Assessing Nurse Interaction with Medication Administration Technologies: The Development of Observation Methodologies

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Abstract. This paper describes the development of the observation methodologies that we have developed to examine the interactions between nurses and two medication administration technologies: point-of-care bar code technology and Smart IV pump technology. Various issues related to the observation methodologies are discussed: procedure for conducting the observations, development of the recording instrument, number of observers, background of observers, and logistic/practical issues.

Keywords. Healthcare, Nursing work, Observation, Medication administration, Technologies.

1. Introduction

The implementation of technologies changes the work of end users in foreseen and unforeseen ways (Carayon and Karsh, 2000; Eason, 2001; Smith and Carayon, 1995). Different methodologies can be used to evaluate changes in work due to technology implementation (Salvendy and Carayon, 1997; Wilson and Corlett, 1995). Questionnaire surveys are often used before and after the technology implementation to evaluate changes in perceptions of work (Carayon and Hoonakker, 2004). They are also used to compare work performed with one type of technology to work performed with another form of technology (see, for example, Carayon and Karsh, 2000). *Direct* observations are used to collect information on human performance (e.g., interaction between the end user and the technology) by observers or from objective recordings of behavior (e.g., videotaping) (Wilson and Corlett, 1995). Interviews and focus groups are used to gather input directly from the end users regarding the technology (Christie, Scane and Collyer, 1995; Sinclair, 1995). Focus groups are a form of group interview (Christie et al., 1995). Because of the presence of the interviewer or facilitator, interviews and focus groups are flexible data collection methods that allow for follow-up and clarification of the information provided by the end users. In this paper, we discuss direct observations as our main data collection method. Following Drury's (1995) advice of talking to workers because "People's jobs are never simple, despite first appearances", we did complement the observations by conducting a short interview subsequent to each observation.

Some observational studies have been conducted on the impact of healthcare technologies on work and processes. Patterson et al. (2002) observed medication administration before and after the implementation of bar code medication administration (BCMA) technology. The observations were conducted in acute care and nursing home wards of three hospitals. One observer conducted all observations before and after BCMA implementation. Before BCMA implementation, 7 nurses were observed for a total of 21 hours during 10 medication administrations. After BCMA implementation, 26 nurses were observed for a total of 60 hours during 23 medication administrations. These observations uncovered a variety of negative human factors 'side effects' of BCMA implementation, such as worsening coordination between nurses and physicians. Another observational study conducted by Patterson et al. (2004) examined human factors barriers to the implementation of computerized clinical reminders for improving adherence to guidelines for HIV care. Two observers conducted all observations for one day each at eight study sites. Each observation lasted from 3 to 5 hours. Semi-structured interviews were also conducted with physicians, pharmacists, nurses, and case managers. Analysis of these qualitative data allowed the identification of several human factors barriers to the implementation of computerized clinical reminders: additional workload, additional time necessary to document decisions when the reminder's advice was not followed, limited training on how to use the clinical reminder software, and perceived reduction in quality of provider-patient interaction when using the software.

In order to capture the changes that occur after implementing medication administration technologies, direct observations and semi-structured interviews of end-users (nurses) involved in the medication use process need to be performed. Based on the work system model of Smith and Carayon (Carayon and Smith, 2000; Smith and Carayon-Sainfort, 1989), we can describe the medication administration processes by studying tasks or steps of the process, the environment in which the tasks are performed, the policies and

regulations governing the work, technologies used to carry out the tasks, communication networks, flow of work, and, most importantly, the complex interactions taking place between all of these factors.

In this paper, we describe the observation methodologies that we have developed and used to collect data on nurse interaction with different medication administration technologies. Observations have been conducted to examine point-of-care bar code technology. We have also conducted observations pre- and post-implementation of Smart IV (intravenous) pumps with medication delivery software to prevent programming errors.

