Medical Device Connectivity Case Study

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Executive Summary

University of Missouri Health, a comprehensive academic medical center that includes MU Health Care, MU School of Medicine and its University Physicians practice plan, MU Sinclair School of Nursing, and MU School of Health Professions, has a mission to advance the health of all people, especially Missourians, through exceptional clinical service, which supports the academic and research mission of the University of Missouri.

MU Health recognizes that an electronic health record (EHR) is essential to our mission and we have had an EHR infrastructure since 1996. Consisting of five hospitals and more than 50 clinics staffed by more than 550 university physicians, MU Health Care has the only Level 1 trauma center in mid-Missouri. Our health system offers primary, secondary, and tertiary services to central Missourians in a 25-county service area with a population of 776,861.

At MU Health Care, we recognized significant variability in the recording of patient data provided by bedside medical devices. That variability, which is tied directly to clinician workload and can drive lags of up to 6 hours in charting critical data, affects patient safety. Moreover, published studies indicate that error rates from manual entry of such data can be as high as 13.5 percent[1,2], which causes further concerns for the well-being of patients.

We responded to the challenge by integrating selected medical devices to the EHR to provide real time data flow. We used a combination of technologies to accomplish the integration, focusing on the approach most appropriate to each medical device. Clinicians and our EHR partner provided critical input on workflows, data requirements, and integration techniques.

The success of the program is highlighted by a demonstrated reduction of documentation lag times, labor efficiencies, and realization of error rate reduction.

Local Problem

Medical devices deliver a large amount of critical patient data. Traditionally, clinicians have manually recorded the data and entered it into the medical record. This "swivel chair" interface results in:

- **Delayed entry of data into the EHR** - Local studies indicated wide variances in data entry times, ranging from 2 minutes to as long as 6 hours.
- **Increased clinician workload** - Many workflows involved a two-step process where data was recorded on paper, and then entered into the EHR at a computer workstation.
- **Increased opportunities to ensure accuracy of data entry** - Studies published in the Journal of Healthcare Information Management indicate that error rates as high as 13.5 percent can be expected with manual data entry.[1,2]

The problem is not unique to MU Health Care; it is experienced in varying degrees across the hospital industry.

We have integrated many types of medical devices with our EHR. The intent is to use information technology (IT) to enable data from the device to flow into the EHR without the need for a clinician to manually record data from the device. The benefits include faster availability of EHR data, reduced opportunity for data-entry errors, reduced clinician workloads, and the opportunity to process data through algorithms, which provide real-time intelligence to the bedside to support medical decisions.

Initial analysis of the problem indicated that the most rapid and efficient gains would result from prioritizing anesthesia and respiratory ventilators, vital sign devices, as well as physiological, cardiac output, fetal monitors, and dialysis machines. We integrated more than 770 of these devices with the EHR.

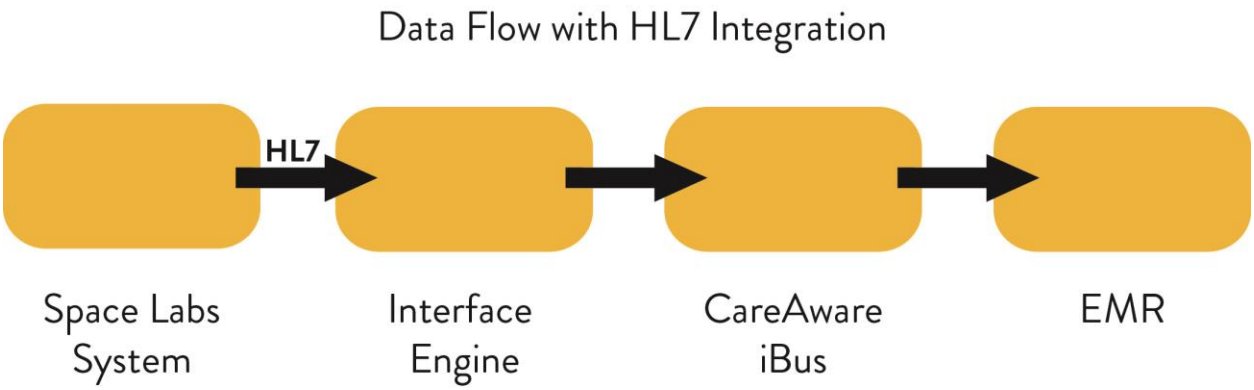
Design and Implementation

We implemented medical device integration with the EHR using three approaches:

- Deployment of traditional HL7 interfaces
- Deployment of new data conversion technologies from our EHR partner
- Deployment of devices designed specifically to flow data to the EHR

In the first approach, traditional HL7 interfaces were deployed where the device vendor had already provided its own system of servers for processing data. This approach permitted the vendor's system to efficiently process the data, and then flow selected data to the EHR. (Figure 1)

Figure 1: HL7 Integration



In the second approach, we worked extensively with our EHR partner, Cerner Corporation, to use new data conversion technologies they developed. The technology known as CareAware employs specialized adapters and servers to process and flow the data from a variety of medical devices. Drivers obtained from each medical device vendor facilitate the connections. This was the most commonly used approach, driving the integration of more types of devices than any other. (Figure 2)

