements. The efficiency of some key functions were evaluated during a study including 4 therapists.

2.1 Context and Requirements Definition

The needs and opinions on this new tool were explored on one hand with the inclusion of a physiotherapist throughout the whole process to evaluate the current state of the process and to conduct the design evolution. And on the other hand with an investigation based on the "Unified theory of acceptance and use of technology" model [14] to define the impact this new technology may have on the process.

2.1.1 The MFM Assessment

An MFM assessment is realized in a space equipped with chairs and tables (adaptable to the patient morphology) and a physiotherapist table. In addition to those utilities the MFM include a manual as a reference for scoring and some commonly found objects (a tennis ball, a pencil, sheet of paper and 10 coins). The MFM is composed of 32 exercises. An exercise takes between less than a minute to 2 min and the whole scale take on average 30 min.

Only one physiotherapist is needed. For each exercise the therapist gives the instruction to the patient, he may ask if the patient think he can do it and adapt the instruction to the patient's capacities, and should check every time on the manual the score levels. In case of doubt, the lesser score is chosen. The patient can do the exercise twice to give the best score, doing anymore trials may be detrimental because this type of patient is easily fatigable. During the whole evaluation the

therapist stays near the patient to administrate care. If the patient is a child then the parents may also stay during the evaluation.

Finally all scores and commentaries are noted on a paper scoring sheet which is kept in the patient folder, the therapist should then compute the results in an excel file to generate a graphic of the successives MFM and send the result to the MFM database.

Several points can be extracted from this description:

- The MFM is a tool made to be easily accessible for clinicians: the objects used are easily found in a "common" physiotherapist or even ergo-therapist room.
- The MFM is quick to administrate: up to 35 mn.
- There is a strong relationship between the therapist and its patients: the therapist has to stay near the patient for his care but also to maintain him motivated and to discuss with him, to adapt the exercise to its capacities and mood.
- The MFM manual is a reference that should always be at hand.
- A training is necessary.

But other points leave room for improvement:

- The clinician may miss a point if he is tired or concentrated on another point.
- Some movements can be difficult to explain or represent into commentaries.
- The storage of the result in the MFM database has to be manually done. This tends to lead some clinicians to not update it.

2.1.2 The Impact of the Introduction of Technology in the MFM

The impacts of the introduction of this technology was investigated with semi-structured interviews and questionnaires. For this investigation 2 groups of therapists were mobilized (for a total of 6 therapists):

- 1 group of non-users: 3 therapists with no prior knowledge of the Kinect.
- 1 group of users: 3 therapists with prior knowledge of the Kinect as a tool for evaluation.

The system acceptance seems to be correlated with 3 factors:

1. The system performance. It's the condition sine qua none for its usability: the data provided have to be reliable and the new information to be interesting enough for the disease comprehension and score's attribution.
2. Distributed cognition: the cognitive attention of the therapist, previously centered on the patient, will now be distributed between the patient and the Kinect-system.
3. The social influence: this new system will impact the profession and the view on the work done

The resulting functions and factors are listed below:

System Performance

- The system should provide validated data (accurate, objective, reproducible, and validated by the community etc.).
- The system should provide additional information useful for the analysis of the disease and the assessment and facilitating the follow-up.
- The system should not stretch the duration of the assessment (limit the increase of workload).
- The system should conserve the "simple and accessible" feature of the classical MFM by remaining into a moderate pricing range and requiring technologies easily accessible.
- The system is an information system and the therapist has to keep the control.
- The system has to be safe and hygienic.

Distributed Cognition

- The capture of the patient movements should be done without
  - Hindering the evaluation capacity of the therapist.
  - Taking too much additional time in installation and in use.
- The analysis of the movements and the data representations should allow the therapist to understand and trust the system.
  - The system should avoid the "black-box" effect.
  - The system need to provide information calibrated to the clinician needs.
  - The analysis should be quick and the access to desired data easy.
- The system should not hinder the relation between the therapist and the patient but try to improve it. It should not distract the patient or the therapist.

Social Influence

- The system should not be seen as an intrusion or a surveillance tool.
- The therapists should not have the impression to lose the control.
- The system should not lead the therapists to lose their expertise.

2.2 The Application

The following installation, named KiMe2 (Kinect Medical Measurement), is proposed. The patient realizes its activities in front of a Kinect sensor with the therapist being at the patient side and able to touch him and interact with him. The therapist is equipped with a tablet that contains its MFM manual and a wireless connection with the computer linked to the Kinect sensor and the KiMe2 software (see Fig. 3).