The paper provides details on the observation data collection tools developed for observing (1) nurse interaction with the bar code technology, (2) nurse interaction with the (old) IV pump, and (3) nurse interaction with the Smart IV pump. We also describe the various forms of observation procedures that we used: single versus team observations, and engineering versus healthcare background of observers.

2. Methods

2.1. Study design

We are conducting a project assessing both the impact of medication administration technologies on medication errors and the work of the technologies' end users. The SMArT^{HF} project is based on collaboration between the Center for Quality and Productivity Improvement and the Medical School at the University of Wisconsin-Madison, and the University of Wisconsin Hospital and Clinics. In the context of the SMArT^{HF} project, we conducted a series of observations to assess nursing work, in particular during the phase of medication administration.

2.2. Study setting

The University of Wisconsin Hospital and Clinics is a 450-bed, university-based, tertiary care center. It includes a 45-bed Children's hospital and provides Level 1 trauma care and regional transplant and interventional cardiac and neurologic care. The institution is an innovator and early adopter of technology and processes in medication use including robotics, unit dose dispensing, and decentralized pharmacists staffing all patient care units. Point-of-care bar code technology was piloted in December 2001 and systematically implemented hospital-wide. This technology is a handheld device containing patient medication administration information. A nurse uses the device to scan bar codes on her/himself, the patient and the medication to be administered. The machine confirms that the patient received the ordered dose of medication at the scheduled administration time.

Smart IV pumps were implemented throughout the institution in October 2003. These pumps have a pre-programmed medication library with upper and lower dosing limits for each medication that are either soft (allowed with override) or hard limits. Multiple drug library profiles can be programmed that contain the medications used in specific patient care areas (e.g., ICU, cardiac and pediatric). When a pump is programmed outside of the medication dosing limit, an alert message appears to check the programmed rate and dose settings for accuracy before proceeding. These two technologies (currently functioning independently) provide consistent double checks in the medication administration process to prevent medication errors.

2.3. Development of observation methodologies

The general steps used to develop and refine the observation methodologies are represented in Figure 1. Two major activities took place in parallel: designing the specific procedure for collecting data (e.g., observers, timing, human subjects issues) and designing the 'recording instrument', i.e. the data collection tool used to record the observation data. During the development process, several meetings of the research team took place to review the methodologies, and make decisions regarding changes.

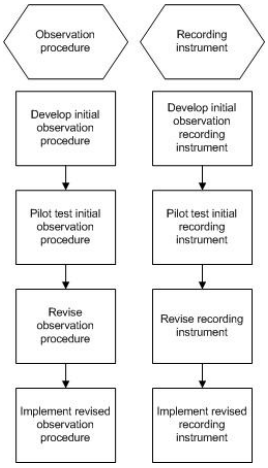

Figure 1. Development of the observation methodologies

The observation methodologies allowed for the collection of information on all the elements of the work system (Carayon and Smith, 2000; Smith and Carayon-Sainfort, 1989): the *individual* (nurse) performing *tasks* (i.e. steps of the medication administration process) using various *technologies* (i.e. bar code technology and Smart IV pump) in specific *physical environments* (e.g., medication room, patient room) and their characteristics (e.g., noise, lighting, crowdedness) under various *organizational conditions* (e.g., sequence of steps used to administer medication, interruptions).

Methods used to complete these observations were approved by the human subjects committee. Verbal consent to be observed was obtained from the technology end users and patients and information sheets were distributed that summarized the research study. Subjects were told that the observations would be used for a research project investigating the effects of the technology on the medication use process. Identifying information was not collected about the patient or end users. As per the human subjects proposal, any variations in process or practice that were identified by the observers and had the potential for patient harm were to be conveyed immediately to the end user.

Observations were performed on a sample of adult inpatient hospital units covering various levels of nursing care including adult general medical, surgical, cardiology, transplant, and medical/surgical intensive care units for both technologies and pediatric general and intensive care units and

the operating room for the Smart IV pump technology. The bar code technology had not yet been implemented in the pediatric settings at the time of the study. Theoretical saturation was used to determine the total number of observations (Sandelowski, 1995). Saturation is reached when additional observation data would not lead to new information.

