white paper

BIOMEDICAL DEVICE INTEGRATION

Getting Vitals Where and When Its Needed Most

Includes Case Study on Sentara Healthcare

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Introduction

In the world of medical technology, increasing connectivity across care settings to get vital real-time patient health information into electronic medical records (EMRs) is of growing importance with the accelerated adoption of EMRs occurring across the country. As The Centers for Medicare and Medicaid Services (CMS) sees their Meaningful Use of Electronic Health Records (EHRs) program helping increase the procurement and implementation of EHRs across eligible hospitals and eligible providers (48% and 19% respectively that have received incentive payments through May 2012),[i] the opportunity for biomedical device integration (BMDI) is becoming ever more important. In this white paper, we provide some insights to key issues in BMDI implementation, a case study on Sentara Healthcare and how they have managed their BMDI program, and benefits from BMDI implementations.

Age of Accountable Care and the Need for Connectivity

The nation's health system is advancing into the age of accountable care supported by the health information technology (HIT) renaissance period occurring in the industry. Federal health reforms incentivizing EMR adoption, increased focus on consumerism, development of more patient-centric systems, and the growing need for real-time patient health information are all contributing to the need for improved connectivity to support care provider teams across the United States (US) healthcare system. The opportunity to leverage data from integration of medical devices is improving care delivery and clinical care administration processes with an ultimate focus of improving health outcomes.

Physicians and their care provider teams are gaining greater access to use of real-time data and BMDI initiatives are enabling this capability. Linking together the components in the technology architecture means integrating medical devices from across a hospital/health network's inpatient, ambulatory, and in some cases home care setting with the EMR. With the growth in Personal Health Records (PHRs), the importance of collating this clinical data becomes even more important as well. More importantly, BMDI enhances the richness of comprehensive data sets available within a patient's health record with data collected from care settings spanning emergency departments, operating rooms, intensive care units, and others where vital information is collected for use in the immediate care setting and made available for health information exchange as part of the patient's longitudinal care record.

Accountable care organizations (ACOs), clinically integrated networks (CINs), health information exchanges (HIEs) , primary care and specialty care practices alike are all facing this need for increased connectivity and richer data on the patients they provide care for in their inpatient care settings. When data feeds directly into the EMR, physicians and caregiver teams have a central repository for the information they need. Overcoming challenges to enable connectivity and improve the value of the knowledge and evidence available for clinician and physician decision-making is critical. A few challenges include:

Topic	Challenge
Data Transcription	Integrating medical devices into a healthcare organization's health information technology (HIT) architecture to decrease manual transcription of data.[ii]
Interoperability and Communications	Ensuring interoperability among components within both the network and data architecture - (e.g. use of common communication standards).[iii]
Device Drivers	Having device drivers that are *"specific to each vendor, type and version of medical device."*[iv] and that maintain the same operational parameters across various software releases
Staff Engagement	Involving clinicians in the selection and set up and configuration between biomedical devices and EMRs.
Alarm Management	Device interfacing to filter critical and non-critical alarm data through appropriate servers to mitigate "alarm overload."[v]
Testing	Medical device integration testing to ensure trust in the system and validation of the data.
Positive Patient Identification	Implementation of positive patient identification (PPID) for vitals collection, validation, and submission to EMRs can cause interruption with clinical workflow.[vi]

Overcoming these challenges to maximize the capabilities of BMDI requires transformation of the processes and structures of care that are increasingly connected through HIT. As noted by Flareau and colleagues, *"For CINs and ACOs, health information technologies serve important functions of giving teams real-time access to patient records; monitoring and measuring quality and outcomes…"*[vii] BMDI enhances this ability for real-time access to comprehensive and meaningful data. Delivering on the potential of ACOs and CINs will require significantly more robust quality reporting to evaluate outcomes and this will only be possible with richer, more timely and more accurate data and patient health information. The vital statistics available through BMDI provide the physicians and clinicians evaluating outcomes with deeper insights at the population level from which quality initiatives can be fine tuned for the benefit of the patients being served by ACOs and CINs.

So what does this more robust data set give us that we obtain from BMDI? One answer comes from the growing interest in Big Data.