Figure 2: CareAware Integration

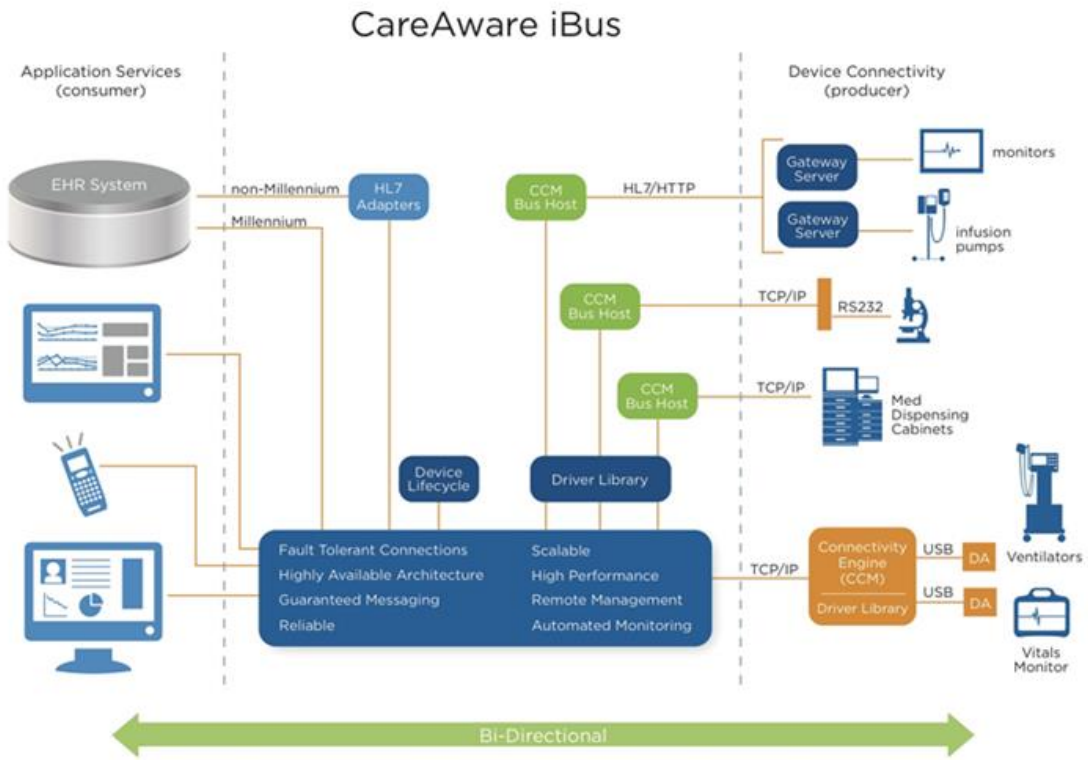
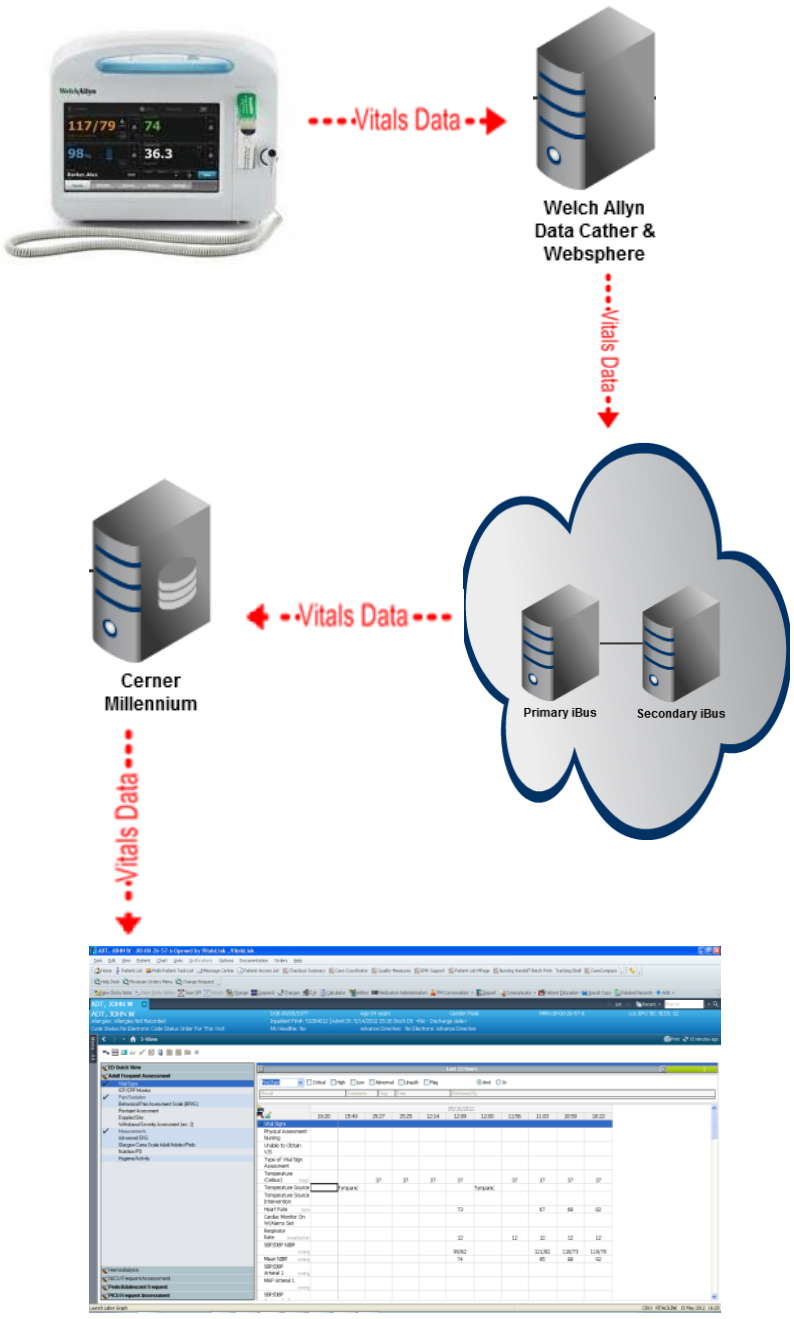


Figure 3: Direct Integration



In the third approach, we deployed medical devices that already contained the technology required to flow data directly to the EHR, without the need for additional adapters or data conversions. We focused this effort on the deployment of vitals sign machines that connected wirelessly to the hospital's network, and then sent the data to the record through application servers in the EHR partner's data center. (Figure 3)

In every approach, each type of device was integrated separately to allow flexibility around the types of data to be tracked. We worked closely with clinicians to determine what parameters could be derived from each device, and what data needed to be moved to the EHR. Then we worked with our EHR partner to prepare the EHR to accept and chart the data.

Factors critical to the success of the project included:

- Acquisition of manufacturer-developed drivers to facilitate data flow
- Implementation of the EHR partner's device and server technology
- Selection of devices that produce high volumes of data
- Partnership with clinicians and device operators to test parameters and determine what data should go to the EHR

- Partnership with infrastructure teams to ensure both hard-wired and wireless connectivity for devices
- Training of local HIT personnel to apply technology and drivers
- Partnership between device experts and application experts to ensure the accommodation of appropriate parameters

How Health IT Was Utilized

Our large scale integrations of medical devices began with physiological monitoring in 2006 with our HIT and Clinical Engineering teams collaborating to use HL7 as the data path.

