



Protecting Patients with Medical Device Data

The recent publication of the report “*To Err is Human – Building a Safer Health System*” by the Institute of Medicine has helped to focus attention in the United States on improving patient safety. One of the longstanding goals of the IEEE 1073 committee has been to enable networking of medical devices to enhance patient safety. This white paper takes specific recommendations from Chapter 8 of the Institute of Medicine report and explains how IEEE 1073 can be used to reduce medical and medication errors to protect patients.

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Each section below starts with an italicized recommendation from Chapter 8 – *Creating Safety Systems in Health Care Organizations* of “*To Err is Human*”. The section is then completed by an explanation of how comprehensive capture of data from bedside medical devices plays a key role in meeting this recommendation. While the strategies below may seem to be obvious, no hospital presently captures data from all devices, in real time, and uses the data to protect patients.

Implement nonpunitive systems for reporting and analyzing errors: Data from patient connected bedside devices offer a key record of what actions were taken on a patient, that patient’s reactions to those actions, and patient status before, during, and after interventions. Infusion pumps and ventilators record several therapeutic actions taken by clinicians, while other devices record physiological parameters that are affected by clinician actions.

One of the major premises in the report is that any safety improvement program demands analysis of exactly what went wrong in every error. This is the reason that flight data recorders are placed on airplanes. These data recorders offer critical insights that help prevent errors from recurring.

Comprehensive capture of all data from patient connected bedside medical devices offers a key component to the analysis of many medical or medication errors. Analysis tools exist to allow data mining of large volumes of data. Medical devices offer a significant volume of data about the condition of a patient every second. The capture of device data coupled with data mining tools offers the level of detailed error analysis envisioned in the Institute of Medicine report.

Implement proven medication safety practices: including reducing reliance on memory; standardization; use of constraints and forcing functions (such as not allowing an infusion of x if BP is greater than y; not allowing an infusion without valid order, etc.); decreasing reliance on vigilance, handoffs, and multiple data entry.



Industry Standards and Technology Organization (IEEE-ISTO)

445 Hoes Lane • P.O. Box 1331 • Piscataway, NJ 08855-1331, USA
Phone 732.981.3434 • Fax 732.562.1571 • <http://www.ieee-isto.org>

Medication safety is one of the major areas addressed in the report. Significant attention is given to the present status a drug ordering, where many drugs with similar names are ordered on paper by physicians with illegible handwriting. Physician order entry systems are an important improvement to drug administration. Networking of medical devices, especially infusion pumps and patient monitors, enables a new level of medication safety during drug administration. Networked data from infusion pumps enables systems to be designed to check the actual drug therapy with physician orders, using a computer network to check. Medication safety systems that have real time data from infusion pumps greatly reduce the clinician's reliance on memory for which drug and which patient.

Medication safety systems can be designed to enable new levels of forcing functions for drug administration. The design of infusion pumps that connect to a network enables checking to prevent the following scenarios: drug delivery to the wrong patient; drug delivery at the wrong time; delivery without a valid order; delivery of an incorrect order; delivery of drugs that are no longer appropriate due to changing patient condition.

Networking of devices reduces reliance on personal vigilance of clinicians. Present practice relies on cyclic checking by clinicians, and audible alarms that may or may not be heard. Alarms for conditions such as end of infusion, occluded lines, or even ventilator problems are frequently ignored or not even heard. Alarms can be easily tied to a network to ensure that clinicians are aware of them, and their priority, regardless of their proximity to patients.

The prevention of errors requires systems that are designed for safety – that is systems in which the sources of human error have been systematically recognized and minimized: System level design requires that all sources of error be considered and minimized. Minimizing errors can be done through a combination of designing them out of the system and in designing checking and monitoring functions. Tubes for ventilators pop out of place consistently enough to have alarms systems for this event designed into all ventilators. System design recognizes that clinicians are not always immediately present and that networking devices would permit the alarms to be sent to the appropriate clinician, wherever they may be.

System level design does not rely on individual talents and memory, but puts tools in place to help skilled workers solve complex and uncertain problems. Decision support tools greatly assist clinicians in determining the cause of patient ailments. Decision support tools can use comprehensive data from medical devices to design specific treatment protocols that are optimized for individual patients. Decision trees can be designed that take into account minute by minute patient condition. For example, with data mining tools used to find data correlations, physicians may find that certain patient populations are best treated by differing drug therapies based on their exact point in time of a cardiac event.

Systems that use device data to build population based treatment protocols are much more likely to assist clinicians in choosing the most effective path of care than clinicians choosing by memory alone. Tired clinicians relying on memory are a large source of medical and medication errors.

