

The Role of Patient Safety in the Device Purchasing Process

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Abstract

To examine how patient safety considerations are incorporated into medical device purchasing decisions, individuals involved in recent infusion pump purchasing decisions at three different health care organizations were interviewed using a structured interview process. Interview questions covered triggers for the purchasing process; the purchasing process itself; how safety was evaluated and incorporated into the process; and the perceived decision and process quality. The results show strengths and weaknesses within the processes. Strengths included (1) a general perception that patient safety was important and played a role in the decision; (2) the inclusion of a wide range of stakeholders in the decisionmaking process; and (3) the use of device user feedback as a component of the device evaluation process. Weaknesses included (1) safer devices may have been overlooked, as very few alternative devices were considered; (2) two important stakeholders, device users and patients, did not participate directly in the purchasing decisions; (3) the device selected for purchase often was determined before the evaluation process had been completed, and the evaluation process then was used to justify the selection decision; (4) although participants felt they had considered device safety, the device evaluation often was limited to technical safety issues, such as operating to technical specifications, rather than device interface issues that may induce or prevent device usage errors; and (5) no explicit, formal usability testing was conducted at any of the three sites for the purpose of assessing device safety. These weaknesses underscore the need for guidelines and tools to help health care employees better assess issues central to patient safety during the device purchasing process.

Introduction

Studies show that more problems are caused by medical device usage errors, than are the result of device malfunctions.¹ Although device users are traditionally blamed for these errors, there is widespread evidence to indicate that a large number of device usage errors are the result of poorly designed user interfaces.² The United States Food and Drug Administration (FDA) and device manufacturers continue to work to improve device safety, but since no device is completely safe in every environment, the medical device purchaser or purchasing committee is responsible for selecting the medical device that is safest for their targeted environment. Unfortunately, anecdotal evidence suggests that many health care professionals believe that FDA approval ensures device safety and that

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any approved devices must be comparably safe. Moreover, it is unclear to what extent the health care professionals charged with making purchase decisions are trained in the techniques of evaluating patient safety, or whether these considerations are being incorporated into the device purchasing process. It is also unclear whether those making the purchase choices understand how to make patient safety issues a priority in the decisionmaking process and what criteria need to be included.

Despite the important role that the purchaser plays in the patient safety milieu, there are no prior studies of how safety considerations are integrated into the device purchase process. Likewise, there are very few published guidelines or procedures for assisting the purchaser in his or her desire to make patient safety part of the device evaluation process. Although the FDA clearly recognizes the importance of the purchaser and the end user in decreasing device usage errors, the Agency has emphasized guidelines and recommendations for medical device manufacturers, and not the purchasers of the equipment.^{3,4} The FDA guidelines for purchasers consist of a one-page list of questions designed to assist in the selection of a usable device; a continuing education document on the importance of reporting device usage errors; a quarterly publication, *User Facility Reporting*, that addresses usability issues from time to time; device alerts that include usage error information; and an online form for reporting device usability problems that do not result in patient harm.^{5,6} And while a very few academic papers have reported on safety evaluation procedures for specific devices, none recommends a conceptual framework that may be used by purchasers to assess the safe operation of any device.^{7,8}

This paper provides an overview of results from a series of qualitative, retrospective studies that examined how, and to what extent, patient safety considerations were incorporated into the device purchasing process at three hospital sites where recent intravenous medication infusion pump purchases had been made. We chose to examine the purchase process surrounding infusion pumps because they are one of the medical devices most commonly used in hospitals, and they are well represented in medical device error reports. The three studies were created using a conceptual framework that considered the interactive role of patient safety in the device purchasing process; the quality of the process as it relates to patient safety; and the patient safety attitudes and knowledge of those involved with or affected by the purchasing decision. First, individuals involved in the purchasing decisions were questioned using a structured interview process, to better understand the procurement process. Next, end users were observed as they operated the purchased infusion pumps in patient care settings, to evaluate the means by which they addressed safety issues that may have surfaced after the pumps were put into practice. Third, focus groups comprised of infusion pump users were conducted at each site, to further assess safety issues with the selected devices. The latter two aspects of the framework provided additional evidence for evaluating the quality of the device procurement process.

