MEDINFO 2004
M. Fieschi et al. (Eds)
Amsterdam: IOS Press

Institutional Decision-Making for Medical Device Purchasing: Evaluating Patient Safety

Alla Keselman[a], Xiaozhou Tang[b], Vimla L. Patel[a], Todd R. Johnson[b], Jiajie Zhang[b]

[a] *Laboratory of Decision Making and Cognition, Department of Biomedical Informatics, Columbia University, USA*
[b] *School of Health Information Sciences, University of Texas Health Science Center at Houston, USA*

Abstract

Many medical devices that are currently on the market are sub-optimal for human use, thus contributing to medical errors. This places significant responsibility for device selection on purchasers. This paper describes a retrospective analysis of decision making processes for infusion pump selection in three large hospitals and focuses on patient safety. Through a series of detailed interviews and a study of relevant documentation we characterized the nature of the decision-making, patterns of communication, and the roles of different participants. Findings suggest that success of the process is related to effective communication among participants with different expertise and adequate device usability assessment during the process. The paper discusses how information technology could provide support to distributed institutional decision making.

Keywords:

Patient safety; Institutional decision-making; Human factors design

Introduction

User errors that involve drug infusion devices account for a significant proportion of medical errors [1,2]. Injuries resulting from medical device use errors far exceed injuries arising from device failures [3]. Studies have demonstrated that many user errors are related to classic interface problems and redesigning the interface using human factors guidelines reduces the number of programming errors [1].

Until recently, human factors issues have received relatively little attention in medicine. The situation is gradually changing, as health professionals and device manufacturers are becoming increasingly aware about the relationship between device design and medical errors. Nevertheless, despite this growing awareness, many devices that are currently on the market are sub-optimal from the human factors perspective [4]. This situation places significant responsibility for the device interface quality on the purchasers. At the same time, device purchasers receive little support in the form of published purchasing guidelines.

The infusion pump is a widely used device for delivering intravenous medication. Given the scope of its use in hospitals, decision making about infusion pump selection is typically done on the institutional level. The process is distributed over time and across individuals and involves a large-scale team effort that requires coordination of expertise from various levels of hospital hierarchy. The potential strength of group decision making lies in its ability to facilitate the achievement of goals that may be beyond the range of one single individual.

Research on collaborative decision making identifies a number of factors crucial for effective team functioning. These include shared goals, clear role differentiation among participants, strong leadership that helps to maintain focus without being too restrictive, shared understanding of the process grounded in group and individual expertise, and effective communication [5]. In the instances of group decision processes where the participants are geographically separated, distributed and collaborative communication technologies can effectively bridge the geographic gaps.

Patel and colleagues [5] studied how different modalities of technology-enabled communication supported different types of interaction in large-scale collaborations. They found that different modes of communication provided various unique strengths during different activities in the course of collaborative decision making. For example, synchronous communication sessions (e.g., conference calls) frequently focused on executive activities. Such sessions allowed participants to ask questions and promptly restore shared understanding in moments of ambiguity. Asynchronous communications, on the other hand, were more frequently used for discussing task-related activities. Although these communications did not allow immediate clarification of meaning, they gave participants more time to formulate their contributions.

The study presented in this paper is part of a large effort, directed at developing technological support for hospital device purchasing, with the objective to promote patient safety. It is our position that in order for such support to be effective, in needs to be based on careful in-depth analysis of current device acquisition practices. This paper describes a retrospective analysis of a decision making process for an infusion pumps purchase in three large urban hospitals. The aim is to characterize the effectiveness of the process, to identify potential venues to promote patient safety, and to provide insights into how technology can support decision making for device purchasing.

Methods

The study involved semi-structured interviews with participants in the latest infusion pumps purchase at three large hospitals

(further referred to as Hospitals 1, 2 and 3). Whenever possible, we also conducted analysis of relevant process documents (e.g., minutes meetings, device evaluation forms, etc.). The data were used to construct representation of the selection processes and information flow. Process documents were used to validate the interview data.

Participants

Representative sample comprised of participants in the latest infusion pumps purchase participated in semi-structured interviews at each site. To ensure adequate representation, selection of the participants was done after an initial informal overview of the process. Seven in-depth interviews were conducted at Hospital 1; eleven at Hospital 2; and nine at Hospital 3. Participants came from many levels of hospital hierarchy and represented various professional groups. For example, participants at Hospital 3 included one biomedical engineer, four administrators, one physician and three nurse managers.

