Gross, Mary

From: Alan Merry [amerry@pl.net]
Sent: Friday, July 12, 2002 6:55 AM
To: grossm@cder.fda.gov
Cc: Ritesite
Subject: BArcodes for drugs - urgent

AA.pdf

Dear Mary Gross,

I have just discovered your websight about barcodes.

I am not able to attend the meeting, but my group has been very actively using barcodes for anaesthesia drugs, and I enclose a copy of a paper describing our system which is aimed at reducing ddrug adminsitration error
in anaesthesia.

The system is in use in Auckland, New Zealand, and has been sed in over 10
000 anaesthetics.

I would very much like to contribute to your discussions, and would be willing to come to the US for this purpose.

I look forward to hearing from you.

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(WRITTEN)

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A New, Safety-Oriented, Integrated Drug Administration and Automated Anesthesia Record System

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Medication errors are an important cause of patient morbidity and mortality and excessive costs, including in anesthesia. Conventional methods of injectable drug administration in anesthesia make little use of technology to support manual checking and are idiosyncratic and relatively error prone. Similarly, conventional anesthesia records are handwritten, time-consuming to make, and often unreliable. There are automated record systems, but they do not provide support for checking drugs. Therefore, by using a multifaceted approach based on established principles of systems design and human factors psychology, we have developed a system that includes trays that promote a well-organized anesthetic workspace, color- and bar-coded labeling of syringes, and automatic visual and auditory verification of the syringe labels by computer just before each drug administration. In addition, documentation of drugs administered and a traditional anesthetic case record are generated automatically. The system has been successfully deployed for 25 mo and has been used by 35 anesthesiologists in 1148 diverse cases, including cardiopulmonary bypass procedures, heart and lung transplants, and orthopedic and otorhinolaryngologic operations. It is in daily use in a tertiary teaching center and in a private hospital.

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Human error is an important problem in modern health care, harming patients and increasing costs (1–3). Medication errors are unacceptably common (1,2) and have been estimated to account for 7000 deaths in the United States and increased hospital costs exceeding $2 billion during 1993 alone (3). Conventional methods of injectable drug administration in anesthesia are idiosyncratic and relatively error prone, and they make little use of technology to support manual checking. A survey of anesthesiologists in New Zealand found that 89% of respondents admitted to having made a drug administration error at some stage during their career, and 12.5% admitted to having harmed a patient in this way (4). In the first 2000 anesthetic incidents reviewed by the Australian Incident Monitoring Study, 144 involved the wrong drug, and more than half of these errors involved either a syringe or ampule (5). Similarly worrying findings have been reported from other countries (6,7). An additional problem concerns anesthetic records (including the record of drugs). Conventional anesthesia records are often unreliable (8); furthermore, making a handwritten record is time consuming and has the potential to distract from the monitoring of vital signs. There are automated anesthesia records, but they do not provide support for checking drugs.

The United States Institute of Medicine initiated the Quality of Healthcare in America Project (3); its goals include the reduction of errors in health care by 50% in 5 yr, and one recommendation is that health care organizations should implement "proven medication safety practices." Several approaches to reducing the likelihood of an error in IV drug administration have been advocated, but they have tended to be adopted haphazardly (4,5).

Therefore, by using a multifaceted approach based on established principles of systems design and human factors psychology, we have developed an integrated injectable drug administration and automated anesthetic record system (IDAARS), with the aim of

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improving patient safety by reducing drug administration error in anesthesia and by facilitating easy and accurate record keeping.

Methods

The system consists of a set of rules and devices for organizing the anesthetic workspace and a computer with a bar-code reader to provide a crosscheck for drug administrations and to generate an anesthetic record automatically.

All drugs, whether administered by bolus or infusion, are identified by preprinted labels (Fig. 1). The labels are color-coded by class of drug according to a New Zealand and Australian standard (9), which is identical to standards registered in the United States and Canada (10,11) [as yet, no standard is accepted in Britain (12)]. Both the class and the name of the drug are displayed in a large, clear font (e.g., "Opioid" and "Fentanyl"). Less salient details (including those required by regulation) are displayed in smaller fonts.