In 2011, Clinical Engineering was combined with IT to accelerate integration efforts. Then, in 2012, we formed a combined team, known as Device Integration, to bring together critical skill sets from both IT and Clinical Engineering into a focused group.

With this change to our organization, we initiated the effort to use the EHR partner's technology. During 2012 and into early 2013, the team integrated devices outside of physiological monitoring into the EHR.

In 2013, the integration effort played a key role in the go-live of our 300,000 square foot Patient Care Tower. We equipped each of the 87 patient rooms in the tower with all of the technology refined during the integration process. We adopted the term "Smart Rooms" to distinguish the high-technology rooms from the standard inpatient rooms.

Users for the integrated medical devices include staff members from the Nursing, Maternal Fetal Medicine, Anesthesiology, Respiratory Therapy, Dialysis, and Cardiology departments.

Support from our leaders was critical to the success of the integration effort. MU Health Care leaders committed firmly to the effort, and hospital executives, physicians, and nurses assumed roles as champions for change.

These leaders recognized the value of incorporating the technology into the design of new patient rooms. They supported forward-looking designs, which incorporated all technology into the space, rather than having it added as an afterthought. As a result, high-technology patient rooms provide a safer and more comfortable environment for patients, visitors, and staff. Technology became an integral part of the environment.

In the design of the integrations and in the planning for their incorporation into the facilities, clinical staff routinely provided input to our technical staff. The interaction between the teams resulted in:

- Joint decisions on requirements and priorities for integration
- Agreement on connectivity requirements
- Agreement on configuration of devices and placement of additional technologies
- Mock-ups of patient rooms that permitted clinicians to make decisions on where devices would be used in the space
- Agreement on criteria for measuring successful outcomes

Value Derived

We derived positive outcomes in all three of our stated problem areas through integration of medical devices with the EHR. We evaluated outcomes through time studies, observation, and published research. Outcomes by device type are outlined in Figure 4.

Figure 4: Outcomes Table

Device	Quantity	Used Annually	Lag Eliminated	Time Savings Per Use (min)	Annual Time Savings (hrs)
Physiological Monitors	384	7,680	2.6 hrs	40	5,120
Vital Sign Monitors	208	303,680	1.8 hrs	5	25,307
Anesthesia Vents	21	9,176	5 min	20	3,059
FetaLink	42	2,320	1 hr	60	2,320
Respiratory Vents	67	2,100	2 hrs	10	350
Cardiac Output	26	636	30 min	10	106
Dialysis	22	720	1 hr	20	240
Total	770	326,312	5 min-2.6 hrs	2.75 hrs	36,501

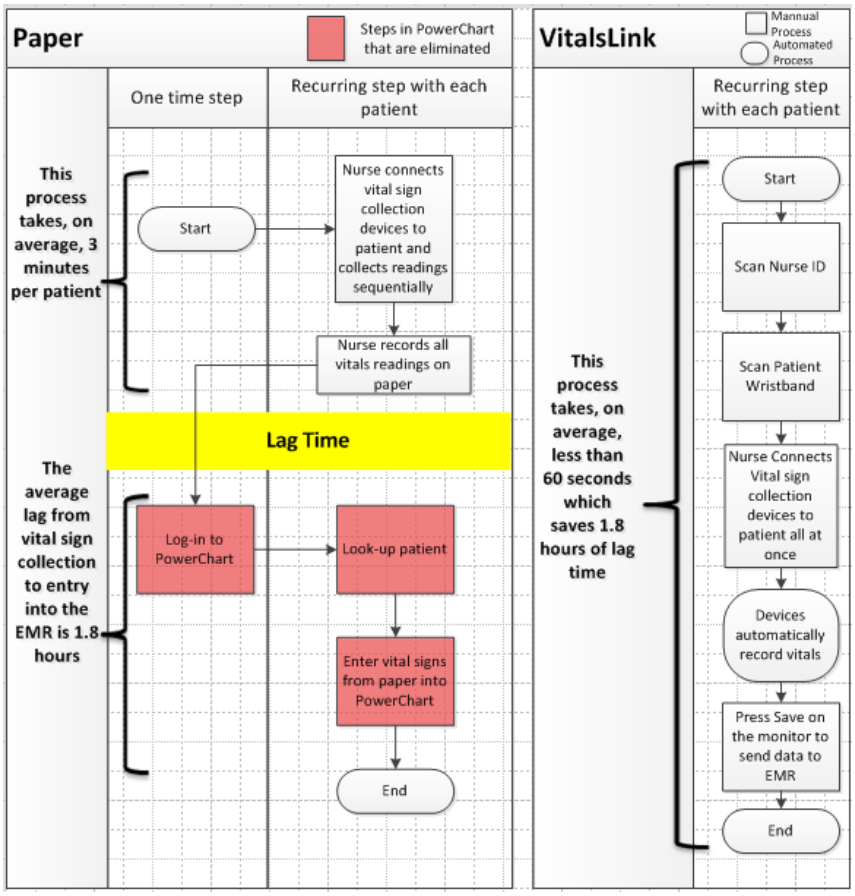
Addressing Problem 1: Delayed Entry of Data into the EHR

Local studies indicated wide variances in data entry times, with average lag time per use ranging from 5 minutes to 2.6 hours. Targeted studies on the entry of vital signs showed an average lag of 1.8 hours. The specific benefit of device integration was to remove the variance; in the same vital signs study, the time to flow data into the EHR was reduced to an average of less than 60 seconds. (Figure 5)

An additional benefit of improved entry times is the opportunity to apply algorithms that enable bedside intelligence for clinical decision-making. Sepsis algorithms alert based upon information that can now be automatically input from the device into the EHR, such as changes in body temperature,

heart rate and respiratory rate. Having this information in the EHR in a timely and accurate fashion enables algorithms that can transform patient care.

