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Nurses' Perceptions of Implant Barcode Scanning in Surgical Services

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The US Food and Drug Administration's 2013 Unique Device Identification System Rule requires manufacturers to label devices with unique identifiers. Implantable devices are now shipped with unique identifiers, and many electronic health records have fields to incorporate them. Health policy changes have prompted hospital systems to assess implementation of implant barcode scanning systems to capture unique device identifiers. Project aims were to assess predictors of operating room nurses' acceptance of a new implant barcode scanning system, describe operating room nurses' perceptions of the system value, and identify operating room nurses' perceived gaps in system implementation. An online survey was disseminated to operating room nurses, and focus groups were conducted with orthopedic operating room nurses in an academic medical center that had recently implemented an implant barcode scanning system in surgical services. Predictors of barcode scanning acceptance included perceived usefulness for patient care, perceived ease of use, and perceived usefulness (self). Nurses perceived the system to be more accurate and valuable for patient safety. Perceived gaps in system implementation related to communication, completeness of the system, consistency in process, and training. Understanding nurse perceptions of new barcode scanning systems and engaging them in the implementation process are key areas for success and optimization of these systems.

KEY WORDS: Barcode scanning, Implants, Unique device identifiers

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Introduction of new health information technology (IT) systems and process has become common in US hospital systems over the past decade. Hospital personnel have been required to transition from manual paper-based systems to electronic systems. Numerous studies have looked at nurses' perceptions and acceptance of, and satisfaction with, these systems, revealing important insights for implementation and operationalization. Areas of focus have included technology in the operating room (OR),[1,2] barcode scanning systems, particularly for medication documentation and reconciliation,[3–5] and links to quality and patient safety.[6,7] Works by Holden et al,[3,8,9] Song et al,[10] and Lu et al[11] have drawn on the technology acceptance model (TAM) highlighting focus areas for user acceptance of and satisfaction with the systems as well as areas in need of development to optimize implementation and use.

Barcode scanning of medical device unique device identifiers (UDIs) and documentation in the electronic health record (EHR) is an area under development in US hospital systems. The US Food and Drug Administration (FDA) in 2013 issued the Unique Device Identification System Rule, which required manufacturers to label their marketed devices with UDIs.[12] Implantable devices are now being shipped with UDIs, and many EHRs have fields to record them. Health policy changes such as inclusion of UDI for implantable devices in the common clinical data set and Meaningful Use Stage 3,[13,14] recommendation for inclusion of UDIs for implantable devices in claims,[15] and recommendation for leadership of a national UDI implementation strategy by the National Evaluation System for health Technology (NEST), the new national system for medical device evaluation,[16,17] have prompted hospital systems to address implementation of implant barcode scanning systems and UDI use. Although some hospital systems have implemented electronic UDI systems for implantable devices at the point of care, more often hospital systems seek information and best practices to guide implementation initiatives.

Medical procedures requiring implantable devices are widely used in the US to reduce patient morbidity and mortality. Unfortunately, issues of safety or effectiveness may become apparent after implantation. Device failures affecting patient health and safety, such as implantable cardioverter-defibrillator leads and metal-on-metal hip implants, have

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been well documented.[18,19] Comprehensive and efficient systems to identify and address patients who have these devices implanted are needed. Robust device evaluation is needed to quickly identify device failure to avoid further use. Even with well-publicized failures and clinical care needs, requirement of a medical device standard for documentation and identification similar to the National Drug Code (NDC) for pharmaceuticals was lacking until the 2013 FDA UDI Rule.

The value of UDI use has been well discussed in the literature. The ability for patients and clinicians to access device-identifying information in the UDI (manufacturer, model, lot/serial number, expiration date) as well as device attributes (contains latex, magnetic resonance imaging [MRI] compatible) supports quality of care and safety for patients. Quick and accurate identification of a device implanted in a patient is needed in cases of recall, revision surgery, an emergency or if the patient requires an MRI, which may occur near-term or years after a patient's procedure.[20–23] The availability of a documentation standard (UDI) supports ability for FDA and researchers to harness medical device data and enrich with clinical data to generate real-world evidence on device safety, to support clinical decision making and device improvement.[17,23–26] There is recognition that UDI documentation in hospital systems is the backbone for UDI availability and use in clinical care, by patients, and for device evaluation and research.

