Chapter 43. Prevention of Misidentifications

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Subchapter 43.1. Bar Coding

Background

Machine-readable automatic identification (ID) systems, including bar codes, magnetic stripes, optical character recognition and radiofrequency labeling, have improved productivity and quality in diverse industries. Bar codes represent the oldest and most common of these machine-readable ID systems,[1,2] and are widely used in industrial manufacturing, shipping and inventory tracking operations. Prior to bar coding, these processes would have involved keystroke entry of identification numbers, producing approximately one error in every 300 entered characters. In contrast, bar coding produces misidentification errors at rates ranging from one character in 15,000 to one character in 36 trillion.[3]

The use of bar coding in health care was first described over 30 years ago in clinical laboratories and blood banks.[1,4] In 1984, Rappoport identified 3 areas for the use of automatic ID technology in lab medicine: patient identification, document identification, and specimen identification.[1] However, in a 1987 survey by the American Hospital Association, the use of bar codes was most widespread in materials management departments, rather than in clinical application.[5] Other areas in which hospitals employed bar codes at that time included the clinical laboratory, pharmacy, radiology, medical records and asset management. Despite the Health Industry Bar Code Council's call for standardization in the mid-1980s, the implementation of bar code technology has been stymied by lack of industry standards and failed cooperation among all stakeholders.[2,6]

As bar coding has the potential to substantially increase productivity and accuracy, one would expect it to be applied to important patient safety practices. Unfortunately, the published literature contains very little evidence regarding health care applications. In this chapter we focus on 4 areas in which bar coding shows promise for improving patient safety: patient identification, medication dispensing and administration, specimen handling, and medical record keeping.[2,7-10]

Practice Description

Patient Identification

Machine-readable patient ID systems could replace conventional wrist-banding, and might reduce patient ID errors ranging from specimen collection to medication and blood product administration. Attempts to create such machine-readable ID systems were reported in the blood banking literature as early as 1977.[11] Transfusion Medicine is particularly attuned to issues of patient identification, as specimen collection and blood product administration account for the majority of preventable transfusion errors.[12,13]

Most scenarios for patient identification involve the substitution or supplementation of the traditional wristband for one with a unique bar code patient identifier. All patient specimens, medications and released blood products then receive the patient's unique bar code ID. No

procedure or treatment can occur unless the patient's ID is scanned with a portable scanner and matched with a bar code generated by the doctor's order. For example, a phlebotomist would carry the scanner, check the patient's ID against a bar coded specimen label or collection list, and draw blood only in the event of a match. Similarly, for administration or treatment, the patient's ID and the intended therapeutic would be scanned at the bedside with a portable reader. If a match exists, the transfusion or medication is allowed and the time and date are recorded and even transmitted directly to the hospital computer system. The nurse's bar code ID can also be scanned and a timed administration record can be created. If there is no match, an alarm is sounded, and the administration delayed until the problem is resolved. [9,14]

Other technological means to reduce error in patient identification have been examined in the transfusion literature. Several researchers explored the use of a system providing a mechanical barrier to transfusion through a series of locks.[15] This system appears to be cumbersome and easily circumvented. In addition, electronic blood banking, with point-of-care crossmatching and computer-controlled release of blood, has been examined for high volume transfusion areas such as the operating room or intensive care unit.[16] Due to major barriers to large-scale implementation, these practices will not be discussed further.

Specimen handling

Clinical laboratories have integrated bar codes in specimen handling with a great deal of success.[3,8] Several authors have described the development of central laboratory information systems (LIS) that employ bar code technology. Collection list and label software can be modified to integrate and produce bar coded information. Confirmation of labeling and patient ID occurs at the bedside. Specimen sorting and aliquoting in the laboratory can be shortened or eliminated by various setups. At Rush-Presbyterian Hospital in Chicago, a central receiving station rapidly sorts and aliquots bar coded samples as they move on a conveyor belt.[3] At the University of Kansas Medical Center, the collection tubes are also used for analysis, thus eliminating the need for aliquoting samples. Additionally, the computer sends the bar code-coordinated orders to each of the 2 chemistry analyzers. Because a sample can then be appropriately processed at either analyzer, the need for sorting samples has also been eliminated.[8] Clinical labs also employ bar code technology in harder-to-automate processes. For instance, the University of Utah uses bar codes to replace common keystrokes for text reporting of microbiology results—eg, a technician might use a bar code "pick list" to scan the single bar code that means "no growth for 24 hours" and eliminate the need to type this phrase.[17,18]