Three alternatives for labeling are presently available (Fig. 1). For some commonly used drugs, ampules have been replaced with prefilled syringes prepared by a local pharmaceutical manufacturer to defined quality standards. Alternatively, prefilled syringes may be prepared by the hospital pharmacy. For some drugs not readily adaptable to prefilled syringes, "flag labels" are attached to ampules by a licensed pharmaceutical manufacturer without obscuring the information provided by the ampule's manufacturer; the practitioner takes one ampule and one syringe at one time and transfers both the contents and the label from the ampule to the syringe. In this way, the chances of incorrectly labeling a syringe are minimized. Finally, for those drugs where prefilled syringes and flag-labeled ampules are not available, sheets of labels are preprinted by a color laser printer and kept in the operating room (OR) to enable the practitioner to label syringes as drugs are drawn up. These sheets may be customized to individual practitioner or case needs—one sheet typically provides all the labels needed for one anesthetic.

All labels (whether applied by manufacturer, pharmacist, or user) have bar codes. When a drug is needed (or an infusion started or its rate changed) the anesthesiologist is expected to read the label and then scan it with the bar-code reader before administering its contents. A laptop computer, attached to the anesthetic machine, is programmed to interpret the bar code, announce the name of the drug (with a prerecorded voice), and redisplay the name on the computer screen in large type along with its color code (Fig. 2). The computer identifies and displays a default dose, which may be accepted or altered by entering

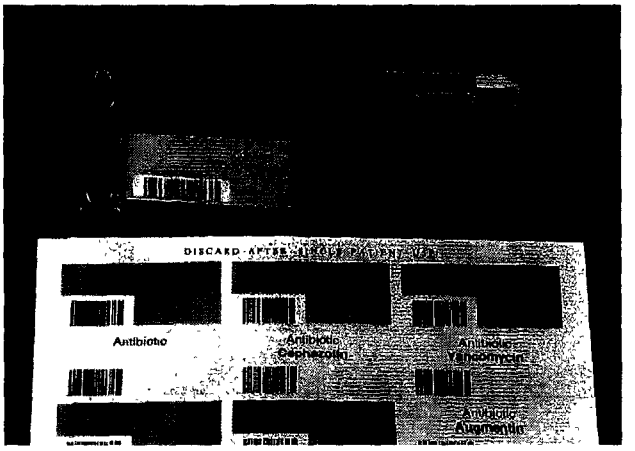

Figure 1. Labels for the system. From top to bottom: prefilled syringe label, ampule flag label, and top of label sheet (comprising generic user-applied labels on left and drug-specific user-applied labels on right). All labels are self-adhesive and colored by class of drug, following an international standard for anesthetic user-applied labels.

numbers from the keyboard. The name, time, and dose of the drug are recorded and may be displayed and edited at will. Infusion rates are distinguished from IV boluses and infusion purges, and it is assumed that these rates remain constant until the next entry related to the same infusion. The voice file contains the drug name but does not indicate concentration, so that the enunciated information will be correct even if the user elects to dilute the contents of the syringe. Generic user-applied labels are provided for use with those drugs without specific labels. These display and announce only the class of drug (e.g., "Opioid") but are in other respects the same. Key discriminatory words are displayed first to avoid confusion (e.g., "Antagonist—Opioid" rather than "Opioid Antagonist").

Prefilled syringes and flag-labeled ampules have their expiration date included in their bar code, enabling the computer to warn of attempts to administer outdated drugs. For inventory and billing purposes, and to encourage cost-consciousness on the part of practitioners, the computer displays a running tabulation of drug cost (Fig. 2).

Plastic trays (Fig. 3) have been designed to facilitate order in the layout of syringes and ampules. Every anesthetic is started with new, empty trays. No ampules or syringes are discarded until after the anesthetic is over. Depending on the complexity of the anesthetic and the number of drugs used, one, two, or more trays may be required.

An "active" area is nominated for those syringes in current use (e.g., one from which intermittent boluses are being administered). A "used" area is designated, in which used ampules or syringes are retained in an orderly fashion. A "prompt" area is set aside for drugs

