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Impact of the context of use analysis for the extension of an existing medical device: an analgesia monitor case study

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Abstract. The EU revised Medical Device Directive introduces a major change in the CE marking of medical devices (MD) aiming at improving their safety. Manufacturers must now comply with an "ergonomics" essential requirement to prevent risks of use errors. This requirement is characterized by the integration of a usability engineering process in the MD design cycle to be documented in a usability engineering file. This study focuses on the first step of the usability engineering process, *i.e.* the analysis of the intended context of use of the MD, and shows the benefits of this analysis when performed early in the MD design cycle. Usability experts have conducted an analysis of the intended contexts of use for the extension of an existing device (analgesia monitor) in order to support manufacturer's design choices. Observations and interviews were carried out in two neonatology units (Maternity and Neonatology Intensive Care units) with a particular focus on pain management activities performed by physicians and nursery nurses. The results highlight irreducible differences between the two environments which led to identify different risks of use errors and specific ergonomics requirements. The results provided the manufacturer enough information to make informed decision about the extension of the device.

Keywords. Human engineering, Equipment and Supplies, Patient Safety, Analgesia

Introduction

To secure patients and users' safety the European Union has adopted a revised Medical Device (MD) Directive (Official Journal L 247) [1] which explicitly aims at "reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety)". Manufacturers are expected to integrate a usability engineering process in the design cycle of their MD and to document it in a usability file. The IEC 62366 harmonized standard [2] has been published to help manufacturers comply with this particular essential requirement. Compliance with essential requirements is necessary to obtain the European Conformity (CE) marking and be allowed to sell the MD in European countries. The IEC 62366 refers to the user-centered design process [3] as a mean for implementing the usability engineering process for MD design and development. The first

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and probably most fundamental phase in the user-centred design process is the analysis of the intended context of use of the MD under development [4]. This analysis provides critical information (i) to support design choices and set usability goals [5] and (ii) to plan the usability verification and validation phases of the MD. We present here a case study illustrating the impact of the analysis of the intended context of use on high level design choices in a project of extension of an existing medical device.

1. Study context

A small company, MetroDoloris®, has designed an innovative analgesia monitor (PhysioDoloris®) equipped with a computer like interface (Figure 1, for detailed description [6]). It provides healthcare professionals with a new pain indicator, namely A.N.I (Analgesia Nociception Index). This index is based on an algorithmic transformation of the cardiac frequency retrieved from patient's monitoring [7].This MD supports monitoring of adult patient's pain during general anesthesia and aims at improving analgesic drugs' management. Usability experts accompanied the manufacturer in implementing and documenting the PhysioDoloris® usability engineering file for its initial CE marking [8].

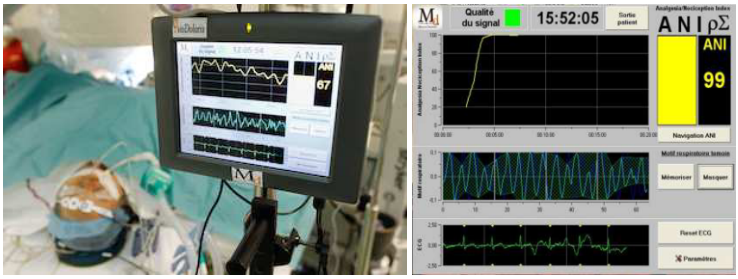

Figure 1. PhysioDoloris®' monitor in the general anesthesia context (left) and its interface (right)

As the device is now in use, clinicians identify new clinical needs and potential for extending its use in other clinical contexts, namely neonatology units. This leads the manufacturer to envision designing a modified device adapted to the new clinical context. The shift in the intended patient population from adults to newborns requires profound modifications justifying new CE marking. The manufacturer involved the same usability experts' team very early in the project to implement the usability engineering process and ultimately document the usability file.

The manufacturer and clinicians participating in the project were well aware that "neonatology" refers to various organizational settings. Therefore, the question raised whether a single customizable device would be relevant for the different neonatal settings or whether a specific device should be designed for each unit. Usability experts started the analysis of the intended context of use to help answer this question, provide design requirements to developers, and support the planning and integration of the usability engineering process in the design and development cycle. The paper at hand aims at presenting the ergonomics analysis of this new potential context of use and the subsequent high level ergonomics recommendations to inform the design strategy.

