Improving the Safety of Heparin Administration by Implementing a Human Factors Process Analysis

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Abstract

Heparin administration errors can have severe consequences for patients. Despite a previous attempt to standardize the heparin administration process through the use of a computerized protocol at a large Midwestern hospital, errors still occurred at unacceptably high rates. A Heparin Error Reduction Workgroup (HERW)—consisting of staff nurses, pharmacists, and a cardiologist—was convened in 2002 to address the issue. The HERW asked human factors consultants to conduct a human factors process analysis of the nursing staff's heparin administration procedures. The consultants observed the work process involving heparin administration in several nursing stations and conducted interview sessions with (1) the physician and pharmacist who developed the heparin protocols; (2) staff pharmacists; (3) nursing administrators; (4) nurse educators; and (5) nurses from cardiovascular nursing stations where heparin is administered extensively, and medical/surgical nursing stations where it is used less frequently. After analyzing the information collected in the interviews and observations, the consultants recommended changes to make the computerized heparin dosing interface more user-friendly, for example, presenting no more than three responses per computer screen to the practitioner, and automatically interconverting English and metric weight and height measurements. The HERW approved and implemented many of the recommendations. The revised heparin dosing computer interface was then tested by a representative sample of nurses and pharmacists from all areas of the hospital. Further modifications were made based on feedback from the participants in the test. A 5-day educational process was then instituted to inform practitioners about the new heparin administration procedure. Following the education, the upgraded computer-driven procedure was implemented hospitalwide. This new procedure has been very well received by the nurses who administer heparin. In the first quarter following implementation of the recommendations, there was an 11.4 percent reduction in the type of heparin errors that resulted in increased monitoring or harm to patients on the cardiovascular nursing stations. In the subsequent quarter (4Q2003), there was a 37.8 percent reduction from 2002 preimplementation baseline data.

Introduction

The Harvard Medical Practice Study, an interdisciplinary study of medical injury and malpractice, was conducted in the early 1990s. The first part of this study focused on the incidence of adverse events, defined as injuries resulting from negligent or substandard care. More than 30,000 randomly selected records from 51 randomly selected acute care, nonpsychiatric hospitals in New York State in 1984 were reviewed. Brennan et al.[1] reported that adverse events occurred in 3.7 percent of the selected cases (95% confidence interval [CI] = 3.2–4.2). Also, they reported that 27.6 percent (95% CI = 22.5–32.6) of the adverse events were due to negligence. Further, 13.6 percent of the adverse events led to the death of the patient.

Similar results were obtained in 1992, when 15,000 randomly sampled records of nonpsychiatric discharges from a representative sample of hospitals in Utah and Colorado were reviewed. Thomas et al.[2] reported that in this sample, adverse events occurred at a rate of 2.9 percent (with a standard deviation [SD] of 0.2 percent). Of these adverse events, 32.6 percent (SD of 4 percent) in Utah and 27.4 percent (SD of 2.4 percent) in Colorado were due to negligence. Death occurred in 6.6 percent (SD of 1.2 percent) of the adverse events.

Extrapolation of the Utah-Colorado and the New York State results to the 33.6 million admissions to American hospitals in 1997 suggests that the number of deaths due to preventable medical error in the United States is between 44,000 and 98,000 annually,[3] surpassing the 38,252 motor vehicle fatalities that occurred in 2003.[4] Not surprisingly, the results of the studies of adverse events that occurred in Utah and Colorado in 1992, and in New York State in 1984, have led to many efforts aimed at reducing medical error and improving patient safety. An important part of these efforts has involved applying human factors principles to the investigation of heath care systems.

The second part of the Harvard Medical Practice Study analyzed the records of 1,133 patients who had disabling injuries caused by medical treatment. Brennan et al.[5] reported that among these patients, drug complications were the most common type of adverse event (19 percent), followed by wound infections (14 percent) and technical complications (13 percent).