Methods

Participants

Three health care organizations were chosen as the study sites; two in Houston and one in the New York Metropolitan Area. Twenty-nine health care employees were interviewed in all: 9 from Site 1, 11 from Site 2, and 9 from Site 3. All subjects were involved, albeit to different extents, in the latest purchase of infusion pumps at their respective sites. The participants represented different levels of the hospital hierarchy and different employee work groups. All subjects at Site 1 were hospital employees, including administrative, management, and technical staff members, as well as five registered nurses (RNs) who were device end users. Three subjects at Site 2 were members of the health care system's corporate office staff and eight were hospital employees. Of the eight employees, four were end users of the infusion pumps (three RNs and one trauma nurse), and four were administrative staff including the biomedical engineering director and the materials management director. The sample at Site 3 included one biomedical engineer, four administrators, one physician, and three nurse managers. The participants were selected following informal discussions at each site to ensure that the samples were representative of all individuals involved. Each interviewed person also was asked to suggest names of others who played key roles in the purchasing process, and efforts were made to contact and interview these additional individuals. The key personnel from all sites were included in the study. Approvals were obtained from the Institutional Review Boards at each site and the subjects gave their written informed consent, prior to the interviews.

While assessing the results presented below, bear in mind that while patient safety was a primary concern for most of the participants, none of those interviewed had formal training in human factors or interface-related device usage safety. Likewise, none of the study sites had guidelines, tools, or a formal process in place for incorporating safety into the device purchasing process. Some technical staff, such as biomedical engineers, were trained and highly skilled at evaluating the technical safety of the devices. Their training, however, did not include formal techniques for user interface evaluation.

Interview instrument

The interview instrument was based on a conceptual framework of the purchasing process.⁹ The conceptual framework captured the aspects of interest in the study domain, including key factors, variables, and the relationships among them. This study addresses three key factors: the role of patient safety in the device procurement process; the efficacy of the procurement process in addressing patient safety concerns; and the attitudes and knowledge that participants in the process had toward patient safety. These three factors were found to interact in various ways and influenced one another.

A list of open-ended interview questions was developed using the conceptual framework. These questions focused on the events that triggered the purchasing

process, the steps identified in the purchasing process; the means by which the safety of the infusion pumps was evaluated and incorporated into the selection process; the patient safety knowledge and attitudes of the participants; and the perceived decision and process quality. The interview instrument contained eight sections: (1) introduction; (2) purchase process; (3) implementation of the decision; (4) results of the decision; (5) quality of the safety evaluation and decisionmaking process; (6) device user questionnaire (given only to device users); (7) safety attitudes and knowledge; and (8) demographics. The introduction contained eight questions designed to examine the subject's work assignment, years of experience, and whether or not they operate the infusion pump in the course of their work. The purchasing process section was comprised of 15 questions. The first three questions examined the subject's role in the process, their past experience with purchase decisions, and their knowledge of the factors that triggered the purchase process. The fourth question asked the subject to describe the purchase process from start to finish. This was followed by 11 additional questions designed to explore the details of the purchase process, including issues such as the selection of alternative devices, how the purchasing group was formed, what factors were used to evaluate devices, how these were combined, who made the final decision, and what role patient safety played in the decision. The third section contained two questions that examined the implementation of the decision. The first of these questions, asked of all subjects, examined how the device was introduced and implemented within the hospital. The second question, asked only of device users, looked at employee feedback and whether it was encouraged during the device roll-out process. The fourth section, results, contained five questions intended to examine safety issues discovered after the infusion pump implementation, whether user feedback had been encouraged, and if the feedback had resulted in any changes. The fifth section contained seven questions that solicited the subject's opinions regarding the quality of the pump safety evaluations and the purchase process. This section included questions that asked the subject to list what they considered to be the positive and negative aspects of the process; whether they felt the best purchase decision was made with respect to patient safety; and solicited suggestions for improving the selection and purchase process. Section 6 was a questionnaire given only to users of the infusion pumps. It was intended to measure their satisfaction with the selected device. Section 7 surveyed the subject's attitudes toward errors and error prevention. It involved a medical error scenario and several followup questions regarding factors that may have contributed to the error and actions that might be taken to prevent a recurrence. Section 8 was used to collect additional demographic information, including age, education, and background training.