Interview with the participants

Interview design was based on a conceptual framework of the process (Figure 1), developed on the basis of Miles and Huberman's guidelines for qualitative research [6]. The framework outlines potential (hypothesized) relationships among various factors that may affect the process of institutional medical device selection and the purchasers' perception of the process. Given the focus of the study, we included purchasers' knowledge and attitudes towards patient safety, as well as their perception of the process and the outcome, in the framework. Arrows in the framework represent directionality of influence.

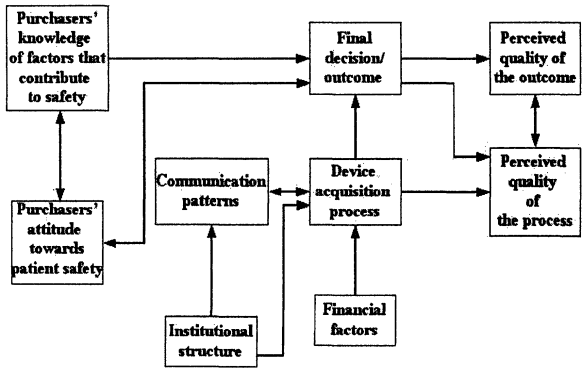

Figure 1 - Conceptual framework of decision-making process for medical device purchasing

Key questions of the interview were developed on the basis of the conceptual framework, and covered various aspects of device selection, process, interaction and communication among participants, safety evaluation, and decision and process quality. Appropriate probes and clarifications followed each question. At one of the sites (Hospital 3), interviews were audio-recorded and transcribed for analysis. At other sites (Hospitals 1 and 2), two note-takers took detailed notes of the interviews.

Analysis

All interviews were analyzed using thematic coding, a method for detecting patterns, or themes, in qualitative data [6]. Preliminary coding categories were based on the core interview questions. After the interview data were collected and transcribed, three researchers reviewed the transcripts for regularities and patterns and developed the final coding scheme. Two coders went through the data, marking each paragraph unit with the appropriate coding category. Finally, for each interview, units of data were grouped according to the codes.

Survey evaluation forms from one of the sites were contrasted with an established usability evaluation method, *Heuristic Evaluation*. In this method, a team of evaluators consisting of usability experts and regular device users walks through the process of device use, noting device's violations of a number of design principles [7].

Results

The results section is organized according to themes that emerged in the analysis.

Participants

In all three hospitals, the process participants involved individuals with three types of expertise, administrative, bio-engineering and clinical. All processes involved many administrative, clinical and mixed groups from the corporate and hospital levels. Administrative and mixed groups tended to be standing, while clinical groups tended to be ad-hoc. Clinicians at lower levels of hospital hierarchy (e.g., floor nurses as opposed to physicians or nurse managers) were least likely to be part of standing decision-making groups. For example, at Hospital 3, three administrative/ technical departments played a major role in device selection: Purchasing, Support Services and Engineering. Clinical groups that participated in the process included a) Committee for Technology in Clinics, a standing committee comprised of high-ranking physicians, engineers and administrators and b) an ad-hoc committee that included nurse managers from major hospital units that used infusion devices.

Triggers

At all three sites, the process was triggered by an institutional/ organizational factor (e.g., budgeting time at Hospital 1, merger followed by a corporate-level decision to standardize devices across all campuses at Hospital 2, expiration of the lease at Hospital 3).

Selection of candidates to evaluate

None of the sites conducted a broad overview of the device market. Instead, all three processes started with selecting one potential candidate. In one case (Hospital 1), the selection was made by the nurses who heard about the pump at a conference. In two cases, the initial selection was made by administrators (e.g., Corporate Purchasing Office for Hospital 2, Core Project Management Group for Hospital 3). In both cases, administrators selected a candidate from a familiar vendor, whose products were already present in the hospital. In both cases, another ven-

dor came into consideration only later, as a result of the opposition against the primary candidate.