Use of constraints, which make it hard to do the wrong thing, and forcing functions which make it impossible: Networking medical devices and making hospital information available to them enables many constraints and forcing functions to be designed for patient safety. A ventilator that has real time access to patient demographics can be programmed to preclude respiration settings that would normally be permitted. Drug delivery through infusion pumps can be prevented unless a valid order is found in the system. Device settings can be automatically changed whenever the patient is known to be pediatric. Drug interactions and overdoses can be prevented by checking previous drug administrations stored in a local or hospital wide record. Devices can be checked, in real time, to assure operational safety. Real time data capture from devices will enable these and many other patient safety applications.

Avoid reliance on vigilance: The report gives the example of infusion pumps that regulate the flow of intravenous drugs rather than relying on human vigilance. Clearly much more can be done with device networking and reporting to reduce reliance on human vigilance. Alarm and status data can be connected, in real time, to an alarm network where every caregiver has a PDA type device that displays warnings for their patients. Additionally, devices perform a very critical patient vigilance function on their own. The present system depends on clinicians to be vigilant in monitoring the vigilance of the devices. This vigilance can be automated easily with device networking.

Individual devices are limited in their vigilance function since they are not aware of the entire care environment. A clinician might be concerned with the blood pressure on a patient based on the specific drug therapy being employed. The ability of computer networks to analyze data from multiple sources enables a new level of automated vigilance for patient safety that is not possible without comprehensive data from devices.

One physician expressed a desire to dynamically calculate a measure of hematocrit values during surgery based on fluid balances and body volume. This would be possible through the real time measurement of infused fluids and drained fluids. Hematocrit values are used to determine when more blood needs to be infused during surgeries. Present practice relies on vigilance, where a clinician orders lab tests, as they deem required. Data capture from devices, coupled with a simple fluid balance application feeding a hematocrit calculation allows for real time estimates of hematocrit, giving real time indications on the necessity of blood transfusions during surgery. This would dramatically improve patient safety, preventing harm from unnecessary transfusions and potential death from the lack of a transfusion.

Anticipate the unexpected: includes: monitoring vital signs, blood levels, and other laboratory values for patients receiving hazardous drugs: There are known events that occur on small portions of the patient population that can be monitored in real time by a computer network that searches for such events and patterns. Drugs often have allergic reactions and side effects that are known and rare. But these events do happen. Additionally, the proper therapies for patients, especially the most critically ill patients, can change drastically and rapidly due to sudden changes in patient status.

All other safety critical industries use real time monitoring on the status of the system to ensure that unexpected events are detected and dealt with promptly. In healthcare the system is the care

of a patient. Unexpected changes in patient health, patient location, and patient care occur constantly. Only through constant electronic monitoring of device data can reports of unexpected changes be brought to the attention of caregivers immediately.

Anticipating the unexpected also includes making unexpected events more predictable. In aviation, the actual usage of electronics is measured, permitting maintenance functions to be done on electronics before they are expected to fail. Real time data capture from medical devices enables the actual usage of individual devices to be measured. This allows maintenance and calibration to be performed to prevent device failures, improving their safe usage.

Design for recovery – includes: making errors visible; duplicating critical functions or equipment as necessary to detect error; intercepting error before harm occurs: Device data is a key component to making errors visible, since devices offer real time data on patient condition and therapies. Capture and analysis of device data and alarms can be used to feed a real time alarm and alert system, greatly increasing the visibility of errors and their prompt resolution.

Device data also plays a critical role in duplicating functions to detect error. In the case of the Boston Globe reporter who died from a chemotherapy overdose, much attention has been given to the need to check physician orders for safety. Real time data from the infusion pump would have allowed a duplicate check on the order, preventing this unfortunate death.

Device data can also help to intercept error before harm occurs. Changes to settings for infusion pumps, ventilators, and defibrillators can be checked for safety prior to permitting any change. Physiological parameters can be checked for unexpected changes that may indicate an error has occurred, or even that an error is in process.

Improve access to accurate, timely information: Medical devices play a critical role in improving access to accurate, timely information. Studies done at LDS Hospital in Salt Lake City have shown that hand transcribed data is highly inaccurate and becomes part of the record so late that it is essentially useless in guiding care. Automatic data capture from devices was used as a duplicate to hand written processes. As much as one-third of the recorded values were written incorrectly, while as much as half of the data was not available until more than five hours after it was recorded. Capture of device data enables real time, accurate physiological data to be available to local and remote clinicians, ensuring that the best possible data is used to direct care.