Important parallels in terms of quality and patient safety exist between barcode scanning medications and implantable medical devices, although implementation and use of medication barcode scanning systems are at a more advanced state in US healthcare. In the case of medications, barcode scanning has been associated with reduction of medication error and enhanced patient safety.[27] Additionally, availability of a coding and documentation standard (NDC) has augmented the ability for FDA and researchers to have access to aggregated data for evaluation and research, to generate evidence on product safety, to support clinical decision making, and for product improvement.[28]

Research and industry initiatives[25,26,29,30] have focused on the challenges and barriers of implementing a successful UDI system including siloed IT systems, gaps in IT system interoperability, inconsistent data standards, and multiple barcodes on device packaging. Unique device identifier implementation case studies highlight the need for cross-disciplinary planning and collaboration, good communication, and strong follow-up to address implementation issues.[29] Assessment of nurse perceptions of new systems to electronically capture UDIs is an important aspect of study, as it has been in other areas of barcode scanning, to illuminate gaps and impact on clinical workflow as nurses transition from a manual or partially manual system (typing numbers into the IT system) to an electronic barcode system.

Project aims were (1) to assess predictors of OR nurses' acceptance of a new implant barcode scanning system in surgical services, (2) to describe OR nurses' perceptions of the system value, and (3) to identify OR nurses' perceived gaps in system implementation.

METHODS

Study Setting and Participants

Project setting was surgical services in a 260-bed academic tertiary care hospital in the southwestern US that was implementing an implant barcode scanning system across surgical services using a UDI prototype for implantable devices (barcode sticker created by the hospital system with the device lot and serial number, placed on the box). The hospital system decided on a UDI prototype so that nurses would know what to scan. The goal of implementation was to move from a manual process (putting implant labels on sheets, typing numbers into an IT system) to an electronic process for implant documentation. The barcode system was implemented across surgical services over a number of months and completed in December 2014. The orthopedic surgery ORs were undergoing implementation of the implant barcode scanning system during the project period.

Theoretical Framework

Perceptions and satisfaction of OR nurses with the new implant barcode scanning system were assessed in the project as part of a process evaluation. The TAM was used as a framework; it has been used in research on IT acceptance in healthcare including medication barcode scanning systems,[8] medical professionals acceptance of EHR,[31] radiological picture archiving and communication systems,[32] and telemedicine technology.[33] This validated model has been shown to reliably predict the acceptance or adoption of new technologies by clinical users. Key constructs in the original TAM framework included users' perceived ease of use (PEOU) ("the degree to which a person believes that using a particular system would be free of effort") and perceived usefulness (PU) ("the degree to which a person believes that using a particular system would enhance his or her job performance").[34] Subsequent work has expanded the model to include PU for self and PU for patient care (PU-PT),[8] social influence (SI) ("the degree to which an individual perceives that important others believe he or she should use the new system"),[35] training, and support (perceived facilitating conditions).[3]

Survey Data Collection

All OR nurses were invited to participate in the study survey. Six months after full implementation of the implant barcode scanning system across surgical services, the nurses received an institutional review board (IRB)–approved invitation via email to participate in an online survey. The survey was

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administered through Qualtrics (Provo, UT) in August-October 2015 and was open for 6 weeks. Reminders to complete the survey were sent via email after 2 and 4 weeks.

The survey instrument was a validated tool used in prior studies on barcode medication administered systems.[3] The multi-item scales consisted of 24 items that measured six dimensions of technology acceptance: PEOU, PU, SI, training, support, and PU-PT. Survey scales are presented in Table 1. The survey also included questions on demographics, age, gender, education level, years of nursing experience, shift schedule, position, and nursing specialization. The main outcome measure was reported satisfaction (SATISF) with the barcode system, used as the measure of acceptance.

Survey respondents were asked to rate their level of agreement with each statement on a seven-point Likert scale ("not at all," "a little," "some," "a moderate amount," "pretty much," "quite a lot," and "a great deal"). A "don't know" option was also included.

The survey underwent a pilot test with five nurses and nursing administrators. Changes were made based on input that they provided. Participants in the preimplementation phase were not included in the formal research project.

Focus Group Data Collection

Focus groups were utilized to further probe participant perceptions of the barcode system. Three focus groups were conducted in February and March 2016, 6 months after administration of the survey. All orthopedic OR nurses, who represented the specialty that had most recently undergone implementation of the barcode scanning system, received an IRB-approved invitation via email to participate in one of three 60-minute focus groups. All participants provided oral consent prior to the focus groups. One researcher led and facilitated all focus groups utilizing an open-ended interview guide developed by the research team. The research team included experts in qualitative research as well as in survey design and analysis. Questions pertained to prior experience with barcode scanning, thoughts when barcode scanning started, impact on workflow, perceived value for the OR team, perceived value for the hospital, perceived value for patients, training, and support. Recordings of focus group sessions were transcribed verbatim by a professional service.

