

Infusion Pumps with “Drug Libraries” at The Point of Care – A Solution for Safer Drug Delivery

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Background:

Medication errors, Adverse Drug Events (ADEs), are the single leading cause of medical injuries, accounting for 19.4% of all adverse events.¹ Several studies have demonstrated that system problems are the underlying cause of most ADEs and the injuries that result from them. The challenge to all who endeavor to make medication delivery safe is to understand what are the key systems issues and, more difficult still, to develop strategies, tactics and tools to make errors less frequent and the overall system resilient to those errors. A large portion of the most costly and lethal errors involves elderly patients; powerful drugs infused directly into the patient vein during hospitalization and mis-programmed drug infusion pumps. While hospital environments are composed of multiple complex systems, the two most common sources of error identified were: 1) inadequate systems to disseminate drug knowledge to physicians and nurses; and 2) inadequate systems to ensure right drug and drug dosing prior to administration at the bedside. One major contributing factor to dosing errors is the complexities of drugs, drug concentrations and calculations. These complexities are aggravated by several factors: the time and cost incurred with training of staff; the shortage of experienced critical care nurses; and the cost of updating and distributing formularies, policy and procedure protocols. The difficulty of establishing standard practices is compounded by significant in-house, local, regional and international variation in practice patterns.

Options for systems re-design to reduce medication errors, include implementing various component modules of comprehensive centralized computing-focused solutions such as computerized physician order entry (CPOE), computerized pharmacy information systems (PIS), medication administration records (MAR), medication dispensing systems (Sure-Med, Pyxis, Omnicell), networked personal digital assistant (PDA) bar code applications for drug dispensing and administration. While these component modules are extremely important to have in place, without further solutions, the clinician at the bedside will remain as the final element in the pathway of medication delivery, without protection or technology assistance to prevent the kinds of medication errors that will inevitably occur when humans are placed in a complex environment with all of the factors that encourage failure. Specifically, when end users bear the responsibility for drug recognition, mathematical conversion of dose rate units into fluid flow units, keypad data entry and recall of key formulary pharmacologic details or titration limits, patients are exposed to significant residual risk.

Several years ago, clinicians, biomedical engineers, and the “drug therapy management team” at Massachusetts General Hospital elected to directly target serious errors associated with programming of drug infusion pumps. It was conceived that a new generation of “smart” drug infusion pumps should be created that could be directly provisioned with drug information knowledge specific to and managed by the institution. Supporting the clinician at the bedside is the objective of the solution described below.

Solution

MGH, in collaboration with Harvard Clinical Technology, Inc, South Natick, MA, has implemented a solution in the Intensive Care Unit (ICU) and Operating Room (OR) environments with patient safety and reduction of adverse drug events as the major focus. It is a standard platform that provides our clinicians with a dynamic, less-complex system of safe drug delivery via an institutionally defined, clinician developed, hospital-sanctioned, customizable electronically loadable drug “library” for all IV drugs that is housed in the infusion pump residing at the bedside.

There are Current, Phase II (December 2002) and Phase III components to the solution that we have developed. The current solution has been implemented and is a prelude to longer term goals of creating a seamless path of protection against human error with infusion technologies

Methodology

Current Solution (Phase I): *Provide the clinician at the bedside with the knowledge, technology and the confidence to deliver highly complex therapies safely.* The common elements relevant to medication error in the ICU include an: aging population, more complex multi-system pathophysiology, need for multiple IV drugs, and the need for limited fluid administration to prevent fluid overload. Of particular concern is the likelihood of an error in the administration of “high priority drugs” such as vasopressors, antiarrhythmics and narcotics in the ICU patient population. A further concern is the need to achieve clinician consensus for standardization of drug therapy practice in the ICUs and ORs thus reducing the kinds of errors that occur from ad hoc practices. These concerns led us to the development and deployment of a hospital specific ICU/Anesthesia Drug Library. A collaboration of the Pharmacy and the Computerized Physician Order Entry Team resulted in a drug “library” that is now the template for the physician order entry module for intravenous ICU medications. This consistency and seamless connectivity from the order entry process to the pump at the bedside provides a high level of safety and reduces the opportunities for human error in the numerous handoffs of the medication delivery pathway.