3. Observing Nurse Interaction with Bar Coding Technology

Direct observations were used to describe nursing interaction with bar code technology. Observations were primarily conducted to identify (1) variations in nursing practice when using the bar code technology and (2) human factors issues concerning the different facets of the work system that were then reported to the bar code technology Failure Mode and Effects Analysis Team (FMEA). The observations were performed by two individuals, with backgrounds in human factors engineering (PR) and pharmacy (JDS). Each observation was completed on an inpatient acute care unit during first and second shifts during regularly scheduled medication passes. Orientation sessions, which included bar code operations training, introduction to key personnel, and a tour of the facility, were completed by each observer.

A naturalistic undisguised observation method was used with time-based elements. With each observation, the observers identified themselves to the nurse prior to the designated administration. The observers used a formal tool to record each interaction. This tool was a modified version of the observation tool used by the IV pump observers that was adapted to suit the specific purposes of the bar coding technology observations. Initial modifications were made to the tool by reviewing the policy and procedure for the medication administration process using bar code technology.

The observation period began at the point the nurse logged into the bar code technology software until final documentation of the administration. Parameters recorded included nursing unit, shift, type of medication administered, name of medication administered, the process steps performed (in serial order) for medication administration, environmental factors such as lighting, noise level, and clutter in the physical environment, comments made by the nurse or patient during the observation period, and total time to complete the process. The observers performed initial observations to determine if the recording tool used was sufficient. Subsequently the tool was redesigned with the process listed in ideal sequential order to allow the observer to note the observed sequence and where the action took place (medication room, patient room, hallway, or other). Minor modifications were also made that involved repositioning of the various elements being recorded to facilitate use.

On each nursing unit, three nurses were observed on three separate medication passes. This provided enough observations with similar data to reach saturation and determine the typical medication administration process using the bar code technology. This information was used by the FMEA team for process mapping and also to identify failure modes in both the current and future administration processes.

A total of 63 observations were performed on seven adult inpatient hospital units. The original design of observing three nurses during three medication passes was modified to performing observation of nine medication passes performed by at least three or more different nurses. The original approach was modified because it was soon realized that it was difficult to return to the same nurses for three medication passes each.

4. Observing Nurse Interaction with IV Pump Technology

4.1. Pre-implementation observations

Direct observations were used to describe current end user interaction with an IV infusion pump prior to implementation of a new IV infusion technology. This information was used primarily to examine the interactions between the end user, the technology and aspects of their environment. Nurses, anesthesiologists and nurse anesthetists were observed as end users of the pumps. The information was also used by the Safe Intravenous Medication Administration Failure Mode Effects Analysis Team (FMEA) for process mapping and failure mode identification. The initial observations were performed by two individuals, with backgrounds in human factors engineering (BH) and pharmacy (TR) and evolved to having human factors engineers (MO, RS, FS, BH) perform observations. Each observation was completed on an inpatient acute care unit during first and second shifts. Orientation sessions, that included pump operations training, introduction to key personnel and a tour of the facility, were completed by each observer. The policy and procedure for administration of IV medications was reviewed. Based on both the training and the policy, an observation tool was created.

A naturalistic undisguised observation method was used with time-based elements. Daily IV administration reports were printed to identify administration times and locations. With each observation, the observer identified him/herself to the nurse with the designated administration. The observer used a formal observational tool to record each interaction. The observation period began at the point of medication retrieval and ended upon starting the infusion. Six parameters were recorded: acute care area/nursing unit, shift, nurse status (experienced vs. inexperienced), type of medication administered, if administration was guided by a protocol, and the order and number of key presses required to program the pump. The observers performed initial observations to determine if the recording tool sufficiently captured the IV medication administration process. The tool was then redesigned to allow the observer to use check boxes at each step in the process rather than writing each step. Results from the initial observations were also used to place the steps in sequential order on the observation tool.