Heparin is a drug which, if administered incorrectly, may cause severe hemorrhagic consequences. Heparin dosing at a large metropolitan hospital had evolved and become more complex over approximately a 5-year period. Prior to that, heparin was inconsistently dosed and monitored by individual physicians. In an effort to standardize dosing, optimize therapy, and decrease the risks, heparin dosing protocols were developed and implemented. As heparin dosing was refined and made more patient-specific, the number of dosing protocols increased. Originally, the protocols were available on paper. The advantages offered by computerized access were then used to enhance the delivery of the protocols and increase efficiency of protocol updates. Finally, an interactive computer program was introduced to decrease the complexity of protocol use.

Despite these improvements, an unacceptable number of errors still occurred—2.01 errors per 1,000 doses charged. In response, a Heparin Error Reduction Workgroup (HERW) at the hospital—comprising staff nurses, pharmacists, and a cardiologist—was convened to address the issue. The HERW decided to conduct a human factors process analysis of heparin administration procedures to identify the types and sources of potential and real errors that occur. Since standardization of protocols had been previously accomplished with computerization, a human factors approach provided a new perspective on the problem. This paper describes the human factors process analysis that was done.

Human factors process analysis

The human factors process analysis began with a two-phase information-gathering approach. In the first phase, the human factors experts (lead authors Harder and Bloomfield) gathered information by directly observing the work process used by nurses who administered heparin. These observations were made at several different nursing stations. Also, as part of the work process-observation phase, Harder and Bloomfield examined the computer-user interface used by nurses to enter the information needed to arrive at the appropriate heparin dose for individual patients.

The information gathered in the first phase gave Harder and Bloomfield the basic knowledge needed to carry out the second phase of the process analysis. In this second phase, they conducted individual and group interviews directed toward the specific goal of discovering, step by step, how the heparin administration process was carried out. The interviewees included the following medical personnel:

- Nurses from five nursing stations—including cardiovascular nursing stations where heparin was administered extensively, and medical/surgical nursing stations where heparin was given less frequently.
- The physician and pharmacist who developed the computerized heparin protocol.
- Staff pharmacists who dispensed heparin.
- Nurse educators responsible for training nursing staff on the use of the drug.
- Nursing administrators.

During the interviews, the core knowledge acquired in the first phase of the process analysis allowed Harder and Bloomfield to ask probing questions with the goal of acquiring a very detailed understanding of the heparin administration process. Probing questions regarding each step in the process were necessary because, in carrying out their daily work, skilled practitioners used a great deal of implicit knowledge which they could not easily articulate. The goal-directed interview process used by Harder and Bloomfield allowed them to uncover the

implicit elements of the heparin procedure that the interviewees would not otherwise have reported. Eliciting these implicit elements greatly increased the depth of understanding of the heparin process. The individual and group interviews revealed a number of differences in the way the heparin administration process was performed in the various nursing stations. Harder and Bloomfield also discovered that there were a number of points in the heparin administration process that had the potential to lead to error.

The information yielded by the two-phase approach was analyzed. This analysis included exploring the various pathways that could be used by practitioners to administer heparin. These pathways were compared to identify anomalies and confusing or ambiguous steps. The analysis also identified several sources of potential error, particularly in situations in which medical personnel might be stressed or fatigued. To address the problems and potential sources of error, Harder and Bloomfield recommended that forcing functions be integrated into the computer-user interface wherever possible. (Forcing functions, as defined by Norman, "are a form of physical constraint: situations in which the actions are constrained so that failure at one stage prevents the next step from happening" [p 131]. [6]) Recommendations addressing equipment needs and staffing issues were also made. The potential sources of error and recommended actions are discussed in the following subsections of this paper.

Potential sources of error

Confusing protocol selection. When the human factors process analysis was conducted, the interface used to determine the appropriate heparin dose was in transition throughout the hospital. Because the transition was incomplete, the heparin administration procedures differed in at least two ways: In the older version, the nurse accessed a computer menu of eight variations of the heparin protocol. Then, depending on the patient's gender, indication for heparin, and route of heparin administration, the nurse selected one of these eight variations. Presentation of the protocol in this manner made it possible for an error to occur if the practitioner selected the incorrect protocol variation. The newer version, which used an interactive Microsoft Excel™ format, employed a number of folders that could potentially confuse the user who opened the folders to access the spreadsheet. Further, the interactive Excel interface was confusing to the practitioners who used it.