Participants' perspectives on usability and patient safety

At two of three sites (Hospitals 2 and 3), participants with different types of expertise had different perspectives on what factors were important in the process. Administrators' tended to give primary consideration to financial and institutional factors (e.g., price, standardization), while clinicians were primarily concerned about ease of use and seamless integration of the device into the workflow. Data from Hospital 3 suggests that while administrators frequently mentioned that the pump had to be "clinically acceptable", they did not provide details about what constituted clinical acceptability. Clinicians, on the other hand, described many usability-related factors that they considered important, such as the location of buttons (e.g., START and OFF buttons should not be next to each other), size of numbers on buttons, and display lighting.

All participants considered patient safety an important factor, but administrators and clinicians had somewhat different views of patient safety. While clinicians' perception of safety reflected the human factors perspective, administrators' tended to view safety in terms of device accuracy and reliability. The following quote from a Hospital 3 administrator exemplifies administrative perspective on what constitutes a safe device, "You want to know if it alarms properly. When the solution gets low, it is supposed to start alarming at a certain point. You also have to set the rate that a patient gets. You want it to be accurate. You want to know if those things were safe." Design features that would reduce errors by minimizing cognitive demand on the users were not mentioned. Many clinicians, on the other hand, viewed administrative perspective on safety as narrow. This is illustrated by the following quote from a physician, who explains that administrators tend to blame users and overlook the role of environmental factors in safety failures, "If the electricity went off and the pump stopped because of it, [in the administrators' view] it's still the nurse's fault, because it is her responsibility to make sure the battery is charged and functions."

Process and conflict

In **Hospital 1**, the purchase was not hospital-wide, and involved one Intensive Care Unit. The process started with the users, and proceeded smoothly. During annual budgeting time, the Director of the ICU asked nurses how they wished to allocate a portion of the budget. Nurses asked for a new 3-channel infusion pump, naming a specific model. After clinical evaluation, hospital level administration approved the request.

Unlike Hospital 1, Hospitals 2 and 3 involved hospital wide purchases and were more complex in nature. The process of decision-making at those hospitals required combining or reconciling different perspectives. The process of reconciling the perspectives was different at the two different sites. In **Hospital 2**, the conflict was **explicit**. Following the hospital's merger with a large healthcare system, the corporate-level purchasing office issued an order to the hospital's Material Management Department to convert an existing pump (pump X) to a different pump (pump Y). The Material Management Department asked hospital ICU directors to evaluate the new pump. The directors found that the pump was not suitable for the hospital, and refused to accept it. In response, vendor Y put pressure on the corporate administration, and the corporate administration put pressure on the hospital. The hospital conducted several evaluations of pumps X and Y (to be discussed later). The process was spearheaded by the Clinical Resource Coordinator (a position, created specifically for this purchasing process). After the evaluations, the Chief Nursing Office and the Biomedical Engineering Department of the Hospital supported the ICU directors' decision to stay with vendor X. Finally, the Assistant Vice President of the healthcare system endorsed the decision, and the hospital purchased a new pump model from vendor X. While the purchasing process in Hospital 2 involved a conflict between the corporate/administrative and the hospital/clinical levels, the conflict was resolved to the hospital's satisfaction.

In **Hospital 3**, the conflict was **implicit**. At the end of the leasing term, the hospital's Materials Management Department was approached by a vendor whose pumps were present on one of the hospital campuses. The vendor (vendor A) had just issued a new pump model (pump A), and was offering the hospital a good deal for leasing and promoting it. Three administrative departments formed a core project management group that coordinated the selection process. The core group appointed an ad-hoc Nurse Managers Committee that helped the core group to organize clinical evaluation of the pump A. The progress was reported to the standing Committee for Technology in Clinics (a mixed committee, which includes high-ranking physicians and administrators). When some significant shortcomings of pump A were noted during the clinical evaluation, another candidate (pump B) came under consideration. This lead to clinical evaluation of pump B. After reviewing results of clinical evaluations of both pumps, core administrators concluded that pump A and pump B were clinically equal and selected the less expensive pump A. Our interviews revealed that administrators and clinicians had different views about the relative performance of the two pumps. Administrators believed that while some clinicians may have preferred pump B, the overall pattern of clinicians' responses to user evaluation surveys showed that the pumps were clinically acceptable. Clinicians, on the other hand, felt that their preference for pump B was ignored.

Communication and coordination of activity among various groups

Since the process in **Hospital 1** involved a small-scale purchase for one department, it did not require complex coordination of activities.

