HARNESSING THE POWER OF MEDICAL DEVICE DATA

INTRODUCING THE MEDICAL DEVICE INFORMATION SYSTEM
NOVEMBER 2018

INTRODUCTION

We have evolved to a technology-driven society. As such, we have become dependent on the speed with which this technology moves data. The quicker we can access, process and turn data into actionable information, the faster we are able to act and respond to the world around us. Healthcare has certainly not been exempt from applying information technology. But in some circles it has been considered slow to adapt IT to areas where the impact on the quality and cost of patient care might be profoundly impacted. Indeed, government mandates over the past six years, quality initiatives and incentives have encouraged healthcare delivery organizations to more rapidly implement information technology.

When it comes to patient data, the emphasis has traditionally been on medication administration, physician order entry, and clinical documentation. Medical device automation was historically scheduled in a secondary project phase. But, as hospitals began to automate, the importance of device integration was elevated with the realization of the time savings and accuracy of data within their information systems that medical devices could provide. Today, as hospitals begin to explore the universe of medical device data elements, they are finding that the near real-time use of a combination of physiologic data, therapeutic device settings, and alarm information can yield powerful innovations to patient safety and clinical care.

Leveraging this extremely valuable asset to its fullest requires a system that not only automates the collection of data from medical devices from dispersed points-of-care, but also converts that data into a language that all systems will understand (HL7) and then distributes specific data to downstream systems. This is a Medical Device Information System (MDIS), the product of an emerging technology capable of providing timely and accurate patient data to any downstream IT system. Utilizing analytical and surveillance tools, an MDIS has the potential to transform this data into insightful information to drive patient care. At the same time, MDIS data can help manage the utilization and health of all devices included in the system.

THE STATE OF MEDICAL DEVICE DATA

Medical device data — such as physiologic vital signs (e.g. HR, SPO2, high-frequency waveforms), therapeutic device settings (e.g. infusion rate, drug type, drug concentration, anesthesia gas type, and ventilation mode), and the behavior of these data (e.g. high frequency waveforms) —are crucial first-line indicators of a patient's condition. There is a clear need to leverage this information for enhanced patient care. Hospitals will benefit from capturing and integrating into clinical information systems near real-time device data from dispersed points-of-care throughout the enterprise. Moreover, the data can do more. It can be transformed into insightful information using analytical and patient surveillance tools.

Delivering actionable patient data and making it available to the right healthcare personnel at the right time is fundamental to realizing the full value of medical device information and to delivering the highest quality of care. However, despite its tremendous value, there has been limited focus on intelligently managing and utilizing medical device data. To accomplish this, hospitals require a standardized method of collecting, analyzing and distributing data from multiple sources across the continuum of care — in short, they need a system.

MEDICAL DEVICES + DEVICE DATA TYPES

Medical devices can be as simple as a thermometer or as complex as a ventilator or infusion pump. Most, but not all, sophisticated devics that monitor a patient's condition and/or provide treatment details generate large amounts of data vital to ongoing management as well as for detailed documentation of care. Device data also provides important information about the equipment itself, such as how well the device is performing, the status of onboard data storage space and battery life, and identification information that helps track device placement throughout the healthcare enterprise. Many devices provide built-in alarms or warning signals that trigger when pre-determined technical or physiological parameters are met. Biomedical team access to this data also is important.

	HIGH ACUITY PATIENT MONITOR	LOW ACUITY PATIENT MONITOR	CARDIAC OUTPUT MONITOR	BIS MONITOR	SCALE	SMART BED	ANESTHESIA GAS MACHINE	VENTILATOR	DIALYSIS MACHINE	CARDIO BYPASS/ PERFUSION	INTRA-AORTIC BALLOON PUMP	INFUSION PUMP
HOSPITAL												
OR	●		●	●			●	●		●	●	●
Pre-Op & PACU	●	●	●					●				
ICU	●		●	●		●		●			●	
ED	●	●								●		
MedSurg		●			●	●						●
POST ACUTE CARE												
LTAC SNF, IRF	●	●			●				●			●
AMBULATORY												
Surgery Center, Physician Office, Home Health	●	●	●		●				●			●

BARRIERS TO ENTERPRISE-WIDE DEVICE DATA COMMUNICATION

For the past few decades, digital communication has become mainstream in the hospital environment. Hospitals have devoted significant resources to implementing new generation enterprise-wide information systems with powerful clinical capabilities, yet they have been slow to achieve enterprise-wide medical device integration. There are many shortcomings that have prevented this type of data from being fully leveraged.