Ambiguous heparin dosing terms. Heparin is used either to treat an existing blood clot (therapy) or to prevent the development of a blood clot (prophylaxis). Thus, variants of the heparin protocol were labeled as "therapeutic" and "prophylactic." The only difference between the two variants is the desired, or targeted, heparin concentration. When heparin is prescribed for a patient undergoing therapeutic treatment, he or she is usually given a relatively high dose of heparin. In contrast, when heparin is prescribed for a patient undergoing prophylactic treatment, he or she usually is given a relatively low dose of heparin. In the mind of many practitioners, there is an association between "therapeutic"

and "high," and "prophylactic" and "low." However, the terms therapeutic and high are not synonymous, nor are the terms prophylactic and low. There are cases where patients who are being treated prophylactically require relatively high doses of heparin.

Unclear data entry measurement. In some areas of the hospital, the weight and/or height of patients were recorded in metric units. In other areas of the hospital, the weight and height of patients were recorded in English units. This is likely to lead to errors, either in the conversion of one unit of measurement to the other or when patients or personnel move from one area of the hospital to another.

Unstructured physician order forms. The physician ordering forms were not structured. A lack of uniformity in the way information was presented on these forms could lead to either an omission of important information or to ambiguity in the way the information was presented and possible misinterpretation by others.

Temporary assignment of nurses. Nurses on temporary assignment to nursing stations where heparin is commonly administered may not have had the requisite training before being assigned to those stations. It is likely that inexperience of this kind would make errors more likely to occur.

Unnecessary repetition of information. A significant number of nurses believed that the full set of data had to be entered each day the patient remained on the drug. In fact, this was unnecessary.

Lack of computers and printers. Because of a lack of computers, the cardiovascular intensive care units continued to use the paper heparin protocol in place prior to the implementation of the computerized procedure. At some nursing stations, accessibility to computers was a problem; at others, there was a sufficient number of computers, but either there were not enough printers or the printers were located far from the computers.

Recommendations

To address the potential sources of error listed above, a number of recommendations were made.

Clarification of heparin dosing terms

The heparin dosing terms should be clarified. The terms "therapeutic" and "prophylactic" should *not* be used. Instead, they should be replaced with the terms "high" and "low." However, if discontinuing the use of the terms therapeutic or prophylactic would confuse health care practitioners, then the terms "therapeutic (high)" and "prophylactic (low)" should be used. This change should help to eliminate confusion regarding appropriate dosing levels. (It should be noted that this recommendation was not adopted. Hospital personnel decided to continue to use the terms therapeutic and prophylactic in order to minimize the problems that may have accompanied the transition to the recommended terms and because

therapeutic and prophylactic are the literature standard when referring to heparin therapy and its indications. For purposes of clarity, therapeutic and prophylactic are used in the remainder of the paper.)

New data entry procedure

When a nurse is about to initiate the administration of heparin to a patient, all the possible protocol variants should *not* be presented simultaneously on the computer screen. Rather, a series of questions should be used. And no more than three options per question should be presented on the screen at any one time.

In the first step, the nurse should be asked whether the patient is male or female (but not pregnant) or female (and pregnant). The response to this question should then drive the practitioner down one of three branching dosing pathways.

In the second step, the nurse using the computer interface should be asked whether the physician ordered that a therapeutic or prophylactic heparin concentration be targeted. If the nurse's response indicates that a therapeutic level is required, then a therapeutic dose to achieve the appropriate heparin concentration is calculated. However, if the response to the second step is that a prophylactic level of heparin concentration is required, the next step should be to ask whether the heparin should be administered by intravenous infusion or subcutaneously. If the practitioner's response to this question is intravenous infusion, then the dose is calculated appropriately. However, if the practitioner's response is subcutaneously, then the practitioner should be asked whether the type of heparin to be administered subcutaneously should be "Lovenox™" (a low-molecular-weight heparin analog) or "not Lovenox." Based on the response to this question, the appropriate type of heparin should be administered.