The program, implemented and fully operational since 1996, in all adult ICUs, the ORs and the Cardiac Catheterization Lab, involves using a high precision syringe pump that houses the MGH Drug Library with infusion defaults and safety rate limit settings and technology that will enable automated drug recognition. LAST-ADR, an acronym we have coined for Library Action Set Technology - Automated Drug Recognition is patented by the MGH. It also relays our ultimate goal, LAST Adverse Drug Event.

For an infusion pump to be used properly, the end user must be acquainted with the operation of the device and the pharmacology and toxicology of the drugs being administered. While drug libraries exist within infusion pumps today, they are only semi-active. LAST allows the pump to automatically set initial flow and allow the end user to make adjustments based on clinical need. The technology allows for warnings to be issued to the end-user if the flow requested is outside institutional limits for the drug being infused or simply prohibits the flow in excess of these limits. For example, if the end-user wishes to administer Potassium at a rate that exceeds 20mEq per hour, the pump will warn the end-user, and in this case, prohibit delivery thereby teaching the clinician safe drug delivery limits.

As a result of the success of the ICU/Anesthesia Drug Library (LAST), the MGH team was approached by the Outpatient Chemotherapy Infusion Center to help investigate root causes contributing to adverse drug events in the outpatient setting. The root cause of incidents involving clinicians misprogramming infusion pumps was due mainly to the complex programming steps required by many devices. Considerable work had been done throughout the hospital to decrease infusion pump related errors. The problem of misprogramming infusion pumps is not unique to the administration of chemotherapy; however, the team felt that a model could be developed for this complex patient population. A potential solution in the form of the Verifuse Pump, by I-Flow, was identified and subjected to a clinical evaluation by the nursing staff of the Infusion Unit. The pump is a relatively small, battery operated with the ability to be programmed using bar code technology. The bar code (Appendix 1) contains information, i.e. the rate and volume to be delivered, and the pump is programmed directly from the printed label. Specifically, the pump scans the bar code on a preprinted label affixed to a fluid infusion bag and programs the pump's fluid delivery parameters (n ml at nn rate/hr every y hours, and so on). The user verifies that the settings are correct before initiating therapy to the patient. The pump is configured so that manual programming of the device cannot be performed with the exception of start/stop functions.

Aredia® was the first agent chosen because the volume of patients was sufficiently high enough to allow for a meaningful evaluation. Aredia® is routinely given over a standard period of time and is relatively non-toxic as compared to other drugs routinely administered in the Infusion Center. A standardized bar code was used for all patients receiving drug during the trial. The outcome of this trial was a total elimination of programming errors for the Aredia-patient population. With this success, the team decided to expand the trial to a second agent, 5FU, which is delivered in the outpatient population for a standard period of ninety-six hours. Before the 5FU trial commenced, it was determined that the pharmacy computer system could be programmed to provide a label that contains all of the usual readable material and a bar code specific to the rate and volume of fluid to be delivered. This technology allows for the possibility of a seamless transition from physician order with COE (Chemotherapy Order Entry) to the PIS system to a printed label that will program the infusion pump. The 5FU trial outcome was similar to that of Aredia; programming errors related to rate and volume to be infused were eliminated. With the positive outcomes from a barcode reader in an infusion pump, the team felt that there would be a wonderful opportunity to combine the LAST with bar code technology into one device.

Phase II, (December 2000): *Provide the clinician at the bedside with the technology that will confirm that they are delivering the right drug.* The ADR (Automated Drug Recognition) technology consists of a bar-code reader in the pump that is capable of recognizing the drug and drug concentration to be administered and provides the end user with preprogrammed initial settings, and minimum and maximum dosing guidelines for administration. MGH will have the full compliment of LAST-ADR for our Pain Management infusion pumps by December 2002.

For example, when a physician writes a computerized order for IV morphine for an elderly, fluid restricted patient in ICU, the pharmacy information system produces the container label that reads “Morphine 50mg/50cc”. The same label will include a “pump readable” bar code that when wanded at the pump by the clinician at the bedside, will call up the drug library entry for Morphine. The drug name and concentration is then displayed on the pump and requires confirmation by the clinician, thereby averting the “wrong drug and wrong concentration” error. If by chance the clinician programs 25mg/hr instead 2.5mg/hr, our institutional limits in the pump will display that “25mg/hr is above the maximum recommended dose of 20mg/hr” thereby averting the “death by decimal” error. Once Pain Management ADR has been implemented, we will expand this process to all IV containers.