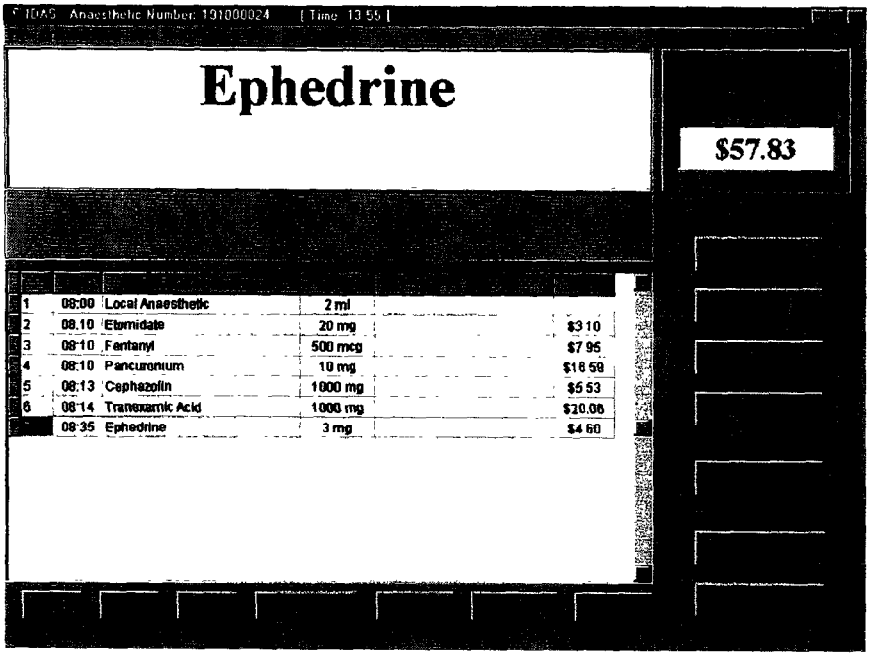

Figure 2. The computer screen. After scanning a labeled syringe with the bar-code reader, the name of the drug is redisplayed in a large font and announced by means of a voice file, thus providing a visual and auditory identity check. A list of drugs administered is maintained, with the relevant times, doses, and costs.

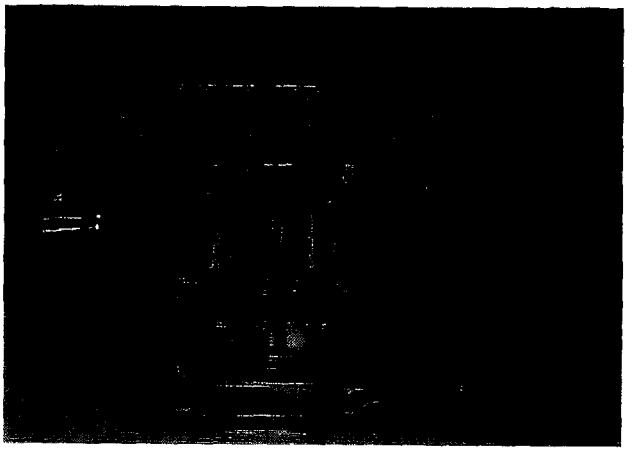

Figure 3. Trays facilitate orderly arrangement of syringes and ampules, to provide a physical means by which drugs used during an anesthetic may be tracked. Note that the elevated position of the syringe tips assists with maintaining their sterility.

that may be needed later in the anesthetic. Order in each area is a matter of individual preference, but a suggested approach is to arrange drugs from left to right in the order in which they are used. It is possible to develop a strongly linear arrangement of syringe layout; the syringes can be selected from these defined positions, used, and then returned to the same position if needed again or returned to a similarly defined place in the "used" area of the tray. This has the effect of generating a physical record of the drugs used in the anesthetic. Thus, by inspection alone, it should be apparent at any time which drugs have and have not been given.

Drug drawers are arranged somewhat analogously to the layout of the trays. Typically two drawers are used to reduce congestion and provide for separation of commonly used drugs (in the first or top drawer) from those (e.g., inotropes, vasodilators, and electrolytes) that are potentially more hazardous or are needed only occasionally (in the second drawer). The layout in the first drawer, from left to right, reflects the order in which classes of drug are often used (e.g., local anesthetic, sedative, induction drug, opioid, muscle relaxant, antibiotic, anticholinergic, reversal drug). From front to back, the order reflects the frequency with which the specific member of the class is used, with the most popular choices nearer the front. Color-coding of the floor of the drawers may be used to highlight this arrangement.

The hardware consists of a standard computer (stand-alone or incorporated into the hospital network; minimum requirements: Microsoft Windows 95, Pentium 200, 32 megabytes of RAM, two serial ports), a handheld bar-code reader, and a locally situated laser printer. The software was written by DJM in C++ (Borland, Scotts Valley, CA) and uses a Borland Database Engine. The system has been programmed to work with Hewlett-Packard (Palo Alto, CA) and Datex-Ohmeda (Helsinki, Finland) patient monitors, but it could be made compatible with other monitor types.

Physiologic data are acquired via a serial connection to the OR physiologic monitor. This allows the compilation of a complete, real-time anesthetic record, with integrated drug and event information, entered

via the bar-code reader as a concomitant of the error-reduction procedures of the system. Sheets of bar-coded phrases and events facilitate the rapid entry of other information typically recorded in anesthesia. Manual entry of drug administrations, events, and comments is also permitted.