In the final step, irrespective of which pathway is taken, the practitioner should be asked to enter information about the patient's weight and height.

A stepwise entry system, like that outlined above, requires the practitioner to look at more screens than were needed with the previously used computerized protocol. However, because fewer choices per screen are required, the process should be clearer and, as a result, there will be less likelihood that an error will occur.

Clarification of data entry measurements

Height and weight measurements should be standardized and metric units should be used throughout the hospital. Because it is unlikely that Americans will easily convert to using metric units, it is recommended that the computer accept weight and height information in either metric or English units. In addition, feedback should be provided and confirmation required before heparin can be administered.

The procedure for entering information regarding the patient's height should be as follows. The practitioner should be able to enter the patient's height in centimeters, inches, or feet and inches. Regardless of the way the practitioner enters height information, feedback regarding the patient's height should be given

in all three ways. For example: If the practitioner means to enter "6 ft" but instead enters "60 inches," the computer would respond, "Do you mean 5 ft/60 in/152.4 cm?" Likewise, if "60" is entered in the cm slot, the computer would respond, "Do you mean 1.97 ft/23.62 in/60 cm?" Giving feedback in all three forms should reduce errors related to possible confusion between inches and centimeters, and should eliminate English unit errors such as mistaking 60 in for 6 ft, the type of error that can occur when a practitioner is highly stressed or fatigued—two conditions that occur far too frequently in hospitals.

A similar procedure should be used for entering weight information. After the patient's weight is entered, the system should query whether it was entered in kilograms or pounds. If the response is that it was entered in kilograms, the system should convert kilograms to pounds, present the result in both kilograms and pounds, ask whether the weight shown is correct, *and* require confirmation from the practitioner before proceeding. For example, if the practitioner enters "180," the computer will ask whether the number indicates pounds or kilograms. If the practitioner responds with "kilograms," the computer would convert the pounds to kilograms, and respond, "Do you mean 396 lb/180 kg?" Similarly, if the response is "pounds" the system should convert kilograms to pounds, present the converted weight in both, query the practitioner as to whether or not the weight is correct, *and* require confirmation before proceeding.

Use of structured physician order forms

Physician order forms should be modified to reflect the changes recommended above for computer data entry, minimizing ambiguity, and making written orders consistent with computer-generated orders. In written orders, the physician should indicate (1) whether the patient is male or female (but not pregnant) or female (and pregnant), (2) whether the heparin dose to be administered to the patient is therapeutic or prophylactic, (3) whether a prophylactic dose is to be administered by intravenous infusion or subcutaneously, and (4) whether subcutaneously delivered heparin should be Lovenox or Not Lovenox.

Instruction of temporarily assigned nurses

When a nurse is on temporary assignment, the nurse in charge of a nursing station in which heparin is administered should explain the following: (1) heparin doses are determined by using a computer querying system, and (2) the temporarily assigned nurse should *always* seek help if he or she is unable to understand any of the steps recommended for the new data entry procedure.

Changing the requirements for updating information

The data entry procedure used for the *initial* administration of heparin to a patient in the hospital should be as outlined above in the "New Data Entry Procedure" subsection. However, on subsequent days, when it is necessary to determine whether or not the heparin dose should be modified, only the following entries should be required: (1) the patient's name, (2) the patient's hospital ID number, (3) the current dosing level, and (4) the data returned daily from the lab.

These four data items should be sufficient to determine whether or not the dosing level ought to be modified for the patient. By making this change, the amount of data-entry work is reduced. In addition, this change eliminates the confusion some medical staff indicated they had about whether "weight" refers to the patient's weight when the heparin treatment was initiated or to his or her current weight (which may be considerably different, particularly after surgery). This was, in fact, the procedure already used. However, it is necessary to ensure that the nurses understand this.