Medication dispensing and administration

The use of bar codes is uniquely suited to the dispensing and administration stages of the medication process.[19] Bar coding may be used to simplify the patient cassette (the medicine tray for bedside delivery) filling and verification process.[20] For instance, a technician fills a cassette according to a computerized, bar coded medication schedule and completes a quick verification by scanning the label of each unit-dose that has been placed in it with a handheld scanner. The computer can generate an error message if an incorrect medication is entered. The administration of bar coded medications can also be tracked at the point-of-care using a portable scanner and compared against the hospital computer's medication orders.[9,21] Bar coded medication administration has the added capability of creating a record of the administration (ie, RN, date, time) and a bill. This type of system could be integrated with a patient identification system in an attempt to eliminate errors resulting in administration of medication to the wrong patient.

Medical record keeping

Radiology and medical records departments use bar code technology to track the location and status of studies and charts.[22-24] Even more creative use of bar coded information has been reported in the emergency medicine and pharmacy literatures. As with the applications in the microbiology lab, bar codes can be used to replace frequently used text for the creation of medical records. "Pick lists" of bar codes with their text equivalents can be employed in circumstances requiring speed and accuracy. Several uses of bar coded scripts have been examined in resuscitation events, and in mass casualty recording.[10,25-27] The use of bar code "pick lists" for the documentation of pharmacists' clinical activities has also been explored.[28-30]

Prevalence and Severity of the Target Safety Problem

Bar code technology may be used to address any number of patient safety issues in medicine. For this discussion, we will define the target safety problem as patient identification in general, using transfusion medicine as a specific example.

Patient identification remains a challenge in hospitals because of the number of complex interventions that occur to patients ranging from meals to surgeries. These interventions occur in a variety of locations and are provided by large teams of staff who work in shifts. In addition, sick patients, or those who have a language barrier, are not always capable of responding to questions about their identity or treatment plans. Hospitals generally rely on standardized wristbands containing the patient's name and other identifying information such as medical record number or date of birth. Unfortunately, conventional wristbands are not reliable sources of patient identification. A 1991 national sample of 712 hospitals estimated error rates for conventional patient identification wristbands to be 5.5%.[31] In half of the errors, the patient's wristband was absent altogether. The error rates were significantly lower in hospitals where phlebotomists had responsibility for monitoring wristband accuracy, as the phlebotomy staff would not perform routine lab work unless the band was corrected. Other errors included more than one wristband with conflicting data (18.3%); wristbands with incomplete (17.5%), erroneous (8.6%), or illegible data (5.7%); and rarely, patients wearing wristbands with another patient's data (0.5%). As patient identification data are only as good as the information entered at registration, the use of bar coded ID data could not be expected to correct certain types of errors such as a wristband with incorrect data entered at admission, although it is potentially beneficial in eliminating other types of errors such as illegible data.

Even when wristbands are free of errors, protocols for patient identification (such as dual witness verification of identification for blood transfusion) are easily circumvented or performed incorrectly.[32] In an analysis of major transfusion errors reported to the FDA over a 10-year period from 1976-1985, Sazama found 10 patient deaths where the actual and intended patients shared the same last name, and 5 deaths where the 2 shared the same hospital room.[13] Consequently, automatic patient identification systems have been proposed as a technological solution to remove human factors (Subchapter 41.1) from the patient identification process.