Figure 5: Lag Time Reduction

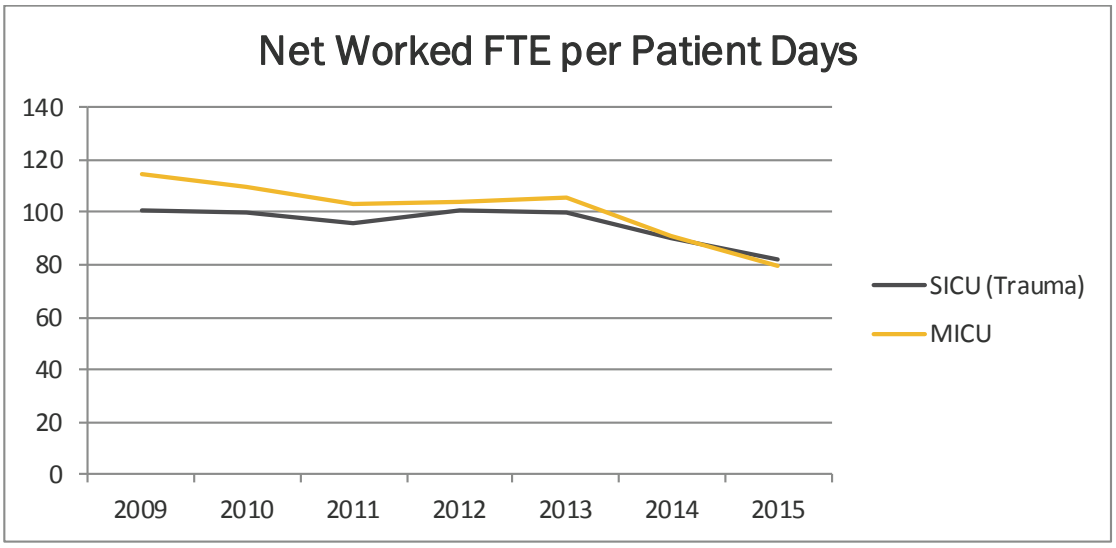


Addressing Problem 2: Increased Clinician Workload

In many workflows, we observed staff members using a two-step process where they recorded data on paper, and then entered it into the EHR at a computer workstation. This resulted in double work. The specific benefit of device integration was to eliminate the two manual steps, replacing them with one automated step that provided the data directly from the medical device to the EHR without human input. Time savings across the full scope of integrations ranged from 5 minutes to 60 minutes per device use, for a total savings of 36,051 hours per year. (Figure 4)

Staffing numbers also show productivity gains in areas where integrated devices are concentrated. Our Medical Intensive Care Unit (MICU) and Trauma – Surgical Intensive Care Unit (SICU) routinely field device integrations first and are representative of the highest concentrations of integrated devices. (Figure 6)

Figure 6



Key operational changes, in addition to the device integration, that contributed to the efficiency were combination of units, growth in unit sizes, and organizational changes in our nursing leadership teams.

Addressing Problem 3: Increased Opportunities to Ensure Accuracy of Data Entry

A study published in the Journal of Healthcare Information Management indicates that error rates as high as 13.5 percent can be expected with manual data entry.[1] Another study published in the same journal shows that the error rate can be improved to a conservative low of 5 percent by automating data entry.[2] To meet the challenge of ensuring accuracy, MU Health Care pioneered an error reporting system, the MU Patient Safety Network (PSN). The PSN system encourages voluntary reporting of incidents and errors, provides the reporter an opportunity to recommend changes, and then tracks the report through to resolution. Resolution of reports may be achieved by activities such as peer-protected case reviews, referral to functional areas for further investigation and follow-up, or implementation of an initiative under MU Health Care's formal Quality Improvement Program.

The PSN system pointed out that our most significant error reduction opportunity was actually related not to direct entry of data, but in ensuring that data was charted against the correct patient. This realization led a focus on positive patient identification when using medical devices.

Barcode scanning was initially adopted for medication administration in 2010. That effort was increasingly successful and resulted in a 17 percent reduction of medication errors as clinician adoption increased from 78 percent to 97 percent (Figure 7). Moreover, the organization has projected a cost savings of over $1.2 Million dollars as a result of the change, based on published research [3] (Figure 8).

Figure 7: Reported Medication Errors

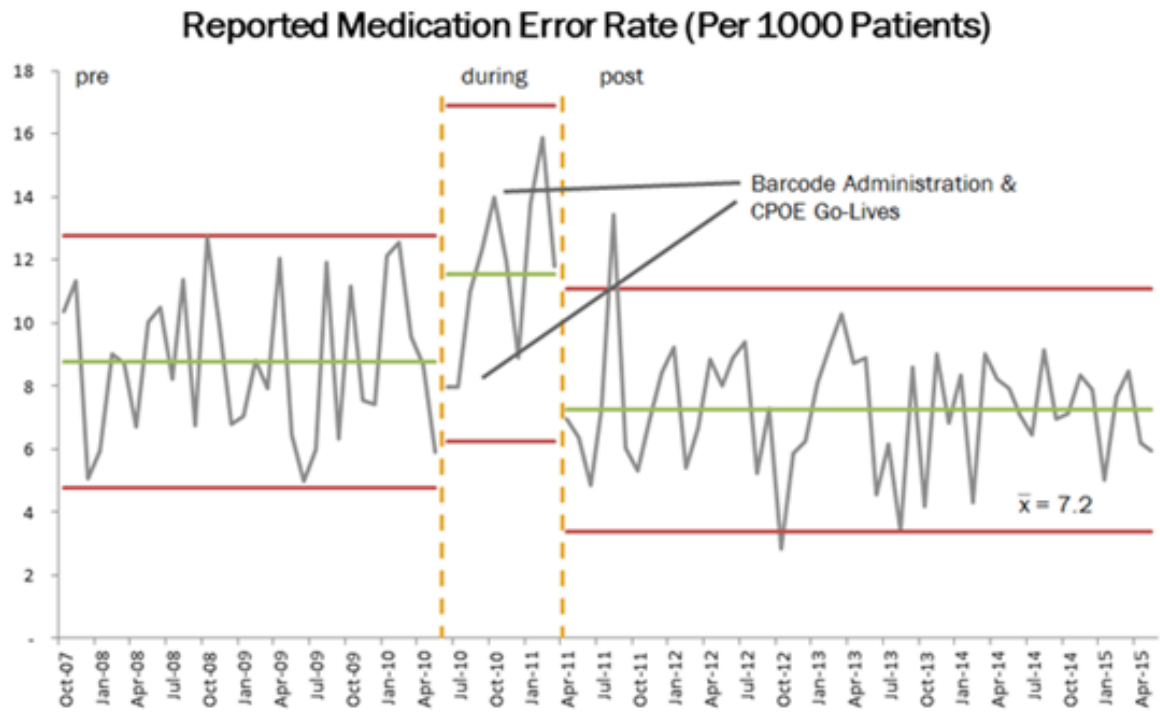


Figure 8: Medication Administration Savings

	Fiscal Year						
	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	Grand
Medication Administration Savings	-	(482,219)	233,184	460,432	563,844	462,034	**1,237,276**

The success of barcode scanning pointed directly to opportunities to eliminate errors in associating patients to medical devices. Our physiological monitors posed a unique challenge, requiring a combination of admissions information, manual entry in the EHR, and manual entry at the monitor to ensure that the data from the device was associated to the correct patient.