Device data can also be integrated into data and knowledge bases to ensure that a complete picture of patient status is available. Real time data from devices enables clinicians to check the status of patients whenever they want, wherever they are. Device data can be combined with lab results, physician orders, and other patient data in a single database. Data dictionary standards efforts are already underway to enable compatible use of data from systems and applications designed for devices, labs, pharmacies, and clinician orders.

Computer based patients records give the ability to access patient data without delay at any time in any place; aggregate data from a large number of patients to measure outcomes of treatment; must commit to using information technology to manage their knowledge bases and processes of care. Computer based patient records (CPR's) have been discussed for decades. CPR's are

presently available for primary care physicians. These records keep track of a cursory level of patient care and history and serve a useful role for PCP's and patients. A true, hospital based CPR must be much more robust. In order to meet the goals espoused by CPR advocates, a true CPR must have all patient data, for every second, and be searchable for a wide variety of queries.

In most other industries, quality and performance data is measured comprehensively and constantly to enable systems to be re-designed as required. The data is also mined to enable new processes and products to be designed. In healthcare, medical devices contain a rich history of an encounter with a patient. Capture, querying, and analysis of device data enable the following scenarios:

- A physician in an office can be consulted, in real time, on the present status of a patient.
- Data mining tools can be used to design probability based, decision tree treatment protocols, where the best treatment options for increasing smaller sub-populations are designed and tested. Protocols that are optimized to specific sub-populations are very likely to improve the quality and safety of care.
- Database queries can be used to properly diagnose patients conditions based on their exact symptoms and reactions to therapies, significantly reducing guesswork. Almost every research study has shown that the best possible decisions are made when humans make them with the aide of computer tools.
- Comprehensive capture of device data enables a rich view of patient status that can be presently in multiple formats to care teams, allowing collaborative decision making on the course of treatment.
- Capture and analysis of data permits the routine capture of patient status to be done by physicians prior to patient visits, making rounds visits to be focused on actual interaction and analysis of the patient, not the devices and charts.

Implement Mechanisms of feedback and learning from error: reporting of events in sufficiently rich detail to create a “story” about what occurred: One of the most important lessons from aviation is the key nature of error analysis is systematically improving the overall safety of the system. Many key people in healthcare are already advocating the use of error reporting systems. Medical devices offer a significant increase in the richness of data to determine the root cause of errors and how to prevent them.

Just as flight data recorders are reviewed after crashes to determine how to prevent this error from recurring, medical device data should be stored and reviewed for every medication and medical error. Second by second analysis of device settings, physiological parameters, alarm status, infusion status, fluid balances, and other data from devices can help give a complete picture of how an error occurred and what can be done to prevent its recurrence.

Selected strategies to improve medication safety: adopt a system-oriented approach to medication error reduction; make relevant patient information available at the point of care: Device data plays a large role in implementing a system-oriented approach to preventing medication errors. The entire system for the ordering and delivery of drugs needs to be improved to add redundant safety checks at every level. Medical devices are deeply ingrained in the drug

delivery system since infusion pumps deliver drugs and physiological monitors measure many of the effects of these drugs.

Infusion pumps measure the rate they are infusing as well as the volume they are programmed to infuse. From this data, dosing information is available. System design can enable patient allergy and demographic data to be available at the point of care, and allow infusions to be checked against specific patient data. Dose calculations based on patient weight can be done at the bedside with real time data. Drug infusions can be checked, in real time, to ensure that no known allergy or drug interaction violations occur.

Limit the number of different kinds of common equipment: The report specifically recommends standardizing the look and feel of devices, reducing the learning required for similar device from different vendors. Errors have been caused due to clinician unfamiliarity with specific devices.

In a competitive market where different devices are optimized for different uses and market segments, a standardized design for the operation of each device is unlikely to evolve. However, device data can be used to ensure that errors do not occur from this diversity in the market. Standardized device data permits constant innovation in device design to be done without an increase in the potential for harm to patients. Rather than standardizing the design of devices, standardize the data from them to permit safety system design and operation.

Conclusion:

The comprehensive, real time capture of data from patient connected bedside devices is a critical component in a systems-oriented approach to improving the safety of healthcare. New levels of safety checking and error prevention are possible with capture and analysis of medical device data.

The IEEE 1073 Standard for Medical Device Communications specifies a complete seven layer communications protocol for patient connected bedside medical devices. Adoption of the IEEE 1073 Standard by healthcare organizations permits them to start designing more effective systems to ensure patient safety today, and enables continuing improvement in patient safety and the quality of care.