2. Method

The study has been conducted in a Neonatal Intensive Care Unit (NICU) and a Maternity Unit (MU) of a French University Hospital between October 2012 and January 2013. Clinicians involved in the project chose those units for being much contrasted. Data have been collected by two usability experts (RM & CB) through several methods to cross-check data (**Table 1**):

- Exploratory interviews to understand units' care aims and identify patients' population, involved clinicians and clinical workflow.
- Observations supported by pictures and field notes: experts shadowed clinicians in their work context.
- Semi-structured interviews with clinicians to refine the data collected and validate the interpretation of those data.

Table 1. Numbers and profiles of the participants.

	Exploratory interviews	Observations	Semi-structured interviews
NICU	1 physician	2 Physicians, 5 Nursery nurses (24h)	3 Physicians, 4 Nursery nurses (average duration=25 min)
MU	1 physician	3 Physicians, 2 Nursery nurses, 2 Child care assistants (15h)	3 Physicians, 1 Physiotherapist, 1 Nursery nurse, 1 Child care assistant (average duration= 20 min)

Data collection focused on pain management[2] and especially on data that support clinicians' decision making: clinical data (e.g. babies' behavior, crying, agitation's level and anamnesis), physiological data (e.g. heart rate), lab results and current treatments. For each data, their sources (e.g. physiological monitors, paper records and communications between clinicians and between clinicians and parents) and their co-occurrences with pain management actions were identified.

All interviews and field notes were transcribed. As pain management is closely related to patients' clinical context, main clinical contexts were first identified by usability experts and validated by clinicians. Then, for each context, information sources, protocols (medications and non medications treatments, frequency etc.), used medical devices and involved professionals were identified. A cognitive model of cognitive control and monitoring [9] supported data interpretation. The analysis process was iterative and clinicians (one physician and one nurse) validated the interpretations at each step of the process.

3. Results

3.1. Context of use

Interviews and observations highlight that differences in NICU and MU patients' population has a great impact on pain management (Table 2). After their delivery, newborn babies are either oriented towards MU if they are in good health, at term or slightly preterm, or towards NICU if they are great/extreme preterm or ill.

[2] « Pain management » refers to a set of activities dealing with monitoring, decision-making and action-taking related to discomfort and pain experiences

Table 2. Main differences between MU and NICU.

	MU	NICU
Nociception consideration	No pain management save a very small proportion of babies who may experience pain due to delivery complications (e.g. cephalohematoma or fracture due to breech birth or forceps delivery) or to withdrawal.	Pain management for every patient to prevent them from experiencing too much pain in order not to endanger their neurological development.
Painful acts	None is performed.	Some are performed (e.g. intubation): most of this pain is anticipated, but clinicians also manage it in a quick reactive way.
Nociception information sources	Clinical observation (crying, agitation etc.) to notice potential pain, observation scale (neonatal pain and discomfort scale, EDIN) to observe the evolution of the experienced pain.	Clinical observation (idem) to notice potential pain, observation scale (idem) to observe the evolution of the experienced pain. Heart rate is also used to notice pain: when tachycardia is observed without apparent cause, clinicians deduct the patient is experiencing pain.
Technological environment	Very little use of sensors: only for oxygen saturation and heart rate for light-preterm/resuscitated babies or babies with cephalohematoma for a very limited duration (max. 48h). Physicians insist on *"MU is no hospital"*: parents are not used to see babies surrounded by high technology.	Highly technological ward: because of their conditions (risk of oxygen desaturation for extreme-preterm babies) every patient' physiological parameters are constantly monitored with up to five different sensors: parents are used with technology surrounded patients.
Expected usefulness of the pain monitor	"*To allow a more precise monitoring of pain*" (physician); "*to supplement EDIN score*" (nursery nurse); "*to reassure parents*" (nursery nurse);"*to support pain diagnostic" for crying babies*" (physician)	To get a more precise evaluation and monitoring of the evolution of pain (physicians and nursery nurses). To support decision making on painkillers prescription and administration.