Interviews

Each subject was interviewed after written informed consent had been obtained. At Sites 1 and 2, two individuals took notes during the interviews, typed them into a word processor, compared the transcripts and combined them immediately following the interview. One of the interviewers at Site 3 audio taped

eight of the nine subjects. One of the subjects asked not to be audio taped, so that individual's responses were instead recorded by hand. The identities of the subjects were removed immediately from all notes and transcribed data.

Data analysis

A coding scheme based on the detailed questions in the interview instrument was developed to summarize the subjects' responses to the interview questions. Researchers used the coding scheme to retrieve and organize the interview data. The scheme included codes for the following components: demographics; triggers; purchasing process; safety evaluation; participants' knowledge of device safety or human factors; quality feedback; organizational information; and suggestions. Each of these components then was further deconstructed, using additional coding. For example, the purchasing process includes participants, purchasing group formation, techniques/steps used, influencing factors, etc. The code "PR-FC," for instance, stands for influencing factors in the purchasing process. A list of detailed code descriptions was developed for use by the coders. Each set of interview notes was coded, after which the researchers reviewed the handwritten interview notes and summarized the interview on a contact summary form, as a means of developing an overall summary of the main points emerging from each contact.

Once all the interviews at a given site were completed and coded, the researchers reviewed the coded data, question-by-question, in an effort to develop an overall picture of the purchase process for the site. The main objectives of this process were twofold: an examination of the consistencies and inconsistencies among the views of the subjects at a given site; and the development of a broader view of the purchasing process. The general overview of the purchasing processes at each of the three sites is reported below.

Results

The results from the structured interviews were categorized according to the major areas of interest: factors that triggered the purchase process; the purchase process itself; how safety was evaluated and incorporated into the purchase process; and the perceived decisionmaking and process quality. Additional details of the purchasing process for Site 3 have been published elsewhere.¹⁰ Detailed analyses of the purchase processes at the two remaining sites are in preparation, as is a detailed analysis of the safety attitudes of the participants and a followup study designed to examine attitudes toward device usage safety in greater detail.^{11, 12}

Triggers

Triggers varied across the sites. At Site 1, a surplus of equipment funding [for a particular intensive care unit (ICU)] prompted the ICU director to ask the nurses on the unit what equipment they would prefer. The nurses requested new 3-channel infusion pumps to replace the 2-channel pumps they had been using. A business merger at Site 2 (involving a large health care system) led those involved

with the purchasing process to replace their existing pumps with equipment specified in a previously negotiated, systemwide purchase contract. The staff at Site 2 felt that the pump selected for use across the system's hospitals did not meet Site 2's unique clinical needs. Onsite administrators set up a purchasing committee to evaluate and recommend a pump, in an attempt to resolve the conflict. The purchasing process at Site 3 was triggered by an infusion pump leasing agreement that was about to expire. Although the triggers varied across the sites, it should be noted that patient safety was not, in itself, a trigger for any of the sites. Participants at Site 2 had named safety as a primary issue in their objections to the pump previously selected for purchase and use within the health care system. In particular, they felt that the pump's physical size and weight and the limited number of channels on the model in use within the system, combined with the clinical complexity of their patients, would lead to situations in which too many pumps would be positioned around each patient. Such a scenario could create a potential safety hazard for the care providers as well as the patients.

Purchasing process

With respect to safety, the important aspects of the overall process include the number of alternative devices considered, those who participated in the purchasing process, and the general process leading up to the selection of one device over the others. Specific device safety evaluations and their use in the process are described in the following section.