A total of 67 observations were conducted during the pre-implementation phase with 3 observation teams conducting observations on 12 different units. Each team consisted of two human factors engineers. All observers were trained by hospital staff for about two hours in order to understand the basics of the IV medication administration process.

4.2. Post-implementation observations

In the 'post-implementation' phase, end users were observed using Smart IV pumps. Because the Smart IV pumps are significantly different from the previous IV pumps, a number of changes were made to the observation methodology. The pre-implementation observation sheet was used as the working document and was redesigned for the post-implementation observations. The observation "began" as soon as the nurse interacted in any way (including insertion of tubing) with the pump.

A flowchart of the pump programming process was designed with three types of programming identified: 1. basic infusion, 2. secondary infusion, and 3. Guardrails® infusion, using the pre-programmed drug library or dose-rate calculator. The flowchart was comprised of two basic branches: 1) the first two infusion types (that included a dose-rate calculator function) and 2) the third type that was unique to the Smart IV pump. This flowchart facilitated data collection to allow the observer to closely follow and record the pump programming steps and any alarms or alerts that resulted during use. Tables of the preset pump alarms and alerts were also created to allow the observer to easily record the type of alarm/alert heard, where it occurred in the process and the end-user's response. These additions to the observation data collection instrument allowed for a more focused and systematic approach to collecting information related to end user interaction with the IV pump.

The observation recording tool consisted of six parts. The first part included demographic data such as nursing unit, shift, medication, and pump-related information concerning the number of pumps and IV bags in use on the respective patient. The objective of the second part (the flowchart of the programming process) was to collect data about how the pump was programmed, when, and at what steps, alarms sound and how the nurse responded to the alarms. The third portion included an audit (based on a visual assessment) of the pump set-up (tube loading and other pump-specific requirements). The fourth part of the observation tool was for recording data on the physical environment (lighting, noise level, room condition and the effect of others present in the patient room). The fifth and sixth sections contained questions posed to the nurses about their perception of the pumps. Here we asked nurses to assess their workload and we also requested an evaluation of the pump's design (what they liked/disliked and how they might change the pump to improve the technology-person interface). NASA-TLX questions on mental and temporal workload (Human Performance Research Group, 1997) were added to establish a baseline on both factors. Nurses responded to the interview questions with relative ease.

The research team attended a pump training session conducted by an expert nurse user. This allowed researchers, in particular non-healthcare researchers, to familiarize themselves with the Smart IV pumps. The researchers also had access to reference materials issued by the Smart IV pump manufacturer.

Initial observations of the Smart IV pumps were performed by a two-person team: one person had an industrial engineering/human factors engineering background (MO) and the other person had a medical background (TBW, ME). After 17 observations were performed, two teams of two human factors engineers (MO & RS, MO & ASH) conducted observations followed by a single human factors engineer observer (MO). This changed the scope of the observations to a primarily human factors focus. To optimize the time spent on a unit and to maximize the time spent observing, a medical/surgical intensive care unit was chosen for the initial observations because of its frequent use of IV medications, including continuous IV medications.

Initially, we did not have any specific guidelines for conducting the observations. After performing a few observations, we developed the following procedure:

1. Set up observation time with the unit manager.
2. Confirm time with the unit's charge staff the day before observations are to occur.
3. Prepare all observation materials.
4. Go to the unit.
5. Meet with charge nurse.
6. Choose a central location on the unit in order to observe nursing activities as much as possible. Try to be close to the unit pharmacy.
7. Explain to nurses present the aims of the research project.
8. From the central location, watch nurses. If any nurse is seen carrying an IV bag, ask her/him whether it is possible to observe her/him.
9. Enter patient room and ask patient if it is possible to observe the medication administration.
10. Conduct the observation.
11. Enter data on the recording instrument as much as possible during the actual observation, or immediately after completing the observation.