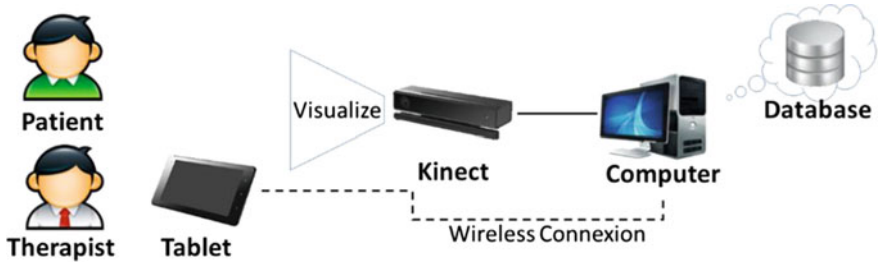

Fig. 3 Physical installation

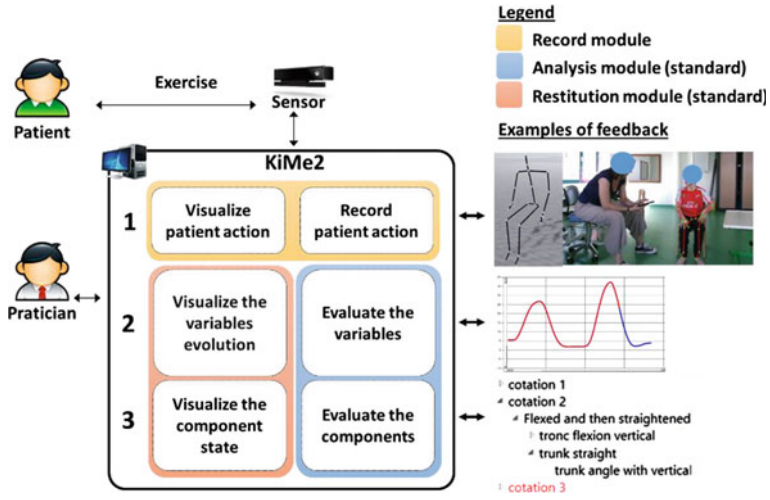

Fig. 4 Software architecture

This tablet and software enable the therapists to see what the Kinect see and if the system function correctly (if the patient is correctly positioned for the sensor and for the activities etc.). The therapist can then ask the patient to do its exercises and record them and then provide its decisions on the tablet which saves them and send them into the database with the record of the movements. The results can be analyzed by the software whom is described on the Fig. 4.

The therapist can use the tablet and thus software to analyze the exercises and can revise or validate its decisions depending on the results. For this, the system provides a score and its justifications. The justification indicates which components (scoring criteria) were validated such as if "a support was used", if a posture were attained, etc. If the therapist has a doubt on a score or more specifically on a component (scoring criteria) of the score, the system provides for each score the list of the components (scoring criteria) mobilized and their states and the numerical variables used for their calculations (see line 3 in Fig. 4). If the therapist has a doubt

on a value in particular he can generate the plot of the variables (numerical variable, see line 2 in Fig. 4). Those graphs are associated to the component to facilitate their access. The exercise can also be reconstructed to re-visualize the exercise (see line 1 Fig. 4). This structure makes the scoring system more transparent to the therapist.

2.3 Adequacy of the Proposition to the Requirements

System's Performance Adequacy

The system answered several requirements: (1) The system Tablet—Kinect—Computer can easily be found and remains on a pricing range way lower than other movement analysis tools on the market, but it should be noted that it is substantially more complex and costly than the current MFM. (2) The system does not bring any physically harm or any hygienic difficulties but the flow of data has to be secured. (3) The therapist control over the final score was kept and comforting: the aim is to provide reassurance and additional information. (4) The record of the exercise takes more time than a classic MFM but stays in an admissible range. The analyzing process takes a significant time that need to be improved. (5) The treatment process (create the MFM graph of the disease and updating the result into the database) could be facilitated and help provide more systematically data on rare disease. (6) On the other hand it should be noted that the Kinect is not quite performant enough for now. The measurement have to be made more accurate and robust.

Adequacy to the Distributed Cognitive Factors

The cognition distribution was evaluated with 4 therapists: they had to use the system to see if they were able to record and analyze correctly the MFM exercises with the KiMe2 tool.

In terms of capture: the therapists were able to easily position themselves in a way that does not hinder the recording of the activities. However the system presence itself made the therapists less incline, even if possible, to be near or in contact with the patient which can be dangerous for the patient care. Globally the system did not hinder the evaluation but the fact the therapist has to stay at the patient's side changes the patient's stare orientation which can be bad for some exercises. During the evaluation of a posture the fact to not be able to go in front of the patient to check the posture is also an inconvenient and can hinder the therapist evaluation.

In terms of analysis: The system enables the therapist to understand the software results proposition. The therapists can know if they have to revise their judgments or maintain it. They understood what were reasons for a score and if the software were missing or misinterpreting a knowledge. They were able to see if this system can monitor components that can be difficult to analyze or be overlooked. The mobilized knowledge were easy to understand and the parallel between the mobilized knowledge and the manual description was made even if the terms

needed to be more medical oriented. The data were easily accessible: the graphs were easy to find and generate. The therapists were able to find the sought information (an angle, what was the knowledge mobilized etc.). The possibility to represent the amplitudes and displacements of movements into graphs were an interesting improvement of the system.

In general the relationship between the therapist and the patient remains the same. The system may distract a bit the therapist from the patient, but it can also be a tool to generate motivation and discussion with the patient. But therapists can have difficulty in managing the patient, the activities and the system (too much dispersion).