The selection of alternative devices varied by site, but was relatively limited across all sites. Only one model of infusion pump was considered for purchase at Site 1, where the purchase concerned a small quantity of infusion pumps for a single ICU. The selected 3-channel pump was already in use in another unit of the same hospital, and the person leading the purchasing process felt that the hospital had a good history with the pump manufacturer and its pumps. The same individual further cited a corporate contract with the pump manufacturer and positive feedback from the nurses who were already using the 3-channel pump. A biomedical engineer at the same site stated that because of the large discount afforded by the corporate contract, the hospital had to go with the manufacturer of the selected 3-channel pump.

The purchasing committees at Sites 2 and 3 considered two pump models each. The choices at Site 2 consisted of the pump that the parent health care system wanted the hospital to use, and another manufacturer's multichannel pump that was already in limited use at the same hospital. Staff administrators at Site 3 recalled that many different infusion pumps were considered early in the process, however, a review of meeting minutes showed that only two devices were given serious consideration. According to the minutes, a newer version of the pump then in use at the hospital was first considered. After entering into financial negotiations and conducting clinical evaluations, the purchasing committee found the pump had significant drawbacks (e.g., heavy weight and poor display readability). It was at this point that the purchasing committee began to consider a second pump. It is possible that the committee may have given some

consideration to additional pumps very early in the process, but this is not reflected in the meeting minutes.

The ICU director and the nursing manager at Site 1 were the only staff directly involved in the purchasing decision. They obtained oral feedback from the unit nurses prior to making the decision. The Chief Financial Officer was involved only from the standpoint of approving the request for the selected pump. In contrast, a variety of professionals from the engineering, administrative, and clinical areas at Sites 2 and 3 were involved in the purchasing process. Across all three sites, however, the role of the infusion pump end users was limited to providing feedback on the pumps under consideration—they were allowed no direct role in the selection of alternative devices or in the final decision.

Although the details of the process varied from site to site, each group followed the same basic format of evaluating the device choices—which included collecting user feedback—and then making a decision. At Site 1, the pump was brought in for a 2-week trial, after which the ICU director and nursing manager collected oral feedback from those who had used the device. Nurses at Site 2 were given a survey asking their opinions on the important features of infusion pumps and both pumps were set up for the nurses to try. The pumps were not put to use in clinical care settings. The most notable aspect of the process at Site 2 is that it appears to have been used, in large part, to demonstrate the inferiority of the health care system's recommended pump, while at the same time emphasizing the ability of the alternative pump to better meet the hospital's unique clinical needs. The two pumps considered for purchase at Site 3 were evaluated in clinical trials that included the use of vendor-supplied surveys to collect solicited user feedback; however, a different survey was provided for each of the pumps.

Safety and cost were mentioned as major factors in the decisionmaking process at each of the sites. However, except for a small number of device characteristics (e.g., the number of channels and the physical weight and size), safety issues were limited largely to technical specifications (i.e., the ability of the device to function properly and operate within the standards of accuracy stated by the manufacturer).

Safety evaluation and its use in the purchasing process

Although technical safety was an obvious consideration during the purchasing processes, factors that play a role in device usage errors rarely were considered. Many of those interviewed seemed largely unaware that a pump's interface design could induce device usage errors. Some users did mention "ease of use" or "ease of programming," which indicates a general awareness that the device interface can have an effect on safety. The number of channels and the pump's physical size and weight—clearly important safety factors—did play prominently in most of the participants' views of the decisions.

As noted previously, feedback at Site 1 was limited to oral comments from nurses who had used the one model of pump brought in for the trial. Those involved in the selection process at Site 2 were concerned more with the weight

and the number of infusion channels, and less with the device interface. To demonstrate the potential for safety problems with the (2-channel) pump already in use at other facilities operated by the same health care system, they placed eight in a room and used photographs to demonstrate their concern that the pumps would become a workspace obstruction and would impede access to the patient. Likewise, the survey conducted at Site 3 contained four questions for evaluating the design of the interface. But the questions addressed only four features of the pump and did not permit an adequate evaluation of the device interface. Thus, the sites collected very little information regarding the safety of the various pump user interfaces, apart from the largely informal user feedback incorporated into the evaluation.