In order to observe a variety of IV pump usage, nursing units were selected to be as varied as possible in terms of patient population. After 17 observations were conducted, we noted that few observations of nurses using the preprogrammed drug library were conducted. Basic and secondary infusions are indeed more common than Guardrails® infusions. It was easier to observe basic and secondary infusions due to their administration times being pre-scheduled and more frequent, whereas initiating continuous IV medications is both more urgent and spontaneous and therefore unpredictable. Also, initial programming of the infusion using the drug library occurs when the first bag of IV fluid is hung and subsequent bag changes do not require re-programming of the pump. As a result, we modified our observation procedure. We initiated the observation either at the central pharmacy sterile products area where medications are compounded or in the central supply area from where pumps are distributed to the units. The observer then delivered the IV medication bag or followed the pump to the nursing unit where it was anticipated that the IV would immediately be administered using the preprogrammed drug library. Unfortunately, this led to very few new observations of Guardrails® infusions. The actual time of administration of these new bags was fairly unpredictable and subject to nurse availability and scheduling. IV bags were sometimes ordered from central pharmacy 4-5 hours prior to the planned medication administration. In addition, many of the IV bags were actually subsequent bags needed for an already-existing continuous infusion.

The observation recording instrument was modified several times after observations were initiated. These modifications included:

- Tables listing the preset pump alarms and alerts to the end-user were removed from the main data collection sheet and placed on a 3x5" card. These tables facilitated recording alarms and alerts. Keeping this information on a 3x5" card resulted in a "cleaner" data collection sheet.
- A section was added to identify the specific drug library profile selected: Adult ICU, Med/Surg, Cardiac, IMC, Peds, PICU. This also facilitated recording basic patient demographics.
- Information on the physical environment was categorized into three different areas: noise, lighting and room condition, taking into consideration both the patient room and objects hanging on and around the IV pole.
- A question on how tubing was loaded (bottom to top, top to bottom, front in) was added. This was done in response to care use issues identified organization-wide.
- The question on the specific time the nurse entered the patient's room was eliminated because the observations focused more on the pump programming itself. In addition, it was difficult to determine the exact time the nurse entered the room because nurses would enter and exit a patient's room several times between the task of getting an IV bag and initiating the pump programming.

A total of 51 observations have been conducted during the post-implementation phase. Observations have been conducted in 16 units. Post-implementation observations are still being conducted.

5. Discussion and Conclusion

Drury (1995) lists four issues germane to observational methods: (1) choice of subjects and conditions, (2) ethical observation, (3) sample size determination, and (4) choice of method. In our study, the focus of the 'who/what to observe' was determined based on our research objective aimed at assessing interactions between the nurses and the respective medication administration technologies. The content of the observation recording instrument was based on the work system model (Carayon and Smith, 2000; Smith and Carayon-Sainfort, 1989). One of the issues we had to address concerning the observations related to identifying the 'beginning' and the 'end' of the medication administration process. This was not always easy, in particular in the case of programming Guardrails® infusions. The observers spent a significant amount of time waiting before actually performing an observation of the nurse programming a Guardrails® infusion. The units where observations were conducted were selected in order to represent a variety of patients and the nurses' consequent uses of the pump. Patients on different units reflect varying types of IV medications used (e.g., diabetic medical service patients have a greater likelihood of having an insulin drip versus diabetic surgical patients who would most likely receive their insulin through normal injections). Likewise, ICU patients will generally have more IVs than patients located elsewhere in the hospital.

The second issue identified by Drury (1995) concerns the ethics of observation. Our observation protocol was reviewed and approved by the health sciences human subjects committee. Several steps were taken in order to insure that individuals (nurses and patients) agreed to being observed. It was recognized that there could be occasions when the observers would recognize that a nurse made an error or deviated significantly from accepted practice. Per the human subjects protocol, if the effect of the deviation could potentially adversely affect the patient and cause harm, the observers were to inform the nurse of the deviation. Fortunately this did not occur during the course of our observations. Interventions by the pharmacist were to resolve an issue a nurse incurred with the bar code technology. In one instance, a nurse, after having problems with a physical aspect of a pump (detaching the "module" from the "brain") refused to be observed at another time.