Table 1. Survey Scales and Psychometric Properties

Scale	Cronbach's α
PEOU	.84
PU	.89
SI	.83
Training	.97
Support	.88
PU-PT	.94
SATISF	.85

Data Analysis

Descriptive statistics were used to analyze demographic information and predictors of satisfaction with the barcode system. Survey data are presented as means (confidence intervals) for continuous variables and percentages for categorical variables. Scales as shown in Table 1 were constructed by averaging all valid items with a floating denominator after first removing "don't know" responses. Internal consistencies among scale items were assessed using Cronbach's α.

In a multivariable linear regression analysis, we examined the association between each of the six technology acceptance constructs (PEOU, PU, SI, training, support, and PU-PT) and user satisfaction after adjusting for age and years of nursing experience. An a priori criterion of 0.05 was used for statistical significance, and 95% CIs were calculated around parameter estimates. Survey data were analyzed using Stata 11 (Stata Corp, College Station, TX).

Thematic coding was used to analyze focus group data. Two members of the research team independently reviewed the transcripts from the three focus groups utilizing a constant comparative approach. The researchers first familiarized themselves with the data by reviewing the transcripts and created a preliminary list of inductive codes. Following this initial independent review, the researchers compared their independent findings and collaboratively developed a thematic framework. Transcripts were re-reviewed by each researcher using the coding scheme. Key data for each theme were obtained including quotes. Disagreements were adjudicated, and consensus was reached on major themes and subthemes from the focus groups.

The study was reviewed and approved by both the academic institution and the study site IRBs.

RESULTS

Survey

Fifty-five of 72 participants (76%) responded to the online survey invitation. Participants were excluded from the final analysis if they worked at the study site for less than 6 months (n = 3) or did not finish the survey (n = 8). The analyzed data set included 44 responses from 44 participants. Survey scales and their psychometric properties can be found in Table 1. Demographics of the studied group can be found in Table 2.

Participant Perceptions and Acceptance of Implant Barcode Scanning

Figure 1 portrays the mean (SD) scores for the individual scale items. Perception scores were positively correlated with one another (all Ps < .05). Overall, participants reported

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Table 2. Demographic Characteristics of Survey Sample (N = 44)

	Response (%)
% Female	80
% White, non-Hispanic	87
Age, %	
18-25 y	—
26-35 y	8
36-45 y	42
46-60 y	39
>60 y	10
Education, %	
Associate	32
Bachelor's	49
Graduate	19
Years nursing, %	
1-5	17
6-10	23
11-15	9
16-20	13
>20	38
Shift worked, %	
Day	98
Other	2
Full time, %	93

high ratings for ease of use (PEOU: mean = 4.67, SD = 0.9). Participants also reported that the barcode system was useful for their job (PU: mean = 4.24, SD = 1.26), although not quite as useful for patient care (PU-PT: mean = 3.4, SD = 2.0). Thirty percent of participants reported that barcode scanning improved their job performance "a great deal," and 24% reported that it improved patient care "a great deal'. Support (mean 4.3, SD = 1.3) was rated higher than Training (mean 3.88, SD = 1.44). Social Influence (SI: mean = 3.39, SD = 2.05) was rated lowest.

Overall, participants had high levels of satisfaction with the system (SATISF: mean = 5.6, SD = 1.2) with forty-seven percent reporting that they preferred the new system to the previous process "a great deal." Significant predictors of satisfaction were PEOU ($P = .003$), PU-PT ($P = .003$), and PU ($P = .008$). Social influence, training, and support were not significantly associated with satisfaction (Table 3).

Focus Groups

Focus group questions were developed based on survey scales. Perceived usefulness was expanded to include PU for the hospital organization (PU-ORG).

Fifteen of 16 participants (94%) attended one of three focus groups. Five of the participants (33%) indicated prior experience with barcode scanning. Demographics from survey results were compared. Participants who were orthopedic nurses were younger (66% were ≤45 years compared to 46% of nonorthopedic nurses); educated at the associate and bachelor's levels; and had fewer years of nursing experience (49% with ≤10 years of nursing compared to 34% of non-orthopedic nurses). Survey responses did not differ significantly between orthopedic and other OR participants; however, regression analyses were adjusted for age and years of nursing experience to account for potential residual confounding.

Table 4 reports the six themes that emerged from analysis of the focus group transcripts: communication, process, efficiency, accuracy, patient care, and operational tasks.