In the case of **Hospital 2**, there was much coordination of activities within the hospital. Clinicians were actively involved in all stages of the process. The initial response to the order to convert to a new pump involved both an administrative group (Material Management Group) and a standing mixed clinical/administrative group (Product Review Committee). These groups communicated the information to ICU directors and asked them to set up clinical evaluation. In conducting the initial evaluation of the pumps, the ICU directors closely collaborated with the Chief Nursing Office. When the corporate administration insisted on

the change of the pump, the hospital created Clinical Resource Coordinator position for coordinating further pump evaluation. The coordinator, who was a nurse administrator, headed the subsequent evaluation. This created the situation where clinicians from all levels – physicians, head nurses and floor nurses – were able to share information and develop a common perspective that could be conveyed to the administration.

In the case of **Hospital 3**, coordination of activities among multiple groups involved some difficulty. The process was managed by an exclusively administrative Core Project Management group. While two clinical groups participated in the process (Nurse Management Committee and Committee for Technology in Clinics), these committees did not coordinate their work. The role of the Nursing Committee was mainly to provide liaison with the users, rather than to contribute to the decisions being made. No interactions occurred between the two clinical committees. Additionally, no direct communication took place between 1) core project managers and floor nurses who used the pumps and 2) the Committee for Technology and floor nurses. Lack of effective communication among different groups may have contributed to the situation in which different groups failed to develop awareness of one another's perspectives and attempt to resolve the differences.

Clinical evaluation of the pumps

While all three sites conducted clinical evaluation of the pumps, neither of the three used an established human factors technique for evaluating device usability. In all three cases, clinical evaluations involved setting up pumps in clinical units for floor nurses to test. Nurses' opinions were later related to the administrative decision-makers. Since in none of the hospitals did floor nurses serve on any of the decision-making committees, they did not directly interact with purchasing administrators. Theoretically, this should place special importance on the design of the instruments through which nurses' feedback could be delivered to the administrators. None of the hospitals, however, had any guidelines for developing survey instruments to assess user satisfaction with devices.

In **Hospital 1**, no survey instrument was used. Instead, the Unit Director and the charge nurse informally gathered nurses' verbal feedback about the pumps.

Hospital 2 similarly did not use survey instruments in the course of the clinical evaluation. The Clinical Resource Coordinator and ICU directors transmitted feedback from the site to corporate-level administrators verbally. The feedback was supplemented by pictures of eight double-channel pumps, set up in the smallest room of Trauma ICU. The purpose of this visual feedback was to demonstrate that the two-channel model advocated by the administration was not suitable for the environment of Hospital 2. In addition to clinical evaluation, Hospital 2 conducted an evaluation of the two competing candidates, based on the instrument developed by one of the vendors. The instrument provided a list of various infusion pump features. Users were asked to classify each feature as important, desirable or non-essential. Upon completion of the surveys, the Clinical Resource Coordinator conducted informal comparison of the two candidates based on the features that users nominated as important. She presented the results of her evaluation to corporate level administrators in a report.

Table 1: Hospital 3. Correspondence between pump A survey questions and design heuristics

Heuristic	Survey question
Visibility of system state	Was the infusion flow rate visible at all times?
Match between the system and the world	Were you able to program the pump without difficulty?
Minimalist design	NONE
Memory load minimized	NONE
Informative feedback	Did alarm sound appropriately? Frequent false alarms?
Flexibility/efficiency	NONE
Good error messages	NONE
Preventing errors	NONE
Clear closure	NONE
Reversible actions	NONE
Users' language	NONE
Users in control	NONE
Consistency/standards	NONE
Adequate help and documentation	Was the accompanying directions adequate?

In **Hospital 3**, clinical evaluation of the two pumps took place at 20 clinical units, and ran for two weeks at each unit. At the conclusion of the trials, nurse managers distributed survey evaluation forms to the users (floor nurses). As in the case of the other hospitals, clinical evaluation was the primary mean for the users to communicate their opinions of the devices to the administrators. Review of documentation revealed that two survey forms were used during clinical trials, one for each pump. Each form was developed by its respective vendor. Pump A form included 12 yes/no questions. Pump B form included 33 Likert-scale questions. During the interviews, none of the participants could explain the origin of the survey questionnaires; none also demonstrated awareness that two different forms had been used. To assess each form's value as a usability evaluation tool, we compared their questions with the well-established design heuristics. A correspondence between 12 Pump A survey questions and 14 established heuristics are outlined in Table 1. Of the 12 survey questions, only four evaluated the pump's adherence to important design principles, and they did it in the most general way. The remaining eight questions evaluated technical aspects of the pump.