The third issue identified by Drury (1995), i.e. sample size determination, was guided by the principle of saturation (Sandelowski, 1995). Finally, the choice of observation method was decided at the beginning of the study; however, the observation procedures and the recording instruments were modified and revised several times.

One important challenge in our study was to determine the background and qualifications necessary for the observers. In the bar coding technology observations, the highly differentiated backgrounds of the observers (one human factors engineer and one pharmacist) provided unique opportunities for evaluating the interaction between the end users and the technology. The pharmacist observer could focus exclusively on the practice variations, while the other could focus on human factors-related issues. Having two people conduct observations also allowed one to record and the other to watch and catch details. The pharmacist recorded the sequence of steps in the medication use process, while the human factors engineer provided constant observation at this time. Roles would be interchanged when observations related to the physical environment and other human factors issues that were recorded. Importantly, this double observer method with a human factors observer and a health care observer allowed for the recording the "what" and the "why" of the observed tasks.

In the IV pump technology observations, most of the observations were performed by either a single human factors engineer or by a team of two human factors engineers. Because we were able to come up with a structured list of the steps for administering IV medications, there was less need for an observer with healthcare background. Having a non-healthcare background for the observer provided two major benefits:

- Nurses may feel more comfortable since they know their practice is not being judged.
- A human factors engineer may be better able to focus on nurse-technology interaction from the human factors engineering point (the "what" was happening) instead of focusing on medical judgments about "why" a task was performed in a certain way.

It was, of course, imperative to train the HFE about the hospital setting and recognize and understand the above-listed factors.

In deciding whether to select observers with a human factors engineering background and/or observers with a

healthcare background, what is most important is that the following considerations are taken into account. The observer:

- must have knowledge of the process steps and how a task should be performed based on policy and procedure;
- must have knowledge about potential variations in process steps;
- must have an understanding about why process variations may occur and on what factors they are based;
- must have knowledge about the technology and user interaction with the technology;
- must have knowledge about how the technology is used in the process and for what purpose;
- when comparing a process before and after technology implementation, must know how the process has changed because of the technology;
- must understand patient factors and medication factors that may cause variation in practice;
- must understand the environmental factors that may cause variation in practice;
- must be generally comfortable with observing in an acute care, hospital setting; and
- must understand HIPAA confidentiality issues.

Another issue we faced was that of having a single observer versus a team of observers. This issue relates to the background and qualifications necessary for the observers, but also to practical issues, such as crowding in patient rooms. The bar coding technology observations were performed around medication pass times to capture the highest number of medication passes possible in a given timeframe. This provided the opportunity to observe how nurses interfaced with the technology during a typical time-pressured environment. Performing observations during peak medication pass times also presented physical challenges. The medication rooms could contain four to five nurses retrieving medications from patient-specific drawers. To watch a nurse using the technology, the observers had to look over the nurse's shoulder to identify each step of the process. At times, the observers became unintentional obstacles to other nurses performing their job. When the nurse moved to the patient room both observers tried to enter the room. Instances did arise when patient quarantine conditions existed. In those cases, the pharmacist alone conducted and documented the observation.

A naturalistic, undisguised observation method was employed. A limitation of this method is the "observer effect" in which the nurses perform tasks differently than their usual routine due to the observation itself and fear of repercussion. The institution was aware that deviations from practice could happen and at times could cause errors in medication administration, but espouses a non-punitive approach to variation in practice and errors. For most observations, the observers felt the nurses were interacting with the technology as they had been trained; however, some procedure and practice deviations were identified. We found that the development and continuous improvement of our observation techniques and data collection instruments led to a streamlined consistent methodology for conducting medication administration observations.

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