Lack of Data Standards

The fragmented medical device landscape is comprised of numerous device types, brands and versions. Vendors have not adopted a unified data standard and supply only limited and inconsistent network connectivity. Proprietary data formats and inconsistent protocols prevent devices from communicating information to enterprise IT systems. The result is device data that cannot be aggregated in any meaningful way for sharing.

Data Silos

With a lack of industry standards, device data remains siloed in the department and often in the devices themselves. Unless manually transcribed into a system such as an EMR, the value of much device data is lost. When it is transcribed, the process typically takes place retrospectively, eliminating any real-time value to proactively drive treatment decisions. Many healthcare facilities are looking to not only send the data to their EMR, but to many other clinical and analytic solutions to innovate around mobile and more intelligent workflows. The ability to supply this data to not just one, but to multiple systems simultaneously and directly in the format that is required by that system helps break down the silos of data and provides critical and timely information for decision making where and when the clinician needs it.

Limited Hospital Funding

Replacing all bedside equipment to create a single-vendor, single-format device system provides the most straightforward approach to sharing device data throughout the enterprise. However, this is often prohibitively expensive and impractical because departments prefer to choose the best of breed device they believe will support optimal care for their patients. Few if any hospitals have the required capital to replace serviceable devices and typically will continue to use a device until it literally ceases to operate, often after more than decade of service.

Piecemeal Approaches

Given these constraints, many hospitals have created ad hoc device integrations to address a limited number of device data use cases, often through point-to-point connections. In the end, these approaches provide low cost/benefit and no scalability to support future hospital-wide communication.

HARNESSING THE USES

So what's the big deal about medical device data? Much of the recent focus is on the automating the data for clinical documentation. The benefits are great — timely, accurate, and comprehensive charting creates enormous clinical efficiencies in patient care delivery — enough to immediately justify funding for these projects in device intense environments. But there is also an array of systems and applications, all requiring medical device data to help enable improved patient care delivery.

Electronic Medical Records

EMRs — incentivized through healthcare reform — have enabled the transition from paper charts to electronic record keeping for many hospitals. While an EMR has significant value in tracking care retrospectively, it can also play an important role in shaping care prospectively if data is available in a timely manner. Further, placing device data in the context of other EMR patient information will help identify patient trends in a broad clinical context. However, without some form of integration, device data continues to be manually transcribed into the EMR (sometimes up to 12 hours after acquisition) losing its value to drive ongoing patient treatment and to recduce healthcare costs. Additionally, manual data transcription is error-prone and takes nurses away from patient care.

Alarm Management Systems

Today, most medical devices incorporate alarms to alert caregivers to potentially adverse changes in a patient's condition or to device malfunctions. A key issue is that alarms are typically inaudible beyond the patient room and have little effect when a clinician is not at the bedside. Devices attached to a single patient may issue alarms several hundred times a day, including many false or unnecessary alarms. The result is a phenomenon known as "alarm fatigue," which can affect both patients and clinicians. Unable to respond to multiple simultaneous systems and distinguish priorities, clinicians can become desensitized, compromising patient care. Patient safety may also be affected due to improper alarm settings, volume and shut-off procedures as well as absent or inadequate alarm systems. Evidence states that common injuries linked to alarm management are patient falls, improper ventilator use, and medication errors.

As a result of the well-documented patient safety risks posed by improper alarm management, the Joint Commission established the National Patient Safety Goals that require hospitals to comply with key alarm initiatives:

- Establishment of alarm safety as an organizational priority as of July 1st, 2014.
- Identification of important alarm signals that require management during 2014.
- Establishment of policies and procedures for managing alarms, including staff education on proper alarm system operation as of January 1, 2016.

Meeting these Joint Commission directives and remedying alarm safety hazards requires a system that captures all medical device data, including alarms, across the enterprise for integration into an alarm management system. Communication of the full range of device data surrounding an alarm in real-time enables a healthcare IT system to interpret the alarm in a clinical context and prioritize clinician alerts — if an alert is, in fact, required.

Clinical Decision Support

The broad push towards digital data and EMR use also furthers other data-driven care improvement initiatives. In particular, the ability to trend physiologic medical device measurements with the assistance of early warning algorithms allows early recognition of patient deterioration and reduced adverse events. Pooling this type of trended data with associated outcomes across a vast knowledge-base of similar prior patient cases will further enhance its value, advancing not only quality of care, but advancing clinical care.