Prior to upgrading to our current physiological monitors network interface, clinicians were forced to perform multiple steps, in multiple programs, and on multiple devices. These steps were required to properly associate and admit a patient to a monitor and to allow for discrete data to populate into a patient's chart. Specifically, this process required the clinician to open patient's chart, open the associated device application, and select the correct monitor. Additionally, the clinician would have to walk around the patient bed to the other side of the room--where the physiological monitor was mounted--and manually enter the patient financial number (FIN) into a specific data field. This step

was required to properly pull the patient's information into the monitor. Obviously, this multi-step process was prone to errors. Frequently, patients were admitted to multiple monitors or the patient information (ADT) would not properly transmit from our registration system into the physiological database. When the ADT did not update properly, clinicians were forced to perform troubleshooting steps that would shift their focus from patient care. These issues were triaged by IT/ Helpdesk staff multiple times per day until the implementation of the current network interface.

A change of support model in 2010 started driving clinicians to call the IT helpdesk when they encountered issues with associating the patients to devices. That reporting channel, along with active compliance tracking and PSN reports, clearly showed issues in 2010, followed by a drop in adoption in 2011. The reporting and compliance efforts permitted MU Health Care to renew its focus in 2012.

Over time, technology permitted further enhancements to the patient-to-device association process and introduced barcode scanning for physiological monitors in 2014. The new workflow reduced complexity of the process from 17 steps [many of which described above] to 7 (Figure 9), and has reduced the association errors by 57 percent (Figure 10).

Figure 9: Physiological Monitor Association Workflow Comparison

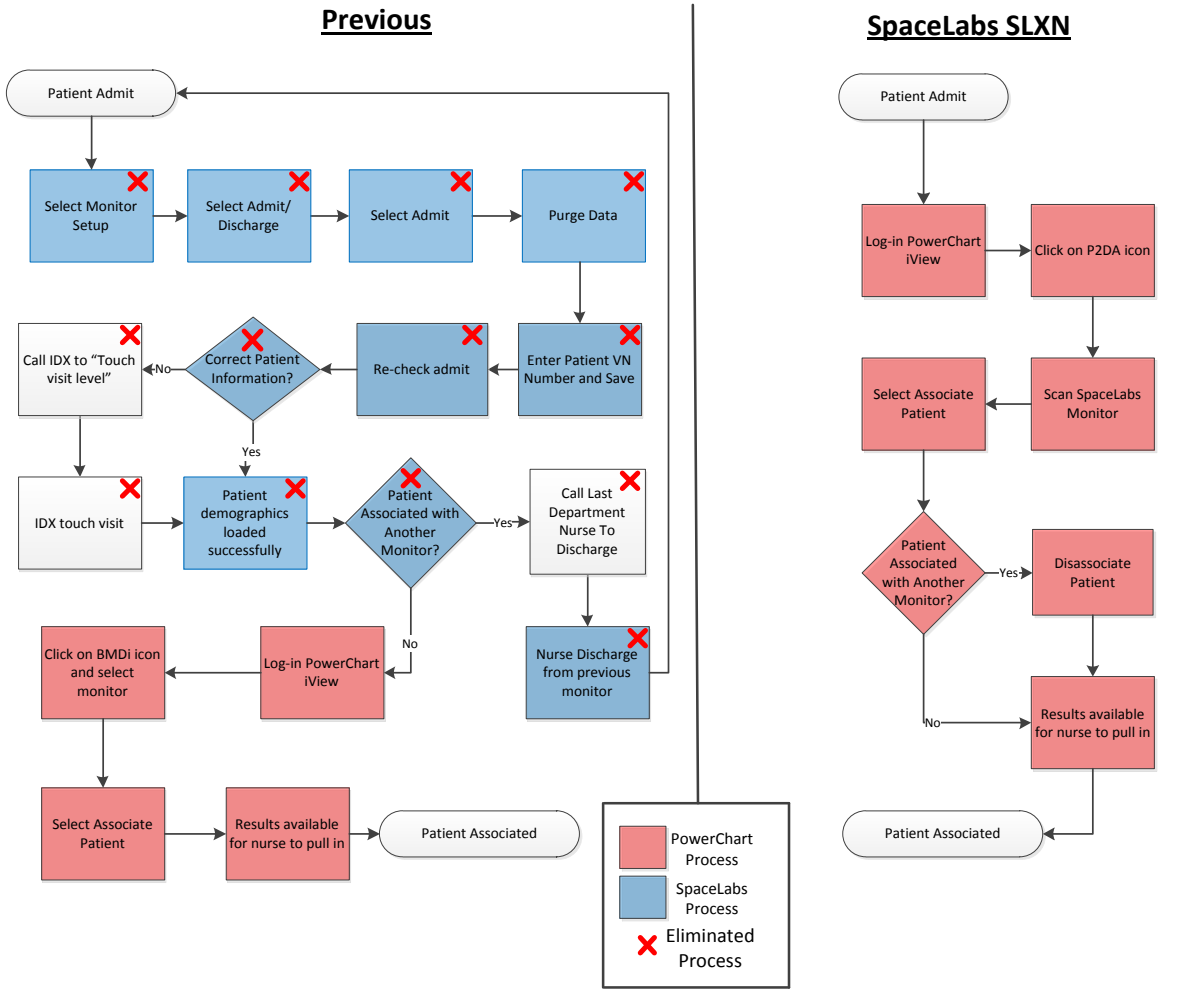
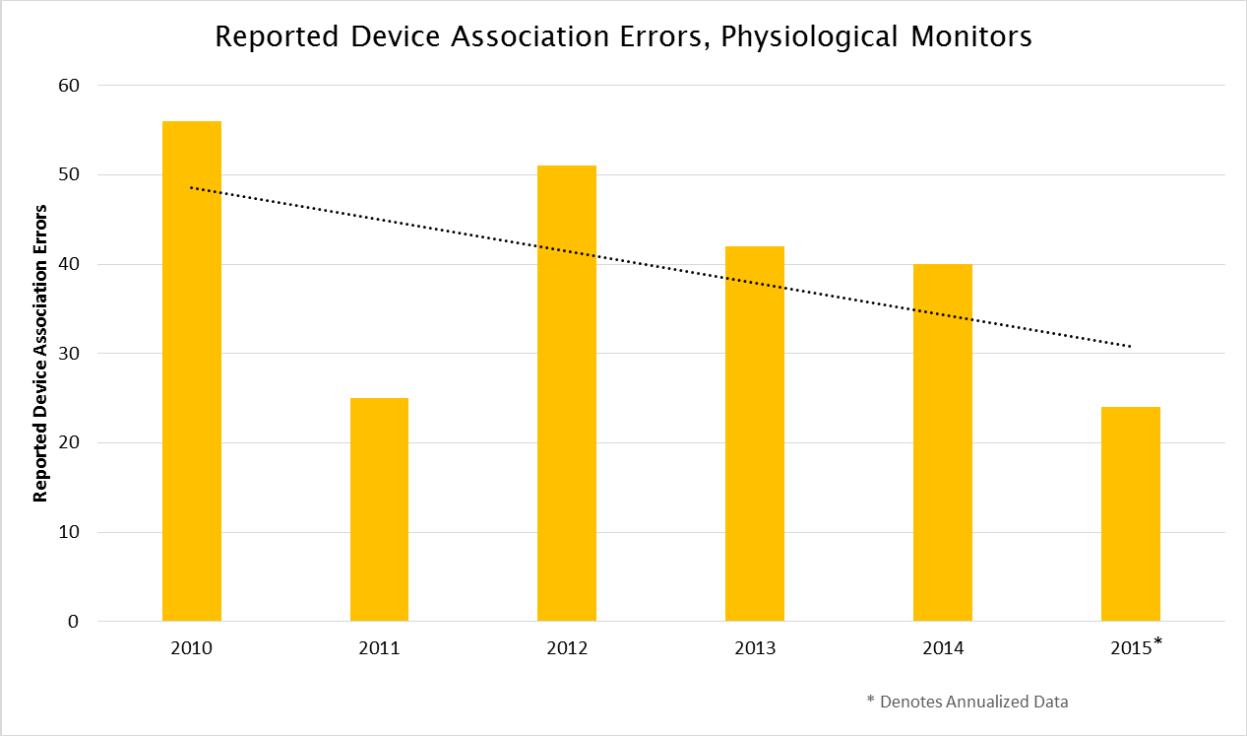