Communication

Communication was consistently discussed as negative except for support. Subthemes included (participant) knowledge of purpose and inconsistency, as portrayed in the following quotes:

> *It just showed up one day.*
>
> *I didn't really know what it was all about or what it was for, like the whole purpose of it. We weren't really well-informed on why we were doing that.*
>
> *Everybody needs to be on the same page.*

Process

Process was also consistently discussed as negative with a subtheme of the system being incomplete, as shown in the following quotes:

> *It shouldn't be brought into the room unless it's complete. If you're going to barcode everything, barcode everything.*
>
> *I find manual things to be much easier unless the system's complete.*
>
> *Scanning all of them, that is easier.*

Efficiency

The theme of efficiency that emerged for PU, PU-ORG, and PU-PT was discussed as positive, as portrayed in the

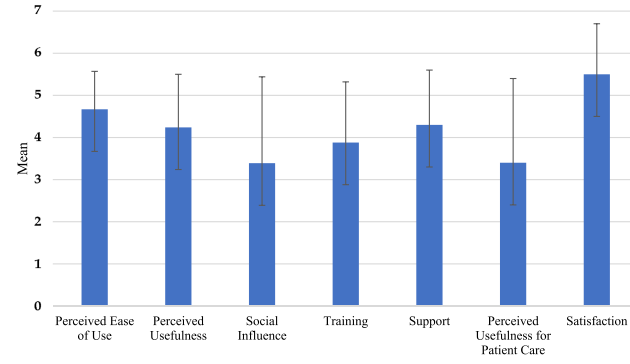

FIGURE 1. Mean (SD) scores for scale items.

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Table 3. Unstandardized Parameter Estimates From Regression Results for Scale Items on Satisfaction

Scale Item	β	SE	P
PEOU	3.61	0.87	.003[a]
PU-PT	.51	0.11	.003[a]
SI	−.001	0.20	.99
PU	.87	0.299	.008[a]
Training	.42	4.57	.0675
Support	.24	0.24	.388

Univariate predictor models are adjusted for age and years of nursing experience.

[a]$P < .05$.

following quotes. Use for recalls and device tracking were subthemes.

Should make it easier… faster.

If they (patient) moved somewhere across the country, and the surgeon there needs to find out what was implanted… it may be easier for them to find out.

However, the theme of efficiency that emerged for PEOU and SATISF was overall discussed as negative with a subtheme of doing duplicate work, as described in the following quote:

It becomes less efficient when you're using the old system and then the barcode system because then you're doing both.

Accuracy

Accuracy was consistently discussed as positive, with a subtheme of error reduction, as evidenced in the following quotes:

I would definitely trust a scan versus writing.

Not looking at messy handwriting.

You know the exact part.

Patient Care

Patient care was consistently discussed as positive, with a subtheme of safety, as portrayed in the following quotes:

Theoretically you can focus on the patient… having your eyes on the patient, as opposed to if you are doing everything manually, typing.

If I were a patient, I'd rather have it electronic than someone's hand writing my numbers.

I think all of us now realize how important it is for patient safety.

Operational Tasks

The theme of operational tasks was consistently discussed as negative with a subtheme of loss of patient focus, as portrayed in the following quotes:

To be responsible for the patient's bill and their clinical care at the same time. No one else has that.

…like the checkout cashier… so not patient centered.

Someday there will be a system where the nurses are not charging, and you're just clinical in the room.

DISCUSSION

This project applied a new healthcare policy, the FDA's UDI rule, to the hospital setting and studied the impact of an implant barcode system on surgical services. Using the TAM framework and a mixed-methods approach, this study provided rich information on OR nurse perceptions and predictors of acceptance with the new barcode scanning system.

In evaluating the impact of a new health IT system such as barcode scanning of UDIs, qualitative benefits for OR nurses, such as increased time for patient care and ease of working, may not be easily quantifiable. Health IT has been described as complex, implementation is very important, and evaluation is challenging.[36]

A mixed-methods approach was utilized to understand with greater depth participant perceptions. Findings from the survey indicated that PEOU, PU-PT, and PU were predictors of acceptance. The focus groups uncovered contextualized issues and provided a deeper understanding of these predictors. Important findings from focus groups were the need for communication of purpose, development of a complete system and consistency in process, and inefficiency due to duplicate work. Importance of the implant barcode scanning system for greater accuracy and patient safety was illuminated in the focus groups.