Phase III: *To create a seamless digital pathway from physician order entry to the vein.*

We at MGH are working towards the total solution of safe drug delivery that involves an array of complex systems working in tandem. While centralized computing infrastructure and applications (CPOE, PIS, Medication Dispenser, MAR and bar code solutions) are critical to long-term progress in medication error prevention, IV patient injury prevention may be immediately, directly, and effectively targeted now with the implementation of smart infusion pumps. There is a healthy competition in the infusion pump industry directed towards even “smarter” infusion pumps that will result in transfer of the technology to other hospitals throughout the world.

Significance/Conclusion:

Year:	<u>1996*</u>	<u>1997</u>	<u>1998</u>	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>
Volume:	120	12	3	3	1	1	1

* Anecdotal Reports

According to the Discussion Paper on Adverse Event and Error Reporting in Healthcare,² underreporting of events and errors occurs despite any mandate. Prior to 1997, undocumented, anecdotal reports of drug dosing errors averaged approximately at least ten per month at MGH. The LAST was implemented over the course of 1996 and fully installed by 1997. Commencing in 1997, these reports were tracked using a database for summary recall, root-cause analysis and follow-up. The downward trend is remarkable given the volume of admissions; in FY01, the hospital admitted approximately 31,000 patients and the average daily census was 679.

In-house audit of clinician reported drug error events have revealed at least a 50% reduction in the number of drug administration errors involving syringe pumps. Interviews of clinicians, physicians and nurses have reinforced the enthusiastic acceptance of these infusion pumps

because of the information available at the clinician’s fingertips. This is demonstrated by the progressive increase in the number of drugs added to the library per clinician request. A random observational survey revealed that of all the syringe infusion pumps in use, 92% of the pumps were in the drug library mode. The drug library empowers the caregiver to provide the highest of quality care.

Providing drug information at the bedside during care delivery is the first step towards a comprehensive safe drug delivery system. Medical therapy results in unintended injuries that have been estimated to effect 1.3million people in the US. Approximately two-thirds of these injuries are attributed to errors in managing drug therapy management. The system we have developed and deployed is scalable and can more broadly contribute to the reduction of medication errors in any setting where potent medications are used. MGH will have a standard infusion platform for syringe delivery through out the hospital with the Harvard Clinical infusion pump being the dominant syringe pump at MGH. Four large infusion pump vendors have licensed the drug library, which is an indication that the industry acknowledges the importance of this technology.

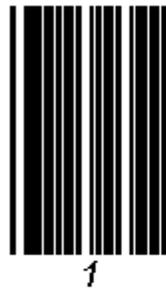
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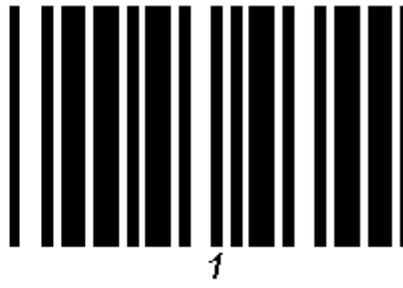
1. Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, *et al.* The nature of adverse events in hospitalized patients: results of the Harvard Medical School Practice Study II. *N. England J Med* 1991; 324: 377-84
2. Discussion Paper on Adverse Event and Error Reporting in Healthcare, Institute for Safe Medication Practices, January 24, 2000

Appendix 1.

Traditional Bar code uses a series of lines and spaces to communicate. The lines and spaces represent start and stop points, check digits and numeric information that is interpreted by an installed program. Traditional bar code is limited in the amount of information capable of being sent. Below is an example of Type 39 linear bar code. This is the oldest and most utilized bar code technology but is limited to 40 numeric.



Single Character - Small "X"



Single Character - Large "X"

Newer forms of encoding such as Aztec allows for the transmission of large amounts of data from small and compact source.



Aztec Code



Mary had a Little Lamb...



It was the best of times,...