Figure 10: Reported Device Association Errors

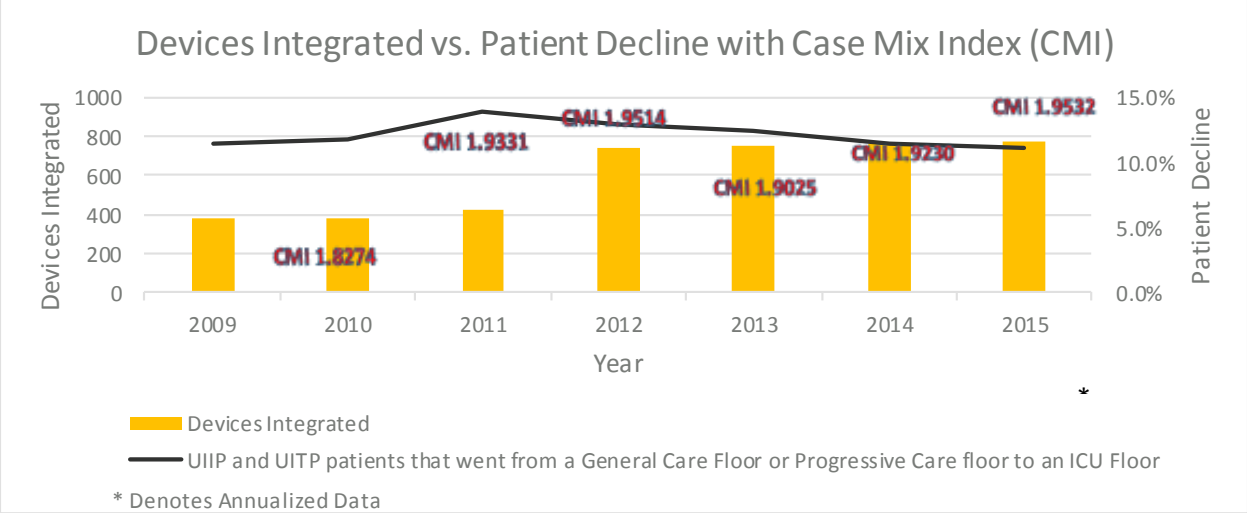


Impact on Patient Care

As the number of integrated devices grew, MU Health Care realized new benefits to patient care.