Additional computers and printers

Additional computers and printers should be acquired and located in the nursing stations that currently have too few. Both computers and printers should be placed in easily accessible locations in the nursing stations. Placing printers in close proximity to computers will eliminate the need for nurses to walk inconvenient distances to retrieve the printouts. This will not only make the work flow more efficient, but it will also help to eliminate possible interruptions that can distract a nurse from administering a patient's heparin dose in a timely manner.

Outcome

As a result of the review, a simplified heparin dosing computer interface that incorporated all but one of the recommendations was developed. This interface was tested by a representative sample of nurses and pharmacists from all areas of the hospital. Included in the sample were nurses from patient care units that used heparin very infrequently (i.e., Women Care) to patient care units where heparin was used daily. Further revisions were made based on the feedback from the testers.

A nurse or pharmacist was available 24 hours a day for 5 days to provide 15–30 minute educational in-services to staff nurses and pharmacists. The educational sessions were used to instruct potential users of the computer interface about the revisions and improvements that were made. A limited number of nurses and pharmacists demonstrated how to use the protocol; they discussed safety features embedded in the protocol and online frequently asked questions/answers within the program. This education occurred on the patient care units 24 hours a day for the 5-day process. Following this education period, the upgraded interface was implemented hospitalwide.

In the first quarter following the implementation of the recommendations, there was an 11.4 percent reduction in the type of heparin errors resulting in increased monitoring or harm to patients on the cardiovascular nursing stations. In the subsequent quarter (4Q2003), there was a 37.8 percent reduction from pre-implementation baseline data (2002). In addition, feedback from users indicated that the upgraded computer interface has been very well received.

Conclusion

A human factors process analysis of a heparin administration procedure was conducted at a large Midwestern hospital. The analysis was conducted because errors in heparin administration can have severe consequences for patients and, in spite of previous attempts to standardize the heparin administration process throughout the hospital, errors still occurred at unacceptably high rates.

A Heparin Error Reduction Workgroup was convened to address the issue. The HERW asked human factors consultants to conduct a process analysis of the hospital's heparin administration procedure. The human factors consultants began by observing the heparin administration process in several nursing stations and by conducting interview sessions with various members of the medical staff. The interviewees including (1) the physician and pharmacist who developed the heparin protocols; (2) staff pharmacists; (3) nursing administrators; (3) nurse educators; and (4) nurses from cardiovascular nursing stations where heparin is administered extensively, and medical/surgical nursing stations where the drug is used less frequently. Next, the consultants analyzed the information they had gathered in the interviews. Based on this analysis, they made a number of recommendations aimed at making the heparin administration computer interface more user-friendly and the process more streamlined:

- A new data entry procedure that would present a series of questions, with no more than three choices per question appearing simultaneously on a computer screen.
- Clarification of heparin dosing terms, with the terms "therapeutic" and "prophylactic" replaced by "high" and "low," or by "therapeutic (high)" and prophylactic (low)." (As noted above, this recommendation was not adopted.)
- Automatic interconversion of English and metric weight and height measurements, displayed so that the practitioner can confirm that the entry is correct.
- Formatting paper order forms used by physicians so that they are compatible with the new computerized data entry process.
- Direct guidance for nurses temporarily assigned to a nursing station at which heparin is administered by the nurse in charge of that station, who should inform the temporarily assigned nurse how computers are used to administer the drug and to always ask for help, if necessary.

The HERW reviewed the recommendations and adopted all but one, as mentioned above. On May 19, 2003, the revised heparin dosing computer interface was then tested by a representative sample of nurses and pharmacists drawn from all areas of the hospital. Further modifications to the interface were made on the basis of feedback from the participants in the test. A 5-day educational process was instituted to inform all practitioners who administer

heparin about the new process. Following this training, the procedure was implemented hospitalwide.

The upgraded computer-driven procedure has been very well received by the nurses who administer heparin. Further, heparin errors that resulted in increased monitoring or harm to patients on the cardiovascular nursing stations have dropped: In the first quarter following implementation of the recommendations, there was an 11.4 percent reduction in heparin errors, and in the subsequent quarter (4Q2003), there was a 37.8 percent reduction from preimplementation baseline data (2002).

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