Patient Surveillance

Patient surveillance applications can aggregate a wide variety of relevant clinical patient data (e.g. diagnosis, lab notes) along with high frequency medical device information (e.g. waveforms) to support a comprehensive view of the patient in a single on application — typically from any location. Automated patient surveillance helps today's overburdened clinicians to remotely view and wade through vast information stores to discern, and quickly understand data of the greatest value. With the addition of real-time device data, predictive algorithms can better identify data clusters and trends consistent with patient deterioration and specific disease conditions, prompting clinical intervention. Surveillance systems such as these also can trigger alarm notifications and put them in context as well as feed into the decision support systems discussed above.

Asset Tracking

Tracking device usage and location across the enterprise to ensure optimal utilization and deployment is crucial to making the most effective use of costly, high-maintenance medical devices so essential to patient care. It can be difficult to find a "clean" and available device when needed. While asset tracking companies help identify the current location of these devices, determining which devices are in use is difficult. Devices do often offer a range of built-in operational checks, or support remote monitoring to ensure device readiness and status of any required supplies. The availability of timely and appropriate device data to biomedical teams will ensure optimal device management and health, easing patient throughput and boosting patient safety and care.

IN NEED OF A MEDICAL DEVICE INFORMATION SYSTEM

As hospitals explore more advanced uses of medical device data, many of the barriers discussed earlier become evident. Larger scale medical device integration solutions — in stark contrast with piecemeal device solutions — more effectively address the above challenges and are becoming increasingly available. These solutions have made significant progress in standardizing information and communicating device data to an EMR or other IT system. But limitations — particularly in functionality beyond data communications — still apply.

Despite the lack of a universal medical device data standard, several approaches have been taken to achieve device data integration. One such approach is to modify each device's outbound message for consistency with each destination IT system, whether an EMR or otherwise. Another approach has been the exact opposite — to equip each IT system with a series of interfaces to accept varied communication protocols from each connected device. However, the complexity and cost of developing and maintaining numerous interfaces is high, and neither solution is scalable.

A more practical approach with far-reaching benefits has been to rely on a middleware solution to accept device data, whatever the format, and translate it to HL7 as each endpoint system requires. Such a solution can adapt to an unlimited number of new devices with the simple addition of device driver software, streamlining system setup and maintenance. Moreover, additional HL7 feeds can be added for compatibility with any new downstream information system going forward.

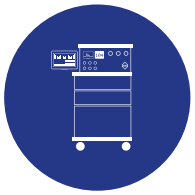
Moving forward, hospitals must anticipate and think holistically about their medical device integration strategies: the need to expand to all device types, communicate to a variety of downstream systems, and fully utilize the data in new and innovative ways. In order to accomplish all this, a medical device integration solution must evolve into a true Information System to derive maximum value from device information.

The concept of a medical device information system brings together the complex environment of device data acquisition, communication, and utilization. Specifically:

- The ability to connect a wide-variety of medical device types and manufacturers in a manner that scales and fits a hospital's clinical workflows, IT infrastructure, and remains consistent throughout a hospital's medical device or EMR replacement strategies.
  - → Intuitive bedside applications facilitating the connectivity of medical devices, enabling patient association, and clinical documentation in a simple workflow.
- The ability to have total control over tailoring and distributing the data to the needs of multiple receiving systems.
- An analytics platform to fully utilize the aggregated medical device data including:
  - → Analytics that provide clinical insight utilizing near real time and trending physiologic device data, including physiologic, therapeutic device settings, device alarms, and waveforms.
  - → Analytics that provide insights into medical device utilization and operation.
- A centralized application for managing the connectivity of all medical devices, and a user-configurable tool to align system output with the requirements of endpoint clinical applications.
- Tools, such as clinical decision support applications, to capitalize on timely device data to enable the earliest indication of patients possibly at risk.

EVERYBODY BENEFITS FROM A MEDICAL DEVICE INFORMATION SYSTEM

Clinicians at the bedside capturing and consuming this data to make clinical decisions based on the status of the patient — comprehensive, timely, and accurate information flowing reliably to their EMR or alarm management system enable them to be more informed about their patients.



IT and Clinical Engineering staff who support the clinicians — ensuring medical devices are up, running, and ready and that the data is seamlessly integrated and flowing to their destination systems at all times.

Administrators looking for data to help improve operational efficiencies in equipment and device management, clinical documentation compliance, and solutions with broad value to achieve cost savings in consolidation of vendor technologies.

A BLUEPRINT FOR THE FUTURE

A medical device information system is bringing about a paradigm shift in the use of medical device data for patient care. A comprehensive system that considers the clinical workflow and technology complexities at each step of the process — collection, communication, and application of data — increases data quality for clinical decision-making. Clinicians as well as those that support them all benefit in such a system. Finally hospitals can harness the true power of device data to analyze and act on it in new and unprecedented ways.

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