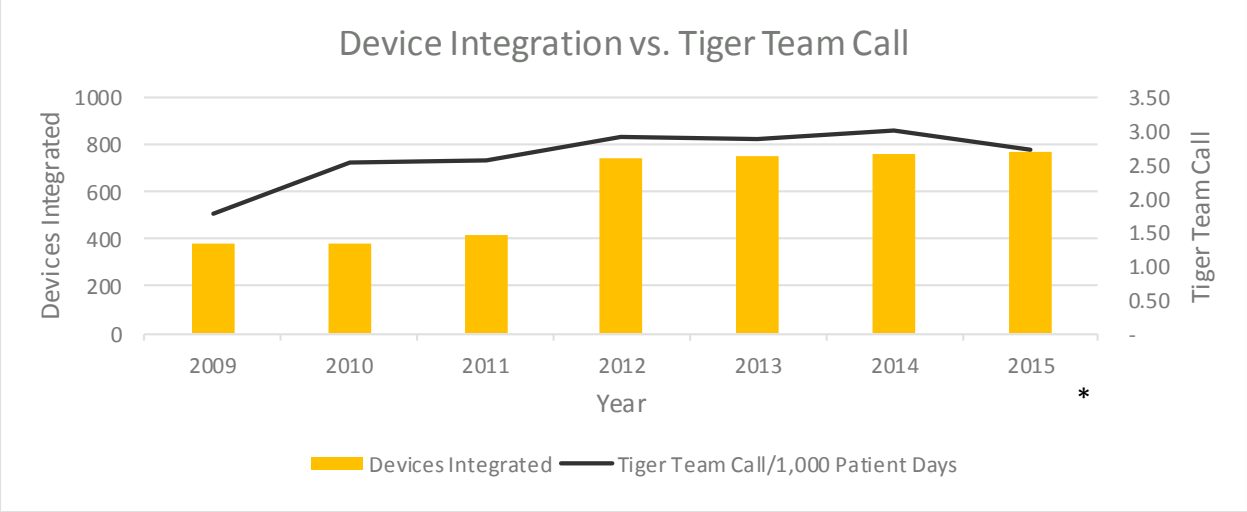
The availability of data in the EHR has changed the way clinicians interact. Physicians no longer need to call a nursing unit to ask about a patient's vital signs; they are in the chart and can be accessed from offices and residences at all hours. The new communication flow focuses on what is being learned from the data provided. The availability of this information has led to more rapid decision making, which in turn has led to a reduction in the number of cases where a patient moves from general to intensive care as a result of clinical decline. The most interesting thing is that this trend is moving positively against an increasing complexity of case mix, as indicated by tracking of the Case Mix Index from 2010 to present (Figure 11).

Figure 11: Patient Decline Trend vs Case Mix Index with Device Integration Growth



The available data has also had a positive impact on MU Health Care's system of rapid response, or Tiger Teams, that are called specifically to counter patient decline. Integrated devices do not necessarily call out decline, though that is a desired state in the future; rather, the rapid availability of data validates other proven methods of detecting decline and results in a more effective deployment of the teams (Figure 12).

Figure 12: Tiger Team Calls vs Device Integration Growth



Finally, the availability of data and the ease of data flow into the EHR has permitted a new level of time saved in patient care. That time saved results in an increased focus on the patient and care, versus the need to spend time documenting. As indicated previously in Figure 4, the integration of

medical devices with the EHR has resulted in over 36,500 hours saved annually. The resulting 17.5 FTEs have been easily absorbed into the growing patient census and case mix, while permitting providers and caregivers more time to interact with patients.

Lessons Learned

Over time, the device integration effort at MU Health Care has evolved into a very structured 26-step process (Appendix A). That evolution was driven by the numerous challenges and lessons learned during the initial integrations of medical devices with the EHR.

The first challenge and most critical lesson learned was the sheer volume of data available from medical devices. Clinical and technical staffs worked together to catalogue the parameters available, in a process that could take more than 2 hours for each device. Technical staff learned a tremendous amount from the clinical staff, and all learned that the integration was going to tell us far more than we originally thought.

The technical staff also learned the critical importance of involving clinical staff early in the integration process. Through the many hours of connecting, testing, cataloguing, and validation of the integrated data, clinical and technical resources worked together to "get it right". The highly successful anesthesia integration was undeniably the most successful roll-out ever provided from HIT to that clinical staff. Among other integrations the partnership with Respiratory Therapy proved to be the most productive, as that team spent many hours in the cataloguing and validation processes.

Partnership with the EHR provider was a key to the success of the integration. The EHR partner had existing relationships with many medical device manufacturers, which simplified obtaining device drivers. Where that relationship did not exist, the local IT team learned from the process and was able to approach manufacturers confidently to ask for the drivers needed to integrate additional devices.

Partnership across local IT teams provided further opportunities for success. When the anesthesia devices clearly produced more data than the EHR was prepared to receive, technology and application analysts worked together to build out the data fields needed to record and report the additional parameters. The result was a positive increase in the amount of data available to clinicians.

The success of initial integrations drove changes to the way we approached facility design, especially at the headwall. We added USB ports to headwalls during construction, providing a micro-infrastructure that permits clinical staff to simply connect device adapters as if they were plugging in an electrical cord or a network cable. When combined with the connectivity engine's plug-and-play functionality, this became a powerful way to simplify workflows.

We realized the great value of forming one team that combined IT skill sets with clinical engineering skill sets to eliminate silos and advance the device integration projects. The team remained in place after the integrations to provide sustaining support and continues to do so today. We formed this team from existing staff without an increase in total headcount and now with gained efficiencies the team manages twice the number of devices.

Facilities did, however, present their own challenges. Older facilities lacked the hard-wired network connections to accommodate some of the newly integrated devices. The team worked through configuration of wireless capabilities to overcome this challenge.

A significant challenge during the planning for the vitals sign machine integration was the concern of hospital staff over infection control and cleaning requirements for the equipment. As a team, clinical and technical staffs developed a “device-per-room” plan, which eliminated concerns about cross-contamination.

Finally, the technical team learned the power of having data immediately available in the EHR. As our clinical staff worked with charts, they were able to determine immediately whether data was flowing. When the data flow stopped, they were quick to engage technical resources for a fix. Technical resources responded enthusiastically and worked every issue to resolution in real-time. Moreover, the feedback guided process and quality improvement efforts, which reduced the need for break/fix resolution.

Financial Considerations

As a result of device integrations, we save 36,501 hours annually in time spent on documentation, for a financial savings of $1,300,166. The annual operating expense associated with the integrations totals $546,456. (Figure 13) As a result, we realize a net annual savings of $799,803, based on an internal nursing labor rate of $35.62 per hour.