Table 4. Focus Group Themes

Survey Scale	Theme
SATISF	(1) Communication
	(2) Process
	(3) Efficiency
PEOU	(1) Communication
	(2) Process
	(3) Efficiency
PU	(1) Efficiency
	(2) Accuracy
	(3) Patient care
PU-ORG	(1) Efficiency
	(2) Accuracy
	(3) Patient care
PU-PT	(1) Efficiency
	(2) Patient care
	(3) Operational tasks
Training	(1) Communication
	(2) Process
Support	(1) Communication

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Some of the issues and unexpected consequences of implantable device barcode scanning that may have affected participant perceptions are issues similar to those seen as barriers in other hospital systems implementing UDI: not being a complete system (100% of implantable devices cannot be scanned); no functional interfaces between health IT systems, so one scan populates multiple IT systems; and duplicate work performed by nursing staff. Change of IT systems, limitations of IT systems, and lack of functional interfacing between IT systems are known barriers to efficient implementation of a UDI process.[25,29,30] Duplicate work performed by nursing staff as identified in our study and by others may reflect the complex and iterative nature of implementation. Lacking a complete system reflects a few issues: the long-term nature of health IT implementation and adoption, so that a complete system requires time to develop, and its use in the clinical setting may begin before this completeness is achieved; not all implantable devices may be in the database to be scanned; and some devices may not have a barcode to scan.

Recent research through the BUILD Initiative on implementation of UDI for implantable devices at the point of care in hospital systems[22,37] has further illuminated some of the barriers faced by clinical staff who do the barcode scanning at the point of care. In some cases, barcode scanning initiatives may begin in a pilot site, such as one specialty area within an OR, with a designated set of implantable devices. Reasoning for this is that a high level of work is required to build a comprehensive database to support scanning at the point of care, time is needed to successfully engage clinical staff, and a smaller set of procedures and implantable devices is more manageable initially. Once the pilot project is done, an organization can learn from their experience prior to implementing barcode scanning more broadly, such as across surgical services. The drawback is that during this process the nurses are not able to scan in all settings where they may provide care (such as in different specialty ORs). Another finding from this research is that some devices that are considered implants from a clinical perspective may not be required to be scanned from an operational perspective. Some implantable devices do not have barcodes that can be scanned (eg, sterilized screws that have been removed from their box). Other devices cannot be successfully scanned because the device is not in the database (eg, implantable device brought in the day of the case or custom implantable device).

This study builds on literature from studies of nurses' acceptance of bar code medication administration technology.[3–5] Perceived ease of use and PU-PT have been previously shown as predictors of acceptance.[3] Our findings are consistent with themes of user engagement and feedback during system implementation.[5] In prior work, nurses appreciated the accuracy and enhanced patient safety but disliked workflow inefficiency.[4]

This study provides important information for leadership as hospitals respond to health policy and move forward to develop new process for implementation and adoption of UDI. Nurse perceptions obtained from research or assessments internal to an organization should inform development of targeted strategies for education, communication, and workflow efficiency surrounding implementation.

Limitations

The study was conducted at one hospital, which may limit generalizability. The response rates for both the survey and focus groups were relatively high, but there was limitation in the total number of potential respondents for both. The focus group participants, the orthopedic nurses, represented one specialty. They were a comparatively younger group with fewer years of nursing experience. Implementation of UDI has tended to be an iterative and stepwise process affected by hospital system operations such as implementation of new EHR systems, decisions on system upgrades and interfaces and time required to do so, and change of involved personnel. This study captured the status of UDI implementation at a particular period of time.

The mixed-methods approach helped identify participant perceptions, predictors of acceptance of implant barcode scanning, and areas in need of attention during implementation: communication, consistent process, development of a complete system where all implantable devices can be scanned, and acknowledgement that efficiency is affected when a system is incomplete. Unique device identifier implementation is known to require collaborative work and interdisciplinary effort,[25,29] lending itself well to nursing engagement and leadership. Areas of focus include better education and communication to understand purpose, development of methods where nurses can provide feedback on the operationalization of a new system, and an interdisciplinary team approach to address and further develop the value and purpose for clinical care.

CONCLUSION

Implementation of systems to capture and document implantable device UDIs when they are used in patients is an area under development in US hospital systems. The UDI links the patient to a device and is the critical first step to make these data available for patient care, research, and eventually for NEST—all critical to support quality and safety and enhance available information for clinical decision making. Implementation of implant barcode scanning systems in hospitals supports advancement of medical device documentation and electronic data exchange using UDI as a best practice. Research findings such as ours augment knowledge to support successful implementation and advancement of UDI use.

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