BMDI and Big Data

Getting the data from biomedical devices into an organization's EMR is a key part of the landscape of data sets supports the drive toward Big Data sets. Big Data has been defined as, *"…Big data (also spelled Big Data) is a general term used to describe the voluminous amount of unstructured and semi-structured data a company creates -- data that would take too much time and cost too much money to load into a relational database for analysis."*[viii] What are some of the benefits to be derived from medical device integration in regards to Big Data? There are three to consider that include data accuracy, timeliness of data delivery to the caregiver and decision maker, and frequency and availability of the data.

First consider data accuracy. A challenge that occurs prior to implementing BMDI with EMRs is the requirement for manual data transcription from one system to another that can lead to both time delays and inaccuracies. When medical devices are integrated with EMRs to have automated data streaming, the opportunity for improving the quality of the patient's information and the timing for which it is available for use by care givers increases exponentially.[ix]

Second, is data delivery to the decision makers. With BMDI in place, clinical decisions by physicians and caregivers at the patient level can be improved from having a more complete picture of the health statistics/data and vitals on the patient. At the executive level, larger data sets are needed (i.e., Big Data) to conduct deeper retrospective and more importantly, predictive analysis for population health evaluations to gauge improvement of outcomes by ACOs and CINs.[x] BMDI makes these data sets more robust at the micro and macro levels thereby improving clinical and relevant administrative decision-making.

Third, is frequency and availability of the data. Once medical devices are integrated into the healthcare organization's HIT architecture, access to the information generated by the devices can be made available in real time. As systems across an architecture change and upgrades occur over time, testing and validation to ensure that interfaces are not impacted become essential (one of the key challenges with BMDI implementations) to ensure that access to information remains available.

One organization that has made tremendous strides in the implementation of BMDI is Sentara Healthcare. The following case study on Sentara provides insights to successful efforts at overcoming the challenges with BMDI and providing an effective solution to help physicians and clinicians with accurate and timely flow of patient health data into the EMR from medical devices across the care delivery setting spectrum.

CASE STUDY

BMDI at Sentara Healthcare

Sentara Healthcare (Sentara), with 10 acute care hospitals and over 100 sites of care across Virginia and northeast North Carolina, is a leading integrated care delivery service provider. In 2008, Sentara having embarked upon the implementation of Epic's EMR solution for their hospitals and ambulatory practices started developing the roadmap for integrating their biomedical devices into their hospital operations. From Sentara's perspective, biomedical device integration (BMDI) is the approach to automate the delivery of biomedical device data into the Epic EMR. Sentara's biomedical device integration team is comprised of one technical manager and three systems administrators. As of the summer 2012, the team at Sentara has integrated more than 2,000 biomedical devices into the EHRs at eight of Sentara's 10 hospitals. Additionally the BMDI team supports their Philips VISICU application for remote monitoring of ICUs, General Electric's (GE) QS application used in labor and delivery departments for fetal monitoring, and mobile EMR applications.

The initial project scope that launched September 2006 included:

- Eight Hospitals. (ED, ICU, PACU, ENDO, L&D)
- Integration of Nursing data points

The follow up project scope that launched August 2011 included:

- Eight Hospitals. (ORs, ENDO, ASC, Cath Lab, ERCP, etc);
- Integration of Anesthesia data points;
- Outfit Anesthesia machine with needed hardware;
- Six completed as of August 14th, 2012;
- Project completion, November of 2012.