Despite technical improvements in testing for blood group identification, fatal ABO-incompatible transfusions in the United States continue to occur at a rate ranging from approximately 1:600,000 to 1:800,000, with as many as two dozen fatalities in the US annually.[12,13] Thus, the chance of a patient suffering a fatal transfusion reaction due to ABO-incompatibility is roughly equivalent to the risk of acquiring HIV infection from a blood transfusion.[33,34] Patient misidentification represents the most common cause of ABO-incompatible transfusion, accounting for 46-57% of these errors.[12,13] Since the rate of patient and

donor having blood group compatibility *by chance* is approximately 60%, it is estimated that the total number of ABO-incompatible transfusions is much higher than the rate of fatal errors. A study from New York State estimated that as many as one in 12,000 transfusions involve administration of a blood product intended for another patient or release of blood of an incorrect group.[*12]

Opportunities for Impact

The implementation of automatic patient identification may present a large opportunity to bring transfusion medicine and other hospital interventions closer to the goal of zero risk. According to a survey conducted by the American Society of Hospital-System Pharmacists, 1.1% of responding hospitals use bar coding of drug products in conjunction with bar coding on the patient's identification tag.[35]

Study Designs

Multiple reports of the use of bar codes appear in the medical literature, but most of these relate to inventory management. Few authors examine bar codes for patient identification. Only one of these studies was a prospective evaluation, and in the study bar coded patient identification comprised only one small part of the intervention.[10] One observational study examined a bar code patient ID system for medication administration.[9] In the study, however, routine patient ID scanning was easily circumvented and the actual error rate was not provided. The remainder of the reports are descriptive in nature.[14,36,37] Therefore, error rates in automated patient identification could not be readily compared to usual practice.

The use of bar coding in other clinical care applications (aside from inventory control) has been examined prospectively in trauma recording[27] and in documenting pharmacists' interventions.[28] One additional observational study examined bar coding in pharmacy dispensing.[20]

*This is based on a reported error rate of 1/19,000 transfusions. The authors estimate a 64% chance that a random transfusion to an unintended recipient would be compatible and assume 100% reporting of incompatible erroneous transfusions

Study Outcomes

Some of the studies report error rates in transfusion or medication errors (Level 2), while others report related outcomes such as speed of data entry (Level 3), transcription errors (Level 2) in a variety of experimental and clinical settings, and user satisfaction (Level 3).

Evidence for Effectiveness of the Practice

A point-of-care information system for medication management was implemented at a tertiary care center in Colorado.[9] The system provided online patient and medication data that verified medication administration at bedside using hand-held scanners to record patient ID, nurse ID, and medication unit-dose bar codes. When intervention data were compared with historical controls, the pre-intervention medication error rate of 0.17% dropped to 0.05%, sustained over 3 years for an overall decrease of 71% (p value not reported). There was a 33% decrease in "wrong drug" errors, a 43% decrease in "wrong time" errors, and a 52% decrease in "omitted dose" errors. There was a 47% decrease in "transcription/order-entry" errors. There was no change in "wrong patient" errors or "wrong dosage" errors, perhaps because the component of the multifaceted intervention most likely to mitigate these errors, the use of the scanners for patient ID, was easily and frequently circumvented. It is unclear if bedside scanning added an unwanted layer of work for the nurses, or if they were uncomfortable performing this task in front of patients and families. Computerized pharmacy and bar code tracking of medications led to qualitative improvements in documentation time, scheduling of administration, nursing-pharmacy communications, and pharmacist drug monitoring. However, the contribution of bar coding to the decreased error rate is not distinguishable from that of the entire intervention. It also appears that the point-of-care patient ID portion of the intervention was easily bypassed, and was therefore not adequately evaluated.[9]

On a large medical ward of a university hospital, the satellite pharmacy was reconfigured to implement bar code technology for drug dispensing.[20] The hospital bar coded all medications, patient medication cassettes, patient wristbands, and employees. Standard dispensing time was estimated at 8.24 seconds, while dispensing time for bar coded medications was 6.72 seconds (p value not reported). Accuracy of the standard cassette fill system was 99.6% (equivalent to one error in 250 doses), while the accuracy of bar coded cassette fill was reported to be 100% (based on 0 errors in about 20,000 doses). The pharmacists were freed to do other work as the burden of dispensing was shifted to pharmacy technicians.

As pharmacists have begun to use bar code technology for medication distribution, 2 pharmacy groups described the use of bar codes in recording their clinical interventions.[28, 29] One group found bar code documentation to have lower overall error rates compared to manual documentation, while the marginal cost of implementing bar coding was less than $100 (factoring in savings in labor costs related to manual entry).[28] These data were limited by the small number of operators who differed on their preferences for manual versus bar code recording.