Moreover, in both units, pain management corresponds to dynamic situation monitoring activities performed mainly by physicians and nursery nurses. Two kinds of activities are distinguished: reactive ones based on clinical observations of babies' behavior and/or physiological parameters (e.g. in MU, paracetamol is administered to babies who seem to experience pain) and anticipative ones mainly based on clinical and patient knowledge (e.g. in both units, two minutes before taking a blood sample, nursery nurses give babies a nutritive sucking with sucrose to prevent them from feeling too much prick). There are as much reactive activities as anticipative ones in NICU because obvious characterization of patients' clinical context allows knowing what to pay attention to. In MU, there are far more reactive activities than anticipative ones because there is no specific typology of babies.

Data analysis reveals that NICU and MU are two different contexts of use. As a consequence, different usages of the pain monitor can be anticipated in both contexts:

- In NICU, the new device would be used to support the current continuous pain monitoring and would therefore be used frequently. There would be no need to put new sensors on babies because the cardiac frequency is already monitored and can be retrieved.

- In MU, the new device would be used to support occasional pain therapy. However, since (i) the pain problematic is not essential for this population, and (ii) the monitoring requires putting a sensor on the baby while parents are not used with technologies in this ward, the monitoring will sooner be punctual, the device being plugged from time to time on few babies.

3.2. Ergonomics requirements

From these results, usability experts highlighted high level risks of use errors with potential negative impact on patient safety. Because of the perspective of rare use of the device and the necessity of putting sensors on babies, MU should be considered as the most critical unit in terms of risk of use errors. In NICU, special attention must be paid to the technological context with a focus on the integration of the information provided by the new device with existing information displayed by other monitors (e.g. redundancy of display of cardiac frequency with EKG). Due to the rare use expected in MU and to the potential interferences with other monitors in NICU, the pain index must be unambiguous. As a consequence, a high level usability goal is defined as "in both units, 100% of users without training and at first attempt should properly interpret the index".

Some requirements based on the context of use analysis are similar for both units (common terminology to support doctors/nurses collaboration, intuitive display of the index to prevent misinterpretation). However, due to the differences observed in the two contexts of use, other requirements are specific to each unit (Table 3).

Table 3. Main requirements according to the intended ward of implementation

	MU	NICU
Device design (look and feel)	Implementing a medical device near babies who are supposed to be in good health may question the parents (emphasized by many clinicians). Therefore, device's design should be as "baby-friendly" as possible.	The implementation of the device will not affect the parents' feelings: therefore, its design may still be medical.
Data capture process	Most of time, most of the babies being not monitored, sensors will have to be put on babies to retrieve the hearth rate.	To avoid adding another sensor (already up to five), it would be preferable to retrieve data from an already implemented physiological monitor, EKG.
Transportability	It is plausible that one monitor will be used punctually for several patients. Moreover, babies are often moved inside and outside the unit. It is then mandatory that the device be easily transportable.	Due to continuous monitoring, each patient must have its "own" monitor. Since patients are very rarely moved, the portability of the monitor is not an essential feature.
User interface and functions	To support the monitoring of the evolution of pain index while data are retrieved punctually, the device must allow (i) recording measures for each identified patient and (ii) displaying those measures in an understandable way. It might be necessary to provide support for the index interpretation. The monitoring of the evolution of the index requires only a mid/long-term monitoring span to supervise patients' pain evolution.	Due to the continuous data retrieving, the pain index evolution can be easily displayed continuously on the device's interface. The monitoring of the evolution of the index must support very-short term (minutes range) and mid/long-term monitoring to allow clinicians managing pain related to painful acts and also to supervise the evolution of patient's pain.

4. Discussion/conclusion

Results have been presented to the manufacturer and the project team. Due to significant differences between both contexts, it proves more suitable to design two pain monitors rather than a customizable one. However, the cost/benefit ratio in terms of development and expected use and the benefice/risk ratio in terms of clinical usefulness were judged detrimental for the MU context of use. Therefore, the manufacturer made the decision to postpone the development of the MU device, saving, according to him, 80 K€.

As for the usability file documentation and the planning of the usability engineering process, intended context of use, high level requirements and patient safety oriented usability goals have been identified. More precise requirements and goals will be defined as soon as an initial mock-up of the monitor is available.

This study shows that early analysis of the intended context of use is useful to provide the manufacturer enough information to make informed design decisions. It also provides critical information allowing to plan, guide and budget design efforts along with UCD activities.

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