Figure 1 offers a high level overview of the BMDI implementation at Sentara

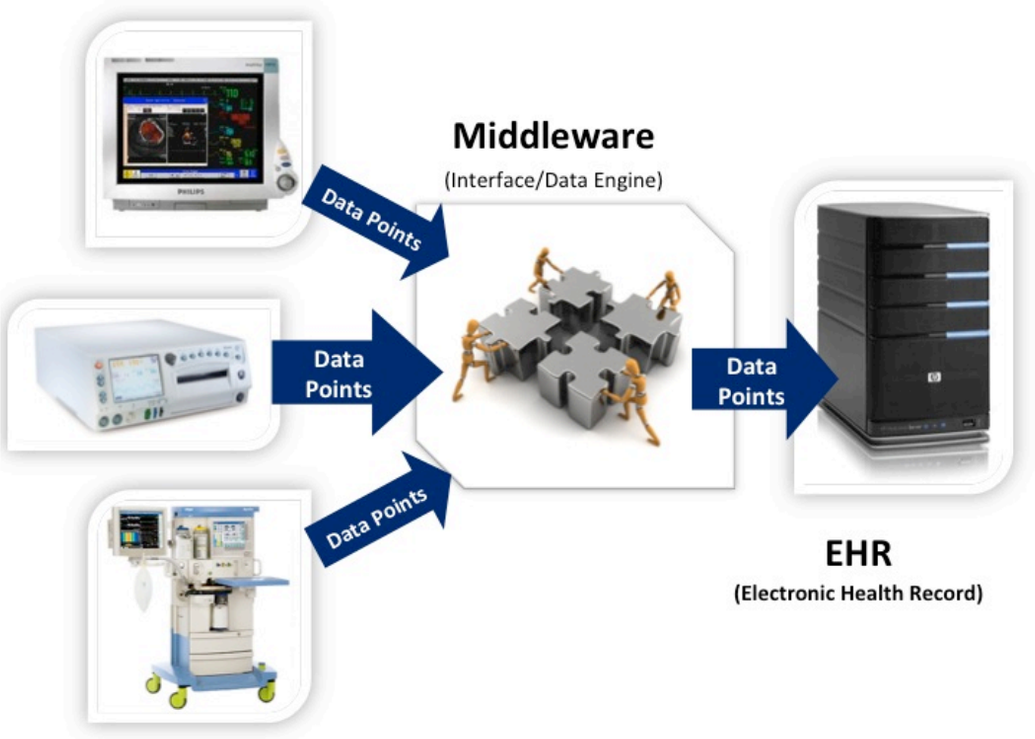


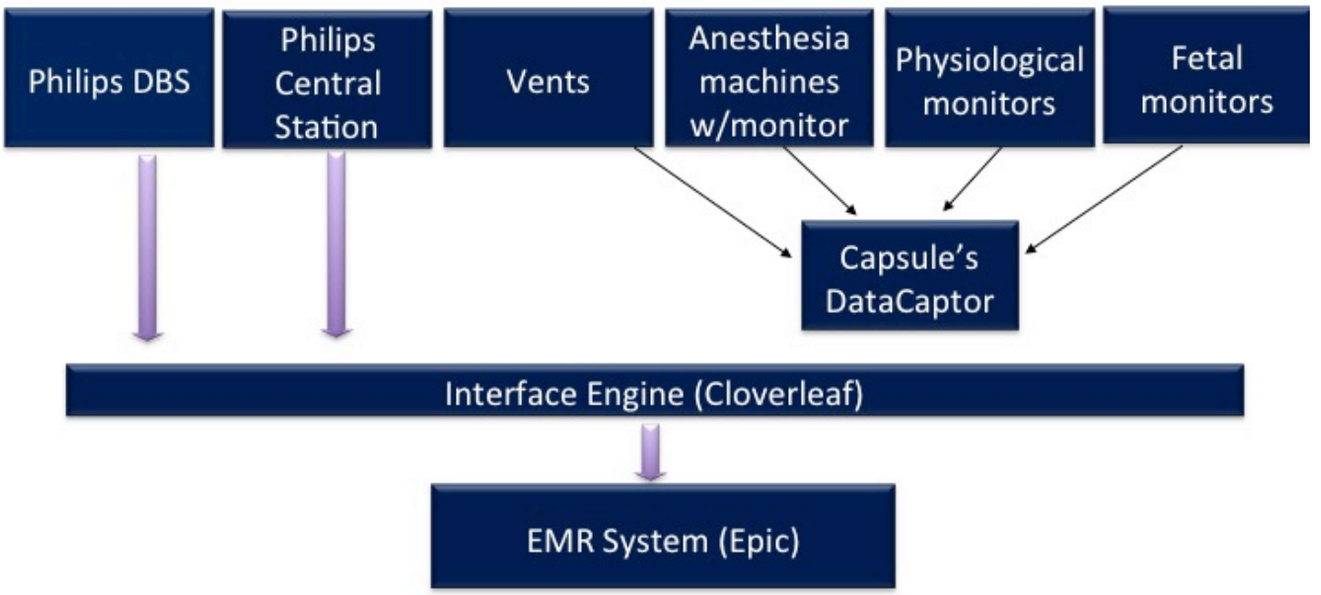
Figure 1. Sentara BMDI Overview

This figure shows the configuration of data flowing from devices into a middleware (interface engine) and eventually into the Epic EMR. Best practices leveraged from Sentara's past health information technology implementations included:

- Have a physician led governance group that makes key decision on system level variables and standards.
- Focus on integrating one facility at a time due to variation in possible workflows and need to ensure optimal customer service at each facility.
- Review hardware in departments at least 3-months (preferably 6-months) in advance to ensure each department is ready for BMDI.