A prospective trial reviewed bar code technology in trauma recording. Experienced emergency room nurses found bar coded pick lists to be easy to use and produced fewer errors per record compared with handwriting (2.63 ± 0.24 vs. 4.48 ± 0.3, $p<0.0001$) for videotaped trauma resuscitations.[27] In a prospective study of simulated mass casualty incidents in The Netherlands, bar coded computer registration produced 25% fewer inaccuracies than handwritten medical charts.[10]

The limitations of these studies are numerous, including their small sample sizes and lack of generalizability. However they demonstrate that bar code technology is generally easy for operators to use, can be applied in a variety of creative ways, and produces easy-to-demonstrate gains in accuracy and efficiency.

Potential for Harm

There is no clear detriment to patient identification with a bar code system. However, as with the addition of any new technology, the possibility exists that the complexity of the information system, especially if it grows, could create more routes for potential failure. For instance, an error during patient registration might be perpetuated throughout the hospitalization by the information systems, and be more difficult to correct than with conventional systems. The system's data are only as accurate as that entered by fallible humans.

Costs and Implementation

Significant barriers need to be overcome before the full potential of bar coding can be exploited in the clinical setting. The process of medication dispensing and administration highlight several examples of these barriers. First, pharmaceutical manufacturers have yet to adopt a universal bar code standard like the UPC system used in grocery store inventory.[38] As of yet, there has been no regulatory mandate by the FDA to serve as an incentive, although the American Society of Hospital-System Pharmacists recently urged the FDA to take action.[39] Second, placing bar codes on unit-doses of medications often requires major changes in packaging (such as an increase of the package size to accommodate the bar coded label). Bar code tracking systems would have difficulty with unusual doses such as halved tablets. IV doses would still require bar code labeling in the pharmacy when prepared.

At this point, implementation of bar coding requires a commitment on the part of the hospital to relabel every unit-dose of medication using a hospital standard. The hospital pharmacies that have implemented these systems have repackaged and relabeled many unit-doses at considerable cost.[9,20] One health system estimated costs at $119,516 annually, with the per dose costs of bar code labeling estimated at 2.73 cents.[20] The bottom line is that, at present, the costs of implementing bar coding in an entire pharmacy inventory are significant and the logistics complex.

The use of bar coding in simpler clinical scenarios (ie, using a blood transfusion wristband for patient identification) may be implemented with very modest outlay of resources (estimated to be less than 5 cents per wristband).[36] The costs of the scanners themselves are moderate. A new model scanner, software and recharger were priced at about $1100 in 1997.[28]

Comment

Bar coding is a fast and accurate method of automated data capture that in experimental settings provides qualitative improvements in speed and accuracy of data entry. Bar code technology might be creatively applied to any number of data-driven processes in medicine. As the rapid and accurate transfer of data is paramount in health care, the thoughtful application of appropriately piloted and evaluated bar code technology is likely to be well received and deserves further investigation.

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Subchapter 43.2. Strategies to Avoid Wrong-Site Surgery

Background

Operating on the wrong site or body part represents a potentially devastating event for all parties involved. Cases of “wrong-site surgery” frequently attract considerable media attention[1-4] and foment malpractice lawsuits. Claims for wrong-site orthopedic surgeries result in indemnity

payments in 84% of cases, compared with only 30% of orthopedic claims overall.[5,6] Although orthopedics represents the largest source of legal claims, the Physician's Insurance Association of America (PIAA) has handled wrong-site surgery litigation from the entire range of surgical specialties and subspecialties.[6] Common factors identified in wrong-site surgery include the involvement of multiple surgeons on a case, the performance of multiple procedures during a single trip to the operating room, unusual time constraints, and unusual anatomy or patient characteristics, such as physical deformity or morbid obesity.[7,8]

Based upon careful review of 43 cases reported through its Sentinel Event Policy[9] over a 3-year period, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) issued the following recommendations for avoiding wrong-site surgery:[7,8]

- *Mark the operative site and involve the patient in this process*
- *Require oral verification of the correct site in the operating room by each member of the surgical team*
- *Follow a verification checklist that includes all documents and medical records referencing the intended operative procedure and site*
- *Directly involve the operating surgeon in the informed consent process*
- *Engage in ongoing monitoring to ensure verification procedures are followed*

Among these recommendations, marking the operative site has received the most attention and is the focus of this chapter.