Perceived decision and process quality

Administrators across the three sites considered the final purchase decisions to be correct and in the best interests of patient safety. The clinicians' opinions of the decisions varied by site. Those directly involved in the decisions at Sites 1 and 2 felt the best decision was made. Some clinicians at Site 3 expressed the opinion that users were less satisfied with the selected pump, and that user feedback had not been made a priority in the decisionmaking process. Several device users at each of the sites said that their opportunity for feedback was too limited and that the provided feedback was largely ignored. Their lack of direct involvement with the purchase process left these users hard-pressed to understand the basis on which the purchase decision had been made, and they said they had difficulty determining if the correct device choice had been made. A technical staff member at Site 1 said during the interview, "I begged and pleaded with administration not to buy the pump," because this person was aware of several FDA recalls and alerts involving the selected pump, and felt that the older model was easier to use.

Perceived quality of process varied by site

Administrators at most of the sites were generally pleased with the process and their role in it. The lone exception was Site 2, where the hospital administrators said they felt the process would have been more efficient if the administrators at the health care system level would have collaborated with them. Administrators with the parent health care system said that they, too, could have made the process more efficient and cost-effective, if only the hospital purchasing committee had been more cooperative. While the device users across all sites had little insight into the purchasing process, those end users at Sites 2 and 3 said they felt that not enough weight had been given to their feedback. The concern they had with "not being heard" was voiced by the users at every level of the decisionmaking process. The device users' opinion of the process quality at Site 1 varied. Half of the users said that they had played a valid role, while the other half said they were given little or no opportunity for input—or that their input was not a factor in the decisionmaking process. Likewise, the technical staff member interviewed at Site 1 expressed the opinion that the process had been flawed because the biomedical engineering department staff had the most knowledge of the pumps, but did not play a direct role in the decisionmaking process.

Discussion

Human factors research has shown the importance of involving all stakeholders in medical device and software evaluations.¹³ Additional evidence also has shown that the successful implementation of new technology depends, in part, on the early involvement of all stakeholders.¹⁴ With respect to purchasing, this research makes a case for involving a wide range of professionals in the process—including anyone whose responsibilities are affected, directly or indirectly, by the device purchasing decision or the clinical use of the device. For infusion pumps this includes, at a minimum, nurses (who program the pumps), physicians (who write the orders), pharmacists (who fill the orders), biomedical engineers (who repair the devices), quality improvement staff, unit managers (who supervise the nurses), and patients, as well as those who train the pump users, and the administrators who must account for the cost of the pumps and their maintenance.

The results of this study reveal strengths and weaknesses in the use of patient safety concerns as a factor in the device purchasing process. On a positive note, participants at all sites regarded patient safety as an important issue, and all used some type of user feedback mechanism to assess user satisfaction and to express safety-related concerns. In addition, Sites 2 and 3 included a broad range of stakeholders in the purchase process. That Site 1 did not do this is likely a reflection of the facility's smaller size, and the modest number of pumps that were being purchased for a single ICU. The variance is worth studying, however, as it could reflect a difference in the decisionmaking processes at smaller and larger hospitals, or a difference in the methods by which smaller and larger purchases are decided.

The results also reveal a number of weaknesses in the current purchasing processes at the three studied sites. The consideration given to alternative devices was limited across all sites, as participants at one site considered only a single infusion pump for purchase, and the groups involved in the process at the remaining two sites considered two pump models each. Purchase decisions should ideally involve a broad range of available devices, to ensure the safest device is selected. At each of sites where two different models of pumps were debated, consideration was given first to a single device and then, after that device showed problems, to a second device.

The study further revealed potential problems with the composition of the purchasing groups. End users have the greatest knowledge of a device's strengths and weaknesses, and of the environment and tasks to be performed with the device, yet none of the three purchasing teams included end users. Likewise, patients were not included on the purchasing teams.