Figure 2 provides a high level illustration of the key architecture components in the BMDI project at Sentara.

Figure 2. Sentara BMDI Projects



Having a variety of devices from different vendors, as is the case at Sentara, requires standardizing the device integration and is a critical element for any BMDI initiative. At Sentara, two integration methods were used to achieve standardization; Philips via their HL7 feed from 34 Philips database servers and secondly, Capsule via their terminal servers (e.g., digi boards). For Capsule deployment, close to 500 four and eight port terminal servers and 12 virtual servers (eight for nursing workflow, three for anesthesiology workflow, and one for NICU alarm integration) were used. The terminal servers are not running on a PC operating system and do not require security patches to be installed. They are solely dedicated to the integration process, and have produced high reliability for several years.

Sentara BMDI Implementation Approach

The approach to a BMDI implementation should be tailored to fit the care delivery environment. At Sentara, the first steps include meeting with the customers to identify departments and devices involved and then setting the scope and frequency that vitals are needed. Next, the BMDI solution is designed that is then followed by the *most crucial step of testing* (one of the key challenges noted earlier) to confirm that cables are pinned out correctly and that hardware devices are functioning correctly prior to go-live. For new devices, always confirm the format and location of the data in the EMR before integration.

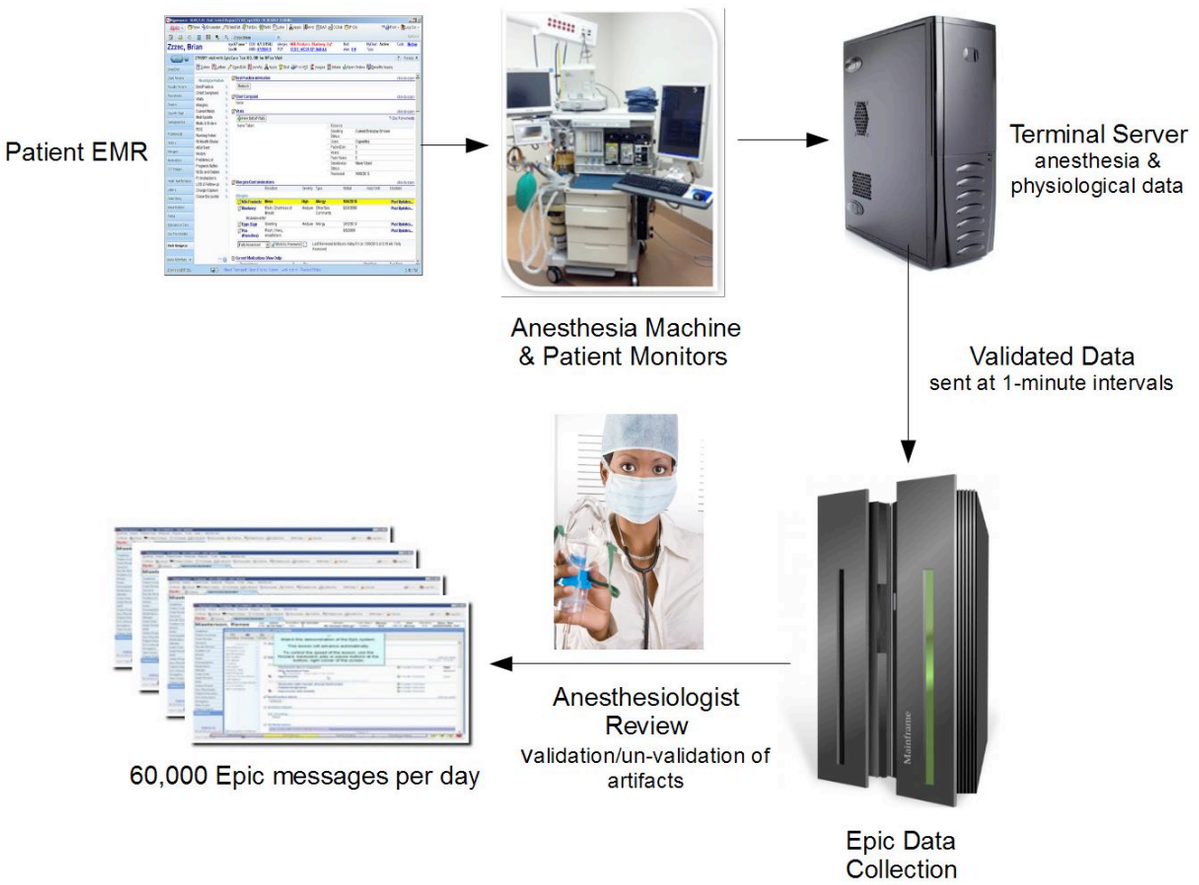
BMDI Clinical Workflows: Anesthesia

A prime example comes from anesthesia data collection and transmission. Some of the key workflow considerations for integrating these devices include:

- The patient's EMR record is linked to a computer that is attached to the Anesthesia machine.
- A Capsule terminal server is attached to the anesthesia machine, which transmits the device data from the anesthesia machine and physiological monitor.
- Device data enters Epic every minute as validated.
- The anesthesiologist can un-validate data artifacts.
- The system generates approximately 60,000 messages/day in Epic.

Figure 3 tracks how the patient-specified data flows through they system

Figure 3. Anesthesia Patient Dataflow

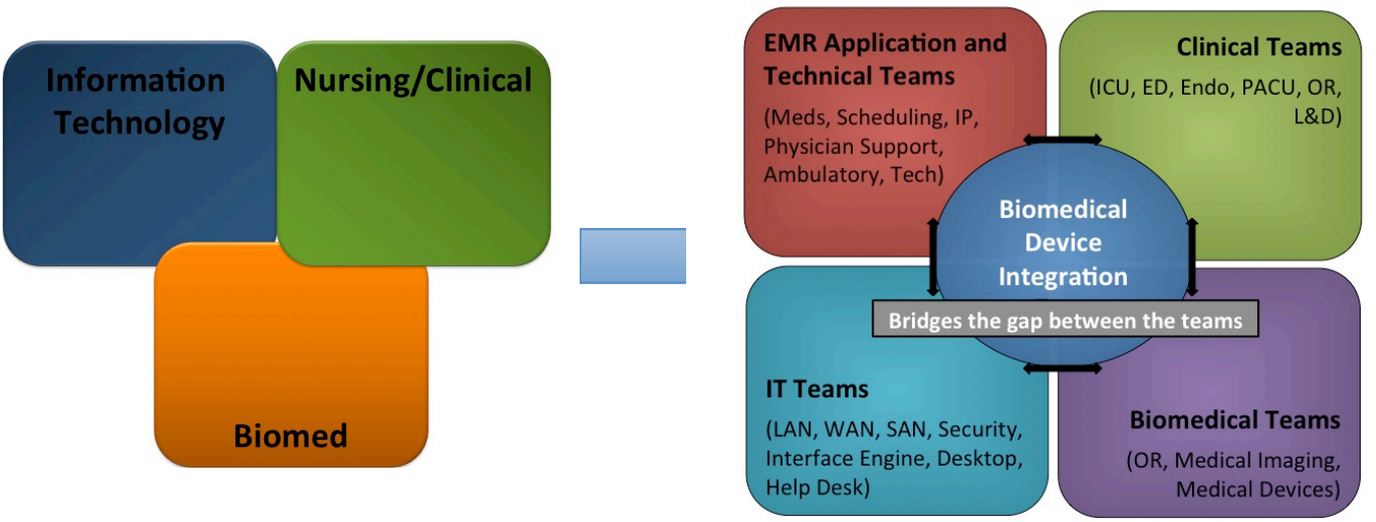


As this project is nearing completion later this year, a number of lessons learned have been gathered that include:

- Investigate medical device inventory and software revisions/configuration.
- Identify legacy devices that need to be replaced.
- Obtain a list of variables from EMR application team and communicate which variables will come in automatically and which ones will not.
- Don't assume all locations are setup the same, even if they have similar hardware.
- Work with EMR application teams to identify level of involvement and expectations.
- Understand how labels on monitors can affect what is being sent to Capsule, IE and Epic.
- Have network drops run 2 months in advance and preferably to the same IT closet.
- Setup equipment at least one month prior to go-live.
- For multiple systems, allow enough time between go live at each facility.
- Standardize as much as possible and choose vendors that provide a neutral solution and allow flexibility for devices.

In June 2012, Sentara's approach and lessons learned in BMDI was presented via a webinar through Healthcare Informatics[xi]. Sentara's strategic BMDI team model represents a novel approach advanced from typical industry approaches to medical device EMR integration projects and is illustrated in Figure 4 with the biomedical device integration team at the heart of the initiative.

Figure 4. BMDI Team Implementation Model at Sentara



Traditional BMDI implementations have engaged a three-team structure with Information Technology teams, Nursing/ Clinical teams and a biomedical team. At Sentara a modified approach has been taken focusing on the four quadrants displayed in Figure 4. Key to this approach is recognizing the matrix requirement for resourcing and partnering. The BMDI team helps the members of each of the other four teams by "bridging the gap" to meet specific needs of mitigating workflow challenges, alert issues, and improving communications across the teams to manage upgrades and updates, maintain focus, and ensure that standards (i.e., HL7 and other protocols) are rigorously adhered to for compliance.

Value from BMDI Implementations

There is great value to be obtained from BMDI implementations. As the challenges are addressed and barriers are overcome the opportunities to capitalize on more timely, accurate, and getting the right data in the right place in a real-time or near real-time manner increase dramatically. Value derived from these projects can be thought of both financially and in terms of clinical efficiency. Total cost of ownership is common for evaluating the financial ROI associated with EMRs (and associated challenges with evaluating it) and is also important for management to consider with a BMDI implementation[xii] When embarking on a project such as this, organizations should therefore consider:

- the original implementation cost
- ongoing support, staffing and training
- required system upgrades for the devices themselves
- device life expectancy from MTBF (mean time between failure) data
- drivers, servers, and other associated network/cloud applications to keep pace with upgrades to the organization's EMR.

In one case from a BMDI implementation at the University of Alabama Birmingham (UAB) the benefits to the nursing operations provided a strong example of improvement in clinical efficiency. These gains were summarized as, *"As a result of the BMDI implementation, nursing has achieved a significant reduction in average time for documenting vital signs, dropping from four minutes to 20 seconds, a 92% efficiency gain. The total time that was reallocated to direct patient care per nurse per shift varied from 227 minutes to 79 minutes depending on the specific unit's care protocols."*[xiii]

Additional benefits to be achieved by organizations such as UAB, Sentara and others may include providing clinicians more time for patient care activities, increased reliability of vital sign data, and improved use of best practice alerts related to changes in vital sign data. As the adoption of EMRs continues to accelerate across the US healthcare system, increased attention to BMDI implementations will continue to be a growing priority for healthcare provider organizations.

About the Authors

Mike Freeman has over 13 years of experience in inforamtion technology, with 11 of those years working in Healthcare IT, and has been operating as Manager of the biomedical device integration team at Sentara Healthcare for over 2 years.

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His career includes serving as Medical Director, hospital CIO and COO, and primary consultant to hospitals, health care systems and government regulatory agencies. Dr. Goldstein has served on numerous regional and national committees for addressing issues to improve America's health by bringing together providers, payers and consumers that resulted in practical and viable solutions for improving clinical outcomes, patient safety and organizational efficiencies..

Dr. Goldstein received his medical degree from CETEC University School of Medicine and completed his Residency training in Family Practice at SUNY Stony Brook – Glen Cove Hospital. He also holds advanced degrees in Electrical and Biomedical Engineering from SUNY Buffalo and the University of Connecticut. He is a Fellow of the American College of Healthcare Executives where he was the national chairperson for the college's Physician Special Interest Group as well as serving on the NJ Regent's Advisory Council and also a member of the American College of Physician Executives.

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