Practice Description

In 1998, the American Academy of Orthopaedic Surgeons endorsed a program of preoperative surgical site identification called "Sign your Site," modeled on the "Operate through your initials" campaign instituted by the Canadian Orthopaedic Association from 1994-96.[5,10] Both organizations recommend that the operating surgeon initial the intended operative site, using a permanent marker, during a scheduled preoperative visit. For spinal surgery, the recommendations additionally endorse the use of intra-operative x-rays for localization of the pathologic spinal level before proceeding with the procedure. Many surgeons already employ their own techniques for surgical site identification such as marking an "X" on the operative site or marking "No" on the wrong limb.[5,11,12] While these practices are commendable, they have theoretical drawbacks including lack of standardization across operating rooms and institutions. These alternative strategies will not be evaluated further in this chapter.

Prevalence and Severity of the Target Safety Problem

From January 1995 to March 2001, JCAHO reviewed voluntary reports of 1152 "sentinel events." Wrong-site surgery accounted for 114 (9.9%) of these reports and included procedures in neurosurgery, urology, orthopedics, and vascular surgery.[13] Despite the high profile of JCAHO's Sentinel Event Policy,[9] under-reporting by health care organizations almost certainly affects these statistics. Only 66% of the 1152 total events were "self-reported" by the institutions involved. The remainder came from patient complaints, media stories and other sources.[13] In fact, using a mandatory reporting system, the New York State Department of Health received 46 reports of wrong-site surgery from April 1, 1998 through March 31, 2000[4] (F. Smith, personal communication, May 2001), compared with the 114 cases JCAHO received nationally over a

period 3 times longer.[13] This suggests that voluntary incident reporting may underestimate the true incidence by a factor of 20 or greater.[14]†

The PIAA reviewed claims data from 22 malpractice carriers representing 110,000 physicians from 1985 to 1995.[5] These claims included 331 cases of wrong-site surgery. The complete PIAA database documents almost 1000 closed malpractice claims involving wrong-site surgery.[6] However, this figure also underestimates the prevalence of wrong-site surgery, as every case does not result in a claim. Most wrong-site surgeries involve relatively minor procedures such as arthroscopy,[10,15] rather than limb amputations or major neurosurgical procedures. Consequently sequelae are minimal. The State Volunteer Mutual Insurance Company (Tennessee) released a series of 37 wrong-site surgery claims from 1977 to 1997.[15] Performing the correct procedure on the wrong side constituted the most common error (eg, arthroscopic knee surgery on the wrong knee in 15 of the 37 cases). Twenty-six of the patients experienced no sequelae beyond a scar, and only three patients suffered permanent disability. Given the rarity of significant harm, estimates of the incidence of wrong-site surgery derived from litigation data likely underestimate the true prevalence of this problem, as do estimates based on incident reports.

Opportunities for Impact

Some surgeons have developed their own methods for surgical site identification,[11,12] but routine preoperative evaluation and marking of the intended surgical site by the attending surgeon has yet to become standard practice in orthopedics or any surgical specialty. One year after its "Sign Your Site" campaign, the American Academy of Orthopaedic Surgeons surveyed its membership. Among the 2000 orthopedic surgeons surveyed, 77% responded that the idea was a good one, but only 40% stated that they complied with the recommended practice. Only one-third stated that their principal hospitals had a “Sign Your Site” or similar program in place, although many anticipated initiation of one in response to the campaign.[16,17]

Study Designs

The published literature includes no studies in which the adoption of a practice related to surgical site identification is analyzed in the setting of a controlled observational design or clinical trial. One report described the experience of 4 orthopedic surgeons in private practice,[18] but included no comparable observations from a control group. The experience of the Canadian Orthopaedic Association remains unpublished, and the observed effect is based entirely on litigation statistics[10] (B. Lewis, personal communication, March 2001).