Discussion

Present study analyzes the nature of institutional decision making in infusion pumps selection in three hospitals. The study characterizes this decision-making as highly complex, with multitude of decision-related factors that need to be reconciled. The process is defined by many environmental constraints (e.g., time pressure, financial pressure from the vendors) and typically involves many individuals and groups with different types of expertise, bringing their unique perspectives to the table. The process of reconciling multiple perspectives and demands often involves conflict (as in the cases of Hospitals 1 and 2). Effective resolution of the conflict, reflected in good and safe decisions,

involves effective communication among various participating groups.

Cases of Hospitals 2 and 3 illustrate the role that effective communication and coordination of activities can play in reconciling the conflict among various perspectives. Both processes involved hospital-wide purchases of similar complexity level. In Hospital 2, a coordinated effort of the ICU directors, nurse managers and nurses helped them relate the importance of the clinical/usability perspective to the hospital and corporate-level administration. In Hospital 3, the information flow among various participating groups was restricted, which resulted in inadequate representation of critical device usability considerations in the process. While administrators left the process feeling that final selection satisfied users' needs, many of the clinicians were dissatisfied with the decision and felt that their opinion was ignored. We believe that information technology has a potential to facilitate communication and collaborating among participants, enabling them to capitalize on the strength of each individual perspective.

As suggested by the study, one of the differences between clinical and administrative perspective was in conceptualizing patient safety. All participants viewed patient safety as a critical factor in device selection. However, administrators tended to hold somewhat limited conception of device safety, viewing it in terms of accuracy and reliability. Clinical evaluation is a stage during which safety and usability violations may potentially be detected and exposed for all participants. This, however, requires using reliable, formal methods of assessing devise design and user satisfaction. None of the three hospitals described in this study had such evaluation procedures in place, relying instead on verbal feedback and user-developed multiple choice surveys. Lack of adequate instrumentation may further complicate integration of various perspectives. One potential way to facilitate adequate assessment is via providing purchasers with guidelines. Given documented difficulties with incorporating published guidelines into the workflow, further research should look into feasibility of developing automated guidelines for medical device purchasing. Information technology may also support standardization of device purchasing process by providing computerized instruments for developing assessment instruments and by disseminating information about HCI methods of device-evaluation.

Acknowledgements

Support was provided in part by grants P01 HS11544 and HS11806 from the Agency for Healthcare Research and Quality. The authors give sincere thanks to the participants for their willing cooperation in this study. We are also grateful to Michal Tamuz for providing assistance with the development of the interview instrument.

References

[1] Lin L, Isla R, Doniz K, Harkness H, Vicente KJ, Doyle DJ. Applying human factors to the design of medical equipment: Patient-controlled analgesia. *Journal of Clinical Monitoring and Computing*. 1998;14: 253-263.

[2] Johnson TR. The role of medical device and users in reducing device-use errors. Submitted 2003.

[3] McConnell EA, Cattonar M, Manning J. Australian registered nurse medical device education: A comparison of simple vs. complex devices. *Journal of Advanced Nursing*. 1996;23(2): 322-328.

[4] FDA. Improving Patient Care by Reporting Problems with Medical Devices.1997. Available at: http://www.fda.gov/medwatch/articles/mdr/mdr.pdf. Accessed June 27, 2000.

[5] Patel VL, Kaufman DR, Allen VG, Shortliffe, EH, Cimino, JJ, Greenes, RA. Toward a framework for computer-mediated collaborative design. *Methods of Information in Medicine*. 1999; 38: 158-176.

[6] Miles MB, Huberman AM. *Qualitative data analysis.* Thousand Oaks, CA: SAGE Publications, Inc; 1994.

[7] Nielsen J, Molich R. Heuristic evaluation of user interfaces. *Proceedings of CHI'90*; 1990; Seattle, WA: ACM, 249-256.

Address for correspondence

Alla Keselman,

622 West 168th St., VC-5, New York, NY, 10032-372, USA,

E-mail: alla.keselman@dbmi.columbia.edu