While user feedback was solicited and collected at each of the sites, most of the end users said they were given only a limited opportunity to contribute feedback. Moreover, they expressed frustration at the lack of weight given to their feedback in the pump selection process. In addition, none of the sites used formal methods for assessing safety issues that may arise from the design of the device

interface. Instead, much of the safety evaluation focused on the technical safety specifications of the pumps and informal user feedback.

Another primary process limitation at all three sites involved assertions that a particular make and model of infusion pump was identified as the preferred product, after which the discussion and selection process was carried out primarily to justify the choice of that product. For example, the lead decisionmakers at Site 2 decided early in the process that the 2-channel pump being recommended for purchase by the parent health care system was not as well suited to the hospital's needs as the 3-channel version of the pump the hospital had been using. The purchasing committee's subsequent work appears to have been done solely to demonstrate the superiority of the preferred pump, and the inferiority of the pump recommended by the health care system. A selection process that is undertaken to justify a prior decision is especially problematic, because it indicates the likelihood of a confirmation bias (i.e., a bias used to solicit data that confirms a particular hypothesis), while further suggesting that information supporting alternative hypotheses may have been discounted or ignored.¹⁵ Studies of the confirmation bias have shown that it often leads individuals to believe in a faulty hypothesis.¹⁶ Thus, individuals on these purchasing committees may have believed that they selected the best available device, when in fact they were not given or chose to ignore data that may have discounted their choices.

Patient safety was named a major factor at each of the sites, however, we found that the purchasing groups gave more consideration and emphasis to technical safety (i.e., whether the pump was operating within certain technical parameters). There was relatively little awareness among the groups of the device interface role and how it might directly impact patient safety by increasing (or decreasing) the incidence of device usage errors. As a result, purchasers showed a tendency to judge infusion pump software features (e.g., drug dosage calculators) as being equal with respect to their influence on safety, whereas human factors engineering has shown that the effectiveness of such features is largely a function of their user interface. In contrast, pump weight and the number of pumps needed per patient played a major role in the purchase decisions, and some users were clearly concerned with "ease of use" and "ease of programming." This indicated some awareness of the human factors issues involved with device use safety. Overall, however, these results reveal inconsistencies with respect to the participants' understanding of patient safety and its role in the decisionmaking process, as well as the extent to which safety was a factor in the infusion pump procurement decisions.

Another perplexing dimension of the purchasing process involved the survey participants' collective concern for patient safety, and their inability to define or articulate those factors with a direct connection to patient safety. All members of the subject groups felt that patient safety was an important dimension and one that should be addressed in the overall process, however, they were unable to agree upon a conceptual model with which they could identify and order the aspects of infusion care most important to a successful patient outcome.

Although most of those involved directly with the purchases felt that the best decisions had been made and that device safety played a primary role in the decisions, the device users were less certain of the decisions. As noted above, some participants directly involved in the purchase decisions expressed concerns that the pump selected for purchase was not necessarily the safest model available. Although our interview results showed that the perceived quality of the decisionmaking process was mixed, our independent analysis—done from a human factors engineering perspective—revealed numerous process limitations. The limitations identified in this study do not reflect a lack of concern for patient safety among the participants. All participants in this study expressed the opinion that patient safety was a major dimension of the purchasing process and they attempted to maximize patient safety throughout the process. Rather, the weaknesses are a reflection of the participants' lack of training in device safety, its integration with the purchasing process; and the need for formal tools or guidelines to advance such a synthesis.

Conclusion

Despite the general awareness of patient safety, its importance, and its role in medical device comparisons and purchasing decisions, this study revealed some serious limitations in the selection process at the three sites. It also calls into question the methods by which device usage is used to generate feedback for the selection process. These results illustrate the need for a more formal method of incorporating patient safety considerations into the medical device purchasing process. We presently have a set of guidelines in development to help hospitals better emphasize patient safety in their device purchasing decisions. These guidelines include recommendations on those types of personnel to be included in the selection group; the overall process of device evaluation, tools and techniques for assessing device interface safety; and procedures for bringing other relevant factors into the selection and purchasing process.

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