Before being used in clinical practice, a prototype was evaluated and tested in a high-fidelity human-patient simulator (Medical Education Technology Inc., Sarasota, FL) presented within a simulated OR and connected to standard equipment for the administration and monitoring of anesthesia (13). After refinements based on this testing, we conducted an observer-based clinical evaluation comparing the IDAARS with conventional methods (14). After further refinement, the system was then offered to interested practitioners at Green Lane Hospital (GLH), a tertiary care hospital specializing in cardiac and major otorhinolaryngologic surgery. A 14-mo period of open evaluation, feedback, and refinement was performed involving two mobile units. One of us (AFM) also used a mobile unit in private practice at three other local hospitals. The system was then progressively permanently installed at GLH in six ORs and is now in daily use. User support has been provided when needed. Each problem requiring assistance has been logged, and users' comments have been noted.

Results

From 5 August 1998 to 18 August 2000, 1148 anesthetics were given with the IDAARS: 5 during August 1998, increasing steadily to 145 in July 2000 and 134 in the first 18 days of August 2000. The comprehensive record facility was available from 20 August 1999 and was used in 699 of the 818 cases (85%) conducted thereafter. These 699 patients were anesthetized by 35 anesthesiologists (13 trainees, 22 specialists) and received more than 13,000 drug administrations. Patient age ranged from 0 to 91 yr, with ASA scores between I and VE. Procedures lasted between 20 min and 12 h 20 min, and they involved cardiac surgery in 344 (including four heart transplants and 27 operations on pediatric patients with congenital heart disease), thoracic surgery in 59 (including two lung transplants), orthopedic surgery in 49, otorhinolaryngologic surgery in 19 (including three tonsillectomies), and a variety of other miscellaneous procedures.

Problems requiring technical or user support were logged on 60 occasions during this period. These included 18 equipment problems (e.g., faulty bar-code reader, printer or bar-code reader not plugged in), 17 software problems (e.g., confusing display because of multiple copies of the program running simultaneously, Windows errors, and crashes), and 12 supply problems (e.g., prefilled syringes not delivered on time, items such as 50-mL syringes missing from trolley). Resolution of these problems involved simple maneuvers (e.g., restarting the computer program or reinserting a disconnected cable) in 21 cases and refinement of software or equipment in the remainder. Despite increased use of the system, calls for support have remained relatively constant at approximately 15 per month. Patient data collected for the anesthetic record were never lost. Users have commented on a learning curve in relation to physical requirements of the system (such as always using the bar-code reader and retaining an ordered workspace); increased familiarity with the system results in greater facility with its use, particularly in emergencies. Surgeons have accepted the presence of the auditory checking during surgery.

Discussion

This appears to be the first report of a comprehensive, safety-oriented approach to administering IV drugs during anesthesia. The IDAARS was designed with two goals: to reduce the opportunity for error in drug administration and record keeping in anesthesia and to detect errors when they do occur to facilitate a rational response and limit harm. It combines various previously reported or well known techniques (e.g., auditory checking) with a few novel features (e.g., the use of a computer and bar codes to provide such auditory checking) into a formalized process for the administration of IV drugs and the concurrent generation of an automated anesthetic record. It is the integration of a number of initiatives into a multilayered system of defense against drug administration error, based on Reason's "Swiss Cheese" model of accident generation (15), which is new. Using a standardized setup with facilitated labeling and having reliable electronic and physical records available is particularly useful when two anesthesiologists are working together or when one is handing over to another. It is also of particular value in an emergency, when the risk of error in drug delivery, or simply in recording what has been given, is likely to be increased.

Bar-coding to identify drugs for automated anesthesia record keeping has been used by others and reported as early as 1985 (16), although that system was abandoned, at least in part because of the limitations of the technology available at that time. In particular, the fast processors available in compact modern computers permit our system to keep pace with the user, even in a crisis. There are a number of contemporary automated anesthesia record keepers, and, like the IDAARS, they provide the benefits attributed to automated record keeping in general (e.g., more accurate, complete, and legible documentation) (17–19). However, our system differs in an important way from

these in its focus on safer drug administration; drug information is entered into the record primarily as a crosscheck against errors, not as a separate task. Furthermore, it is underpinned by basic rules aimed at promoting safety (e.g., in relation to labeling, layout, retention of used ampules, etc). These rules could readily be adopted, anywhere, without the need for a computer and with little additional cost.