Figure 13: Medical Device Integration Costs

Category	One Time	Recurring
Hardware	1,453,473	0
SpaceLabs Software	250,000	0
EMR Partner Software & Services[1]	762,940	546,456
Totals	**2,466,413**	**546, 456**

[1] Market value for products and services

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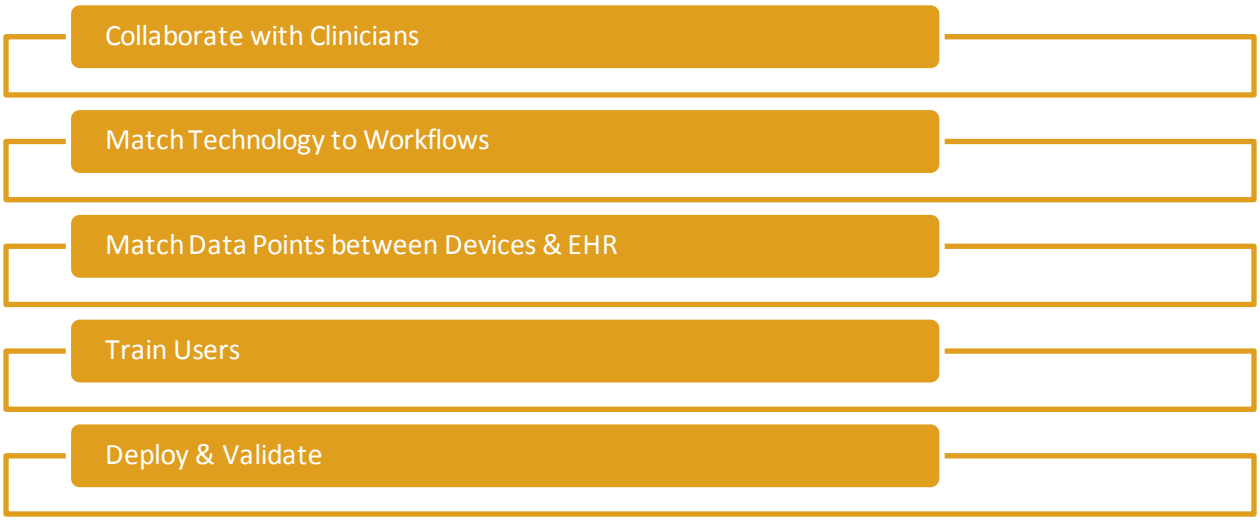
Appendix A: MU Health Care 26-Step Device Integration Process

Recommended Focus Areas



MU Health Care Medical Device Connectivity Work Plan

1. Inventory integration capable equipment(CE / IT):
    a. Acquire equipment count by unique manufacturer / model combination from clinical engineering.
    b. Identify which devices currently have drivers available from your middleware vendor.
2. Work with clinicians to prioritize the integration priority based upon equipment counts, workflow impact, and integration capability. (CE / IT / Clinicians)
    a. Integration capability can be a combination of any of the following:
        i. Device data export limitation (device / software)
        ii. Middleware driver creation (software)
3. Perform workflow assessment for the equipment intended to be integrated. Workflow will vary based upon the specific project, but can include: (IT / Clinicians)
    a. What parameters are being manually charted in the EMR?
    b. What application(s) are the parameters being charted in currently?
    c. How long this manually charting takes?
    d. Lag time between time of vitals taken and being entered into the chart?
    e. Any other potential workflow impacts/improvements
4. Perform technical call with identified resources: (CE / IT / Vendors / Networking / Security)
    a. Including, but not limited to: IT, Clinical Engineering, Middleware vendor, Device manufacturer, Networking, and IT Security
    b. Purpose of this meeting is to determine the architecture and infrastructure requirements for the proposed integration

5. Survey the proposed care area that the equipment resides in order to determine any infrastructure requirement gaps. Infrastructure is dependent upon the actual project, but can include: (CE / IT / Clinicians)
    a. Power
    b. Data
    c. Wireless Network Coverage
    d. USB cabling
    e. Middleware Connectivity Devices
6. Create project charter document to include the following information as a minimum: (CE / IT / Vendors / Networking / Security / Clinicians / Education)
    a. Stakeholders
    b. Scope
    c. Deliverables
    d. Milestones / Timelines
    e. Project Resources
7. Schedule and hold meeting with the resources responsible for education surrounding the project to discuss training requirements, associated timelines, and cost for training.
8. Schedule and hold a kickoff call including all project resources to discuss the project charter, receive all necessary approvals, and determine an appropriate pilot unit(s).
9. Perform connectivity test for integration components in the proposed patient care area.
    a. Remediate any network / connectivity related issues identified.
    b. In the event of a wireless device:
        i. Validate that the device will communicate in all expected areas.
        ii. Verify that wireless best practices for device are referenced if issues are identified.
10. Acquire testing device from the hospital and perform data flow testing from the device to your test integration middleware.
    a. Perform an inventory of the parameters flowing from the device.
        i. Be sure to validate every mode and setting on the device to make sure all parameters are captured.
11. Meet with the clinicians to review parameter inventory previously acquired. The purpose of this meeting is to:
    a. Determine device parameter mapping into the EMR.
    b. Determine if the EMR is configured to accommodate the new parameters. If not, make a listing of required changes for the EMR related project resources.
12. Perform requested mappings and changes to the Test system.
13. Create work plan for tasks that will be completed in the Production environment based upon work completed in the test system to include a very thorough back out plan.
14. Validate integration performance in the test system.
15. Schedule and hold a subsequent meeting with clinicians to validate the integration is performing as expected in the test system.
    a. Document any discrepancies, resolve, and repeat step 14.
    b. Document clinician approval.

16. Begin training end users of the integration accordingly in order to meet the proposed go-live date.
    a. This schedule must factor in the type of training, number of recipients, and number of locations.
17. Complete the appropriate change management as determined by local policies and procedures.
18. Notify stakeholders and impacted users if the changes required by the integration require any potential downtime that would impact their workflow.
19. Perform requested mappings and changes to the Production system.
20. Validate integration performance in the production system.
21. Schedule and hold a subsequent meeting with clinicians to validate the integration is performing as expected in the production system.
    a. Document any discrepancies, resolve, and repeat step 17.
    b. Document clinician approval.
22. Identify pilot support model, to include clinician support process and expectations.
23. Begin pilot in the unit(s) identified during the kick-off.
    a. Document any discrepancies found during the pilot, resolve, and discuss during project meetings to determine any cascading issues.
24. Once all identified pilot issues have been addressed satisfactorily, begin the organization roll out.
    a. This method will vary dependent on the solution and the infrastructure.
25. Thirty days after the completion of the roll-out hold an after-action review meeting.
    a. Discuss what went well and what you can improve upon next time.
26. It is highly recommended at this point to create a committee tasked with:
    a. Helping to vet upcoming integrations
    b. Helping to scope upcoming integrations
    c. Providing functionality and workflow related feedback from the clinicians regarding previously implemented integrations
    d. Facilitate / Schedule upgrade of the technology stacks required for integrations
    e. To centrally manage configurations for medical devices from an organization level