Several points were highlighted and will have to be corrected into the next UCD cycle. This system make notable change on the therapists practices. The therapists and the patient, not positioned as before, change their stares orientation which is not straight anymore, the system makes the displacement around the patient more difficult (since the therapist should not pass in front of the sensor) and naturally tends to stay far from the view of the sensor, this makes the evaluation of posture more difficult and may endanger the patient care. The introduction of the system distracted a bit the therapists which did not behave as usual and thus made mistake during their evaluation. Finally the installation and system increase the assessment duration and the workload but the simplicity of the result and of the installation in regards to other system as the VICON for the gait analysis was noted and the capacity to understand the system analyze was well appreciated.

Adequacy to the Social Influence Factors

A formation will be needed to prevent the negative factors in the social influence sphere. The formation should emphasis the fact that this tool does not monitor the therapist's activities and has to be seen as a support system for the therapists and not a replacement for any role of the therapist (the therapist stays the main relation with the patient, he keeps the control on the control and result, etc.). It should also emphasis the fact that the system is not a perfect but that it may provide more consistency on specific values or data but should in no way replace the therapist or its expertise which will always be essential.

3 Conclusion

In this paper a UCD process, involving a physiotherapist, was applied to develop a medical device for motion analysis during assessments. The process allows the description of the needs, the creation of a solution and its evaluations. The evaluation of this systems provided 4 main good points to maintain:

1. The systems allows an easy capture of the exercises with a good visual feedback to follow the assessment.

2. The analysis allows a new standardized point of view.
3. The software analysis can be understood and interpreted by therapist. The representations allowed a good transcription of the exercise.
4. The system may brought new information with new representation of the movement such graphs of displacement and amplitude not available until now.

But the systems still need improvements on 4 mains points, and will ask for an iteration of the process

5. The systems increases the assessment duration and the workload of the analysis. The used of the representation tools taking times.
6. The system is still heavy for the cognitive: the therapist has to manage the assessment, the patient and the system.
7. The system changes the practice and notably the position of the therapist and of the patient that can hinder the assessment of some exercise.
8. The Kinect system needs to be perfected to provide more reliable score.

The UCD cycle allows to anticipate positive factors and prevents the negative factors that will be corrected on the next cycle. This type of process should facilitate the introduction of new medical device that may be helpful in common medical practice.

References

1. Pahl, G., Beitz, W., Feldhusen, J., Grote, K.-H.: Engineering Design, vol. 11. Springer, London (2007)
2. Fox, D., Sillito, J., Maurer, F.: Agile methods and user-centered design: how these two methodologies are being successfully integrated in industry. In: Agile 2008 Conference, pp. 63–72 (2008)
3. ISO 9241-210: International Organization for Standardization. Ergonomics of Human-System Interaction—Part 210: Human-Centred Design for interactive Systems, p. 36 (2010)
4. Vredenburg, K., Mao, J.-Y., Smith, P.W., Carey, T.: A survey of user-centered design practice. In: Proceedings of the SIGCHI Conference on Human Factors in Computer Systems: Changing Our World, Changing Ourselves—CHI '02, no. 1, p. 471 (2002)
5. Shah, S.G.S., Robinson, I.: Benefits of and barriers to involving users in medical device technology development and evaluation. Int. J. Technol. Assess. Health Care. **23**(1), 131–137 (2007)
6. Teixeira, L., Ferreira, C., Santos, B.S.: User-centered requirements engineering in health information systems: a study in the hemophilia field. Comput. Methods Programs Biomed. **106**(3), 160–174 (2012)
7. Rinkus, S., Walji, M., Johnson-Throop, K.A., Malin, J.T., Turley, J.P., Smith, J.W., Zhang, J.: Human-centered design of a distributed knowledge management system. J. Biomed. Inform. **38**(1), 4–17 (2005)
8. Zhou, H., Hu, H.: Human motion tracking for rehabilitation—a survey. Biomed. Signal Process. Control **3**(1), 1–18 (2008)
9. Hondori, H.M., Khademi, M.: A review on technical and clinical impact of Microsoft Kinect on physical therapy and rehabilitation. J. Med. Eng. (Hindawi Publishing Corporation) **2014**, 16 (2014)

10. Webster, D., Celik, O.: Systematic review of Kinect applications in elderly care and stroke rehabilitation. J. Neuroeng. Rehabil. **11**, 108 (2014)
11. Da Gama, A., Fallavollita, P.: Motor rehabilitation using Kinect: a systematic review. GAMES Heal. J. Res. Dev. Clin. Appl. **4**(2), 13 (2015)
12. Bérard, C., Payan, C., Hodgkinson, I., Fermanian, J.: A motor function measure for neuromuscular diseases. Construction and validation study. Neuromuscul. Disord. NMD **15** (7), 463–470 (2005)
13. Vuillerot, C., Payan, C., Iwaz, J., Ecochard, R., Bérard, C.: Responsiveness of the motor function measure in patients with spinal muscular atrophy. Arch. Phys. Med. Rehabil. **94**(8), 1555–1561 (2013)
14. Venkatesh, V., Morris, M.G., Davis, G.B., Davis, F.D.: User acceptance of information technology: toward a unified view. MIS Q. **27**(3), 425–478 (2003)