Factors that have been identified as contributing to drug error relate to labels and to appearance and location of ampules and syringes, and to inattention, poor communication, carelessness, haste, and fatigue on the part of the anesthesiologist (5,7). Prefilled syringes and flag labels prepared with appropriate quality assurance should substantially reduce errors in drawing up and labeling drugs. Other features (layout, labels, bar-coding, and auditory checking) address factors associated with the large proportion [63% (5)] of errors involving correctly labeled syringes.

Many drug administration errors are slips or lapses (20,21) precipitated by episodes of momentary distraction that inevitably occur during the multitasking required of an anesthesiologist. Such errors are inherent in any human activity and cannot be avoided simply by resolve—indeed, the person will often not even realize that an error has been made. Their reduction depends on improving the design of the system (15,20,21). The IDAARS seeks to achieve this in several ways: the process of passing the syringe past the barcode reader and of listening to the spoken information tends to introduce the appropriate element of focus to recapture the practitioner's attention immediately before the drug is actually administered. Checking and rechecking is another important way to reduce error (5). The IDAARS provides a computerized "two-person" check that is rapid, accurate, and not subject to human suggestibility.

An additional factor in the generation of error is the fact that people tend to see what they expect to see. In particular, words are not read one letter at a time, but instead are recognized by their shape (22). Drug names are often similar, and labeling is often of poor legibility. These difficulties are addressed by using sound and color, by including both the class name and the name of the drug on highly legible labels, and by redisplaying label information on the computer screen. For example, "Dopamine" has been mistaken for "Dopram™" (Wyeth-Ayerst International, Philadelphia, PA) (doxapram), with disastrous results (23), but "Inotrope, Dopamine" on a purple label is quite distinct from "Analeptic Agent, Doxapram" on a white label, and the spoken name uses a second cognitive modality (sound) to reinforce the distinction.

Rule-based or knowledge-based mistakes (20) are also sources of error in anesthesia that are manifested as faulty decisions. These occur because human beings' cognitive ability is limited, particularly under constraints of time and while coping with multiple tasks (including record making). Reducing cognitive load is helpful to decision making, and so is the clear display of accurate physiologic data; the automated record achieves both of these. Future developments are planned to extend the support provided in decision making. Examples include the provision of online information when needed, such as the essential pharmacology of the drug scanned, and algorithms to provide additional alarms (e.g., in relation to known drug allergies or drug interactions). Interfacing with other computerized equipment (e.g., infusion pumps) or with the hospital information system could contribute further to the reduction of cognitive load and to the information available for support algorithms.

Redundancy and standardization are basic principles in the design of safe systems (15). The IDAARS provides multiple layers of protection against error to increase the chance of intercepting an incipient accident, or at least of identifying that a mistake has occurred, before harm results (15,20). The latter is achieved by its physical and electronic records. Because no system can be expected to eliminate error entirely, provision is made to identify errors that do occur (20,24).

Reducing complexity by making a process simpler and linear should enhance safety (15,20). The production-line preparation of prefilled syringes and the emphasis on an orderly and well laid-out working surface and trolley are directed at creating greater linearity and reproducibility of process.

In summary, we have developed and deployed a system designed to improve patient safety by reducing drug administration errors in anesthesia and by facilitating easy and accurate record keeping. It is too soon to know if we will succeed in our goal of reducing the occurrence of errors or the likelihood of harm to patients when errors do occur. Preliminary evaluations of prototypes of the system have been encouraging (13,14). However, further assessment is needed, not only in our unit, but also in other institutions, countries, and clinical settings. When sufficient data have been collected, we plan to compare the reported incidence and nature of drug errors and near misses associated with anesthetics at GLH using the system with baseline data established while using conventional methods in more than 7000 anesthetics (25). There are limitations to this approach, and a randomized, controlled trial would in theory be more robust, but the latter would be more difficult and very expensive, given the large number of anesthetics needed for adequate power to show a difference in error rates. Indeed, evidence at this level may prove elusive. Nevertheless, we clearly have achieved a formalization of the process by which an anesthesiologist administers

IV drugs and records these as part of a full, automated anesthesia record. Unlike traditional methods, this process can readily be described and taught. This means that the system can be adopted as a uniform standard within an institution (or part of an institution) and that it can be evaluated (e.g., by user assessments, observational studies, and error monitoring). Therefore, it can become part of a continuous process of constructive criticism and improvement. Over time, this should provide a sound basis for achieving our goal of increased patient safety.

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