Study Outcomes

Given the egregious and distressing nature of wrong-site surgery, the error itself represents the outcome of interest, regardless of the clinical outcome. Unfortunately, in the absence of observational studies that include controls, the number of malpractice claims for wrong-site surgery represents the most widely cited outcome.

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† Mandatory New York reporting system (NYPORTS) documented 46 events in 24 months. New York State has a population roughly 1/15th of the entire country. Thus, had JCAHO captured wrong-site surgeries with the same sensitivity, one would expect 2484 wrong site surgeries to have been reported during the 87 months covered by the JCAHO sentinel event policy. This figure is 21 times the actual figure of 114 cases.

Evidence for Effectiveness of the Practice

The Canadian Medical Protective Association reported a baseline level of litigation for wrong-site surgery at 7% of all orthopedic surgery settlements before 1994 when the Canadian Orthopaedic Association instituted their "Operate Through Your Initials" policy.[10] Currently, there are no known wrong-site surgery claims against orthopedic surgeons in Canada. (B. Lewis, personal communication, March 2001) Interpreting the difference in the rates of litigation of a rare occurrence is difficult, however, especially without an accurate estimate of the denominator (ie, the total number of relevant procedures performed during the time periods involved). Moreover, the degree to which Canadian surgeons complied with the policy is unknown. As mentioned above, only 40% of responding American orthopedists reported adoption of preoperative site identification in routine practice.[16]

In a North Dakota private practice that used preoperative site identification with indelible ink, there was one incidence of wrong-site surgery (pinning of the wrong phalanx in a hand) in 15,987 consecutive cases.[18] Even assuming that the sole detected case represents the only wrong-site surgery in this sample, interpreting this low event rate is impossible without a control group. Comparing this result with national data is also problematic. National data on the number of orthopedics procedures performed each year might generate an estimate of an appropriate "denominator," but the nationwide "numerator" is unknown. Because we do not know the extent to which incident reporting and malpractice litigation underestimate the incidence of wrong-site surgery, we cannot accurately estimate the baseline rate of wrong-site surgeries for comparison with results of a case series such as the North Dakota report cited above.[18]

Potential for Harm

Some surgeons may worry that marking the surgical site increases the risk of contamination, but this concern appears unwarranted.[15,18] More concerning is the potential harm that may arise from confusion caused by practice variability in "signing the site." Although the original recommendations called for surgeons to initial the intended operative site, some surgeons and hospitals mark the site with an "X."[15,16] Still others use an "X" or "No" to mark the limb or site that should not be operated upon.[11,12] In addition, there are reports of patients crossing their legs before the ink is dry and producing an identical mark on the contralateral knee, thus subverting the intended effect of the intervention.[10] Confusion may also ensue if operating room personnel cover the mark with surgical drapes prior to the start of the surgery.[10]

Costs and Implementation

The costs of marking a surgical site are negligible. Marking procedures that require the presence of the surgeon in the preoperative area prior to the initiation of anesthesia may require a culture shift among surgeons and involve the costs of surgeons' time. Implementation strategies designed to more efficiently utilize the operating surgeon's time could be designed. For hospitalized patients, implementation might involve the operating surgeon initialing the intended operative site at the time consent is obtained, thus requiring that the physician be present at the time of consent. The nurse/anesthetist, anesthesiologist or other responsible party in the preop area would then be required to contact the operating surgeon only in cases where the operative site has not already been initialed.

Comment

While "signing the site" represents a low-tech solution with high face validity, no evidence supports a particular version of this practice. Additionally, the existence of different versions of the "signing the site" practice may cause confusion to the point of increasing the likelihood of error. Strategies that focus only on a single aspect of the identification problem, without considering the preoperative and operative processes as a whole may fail to avert error. For instance, protocols that rely on review of key preoperative x-rays in the operating room creates a new mandate to ensure that the correct patient's x-rays are brought to the operating room.[6]

Practices to successfully reduce (and eventually eliminate) wrong-site surgeries will likely combine a standard method of marking the intended site with collaborative protocols for verification of the intended procedure and operative site by all members of the operating room staff.[7] Straightforward as each of these processes may appear, successful implementation may require substantial investments of time and resources for protocol development and team training. Whatever multifaceted practice is developed should be implemented within the setting of a planned observational study.

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