Quantifying the Business Value of Medical Device Connectivity

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More timely, inexpensive, accurate data capture enhances a hospital's competitive advantage, but networking medical devices takes real expertise.

The Elevator Story

Each Connected Medical Device (CMD) saves from *4 to 36 minutes* of nursing time and prevents *up to 24 data errors* daily. CMDs can save *over 100 hours of nursing time* per day in a typical hospital, giving nurses more time with patients and improving the quality of care. They can also stop *over 800 data collection errors* each day, leading to greater efficiency and improved patient safety. Hospitals must connect their devices to an Electronic Medical Record (EMR) to meet new regulatory requirements. CMDs will play an increasing role outside the hospital in the management of chronic conditions and prevention of hospital readmissions.

Medical device manufacturers must help *translate device data* into a format that can be read and understood by EMRs, and support industry standard *wireless networking security protocols*, *dual band wireless communications*, and *multiple interfaces* to help hospital customers realize the potential benefits of device connectivity.

Changing Competitive Dynamics for Hospitals

The economic crisis of 2008, the HITECH act of 2009 and the healthcare reform bill of 2010 have effected the greatest change in hospital competitive dynamics in generations.

The successful hospital of the past delivered safe and effective care during acute and emergency care episodes, within a relatively small geographic area. Professional reputation, accreditation and the avoidance of publicized adverse events were the surrogates for quality. *The successful hospital of the future* will keep patients healthy throughout their lives, wherever they go. Quality will be judged by a host of quantitative, publicly reported metrics.

The successful hospital of the past drove patients to the hospital through contracting, network-building and advertising. *The successful hospital of the future* will help patients avoid acute episodes of care through reliable, high-quality preventive, chronic, post-acute and long-term care.

The successful hospital of the past attracted patients with favorable demographic and payment characteristics, which overcame many operational inefficiencies. *The successful hospital of the future* will operate in a highly efficient manner to survive with a higher percentage of government reimbursement, at lower rates.

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Data Requirements and Regulations Promote Device Connectivity
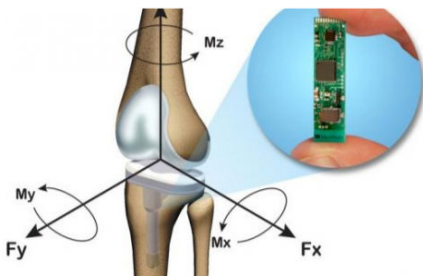
The "e-Knee" wirelessly reports digital, three-dimensional torque and force data.

In order to deliver high-quality care and meet upcoming regulatory mandates, hospitals must collect increasingly detailed clinical data from inpatients, while reducing staff costs. In the near future, hospitals must also take responsibility for the data required to achieve measurably superior outcomes beyond their walls. Obtaining the additional data required to manage and coordinate care inside and outside the hospital, without spending a fortune on staff, requires the ability to automatically retrieve information from medical devices.

Medical devices come in many different forms and levels of complexity, from tongue depressors to artificial hearts. The number of medical devices that produce electronic data is growing as sensors are added to devices that were formerly only mechanical in nature, such as the e-Knee prosthesis shown on the left.

While device connections can be used to remotely monitor, control and configure devices, it is their patient monitoring function that adds the greatest value. Device data include vital signs and other patient physiology data; drug administration data including dose, timing, rate, etc.; ventilator therapy data; and many other key pieces of information that help clinicians provide optimal care to patients.

When these devices are automatically connected to an EMR the completeness, timeliness and accuracy of the data that become available are much greater than what could be manually charted by nurses, and the potential quality and safety of care improves, while the time and cost required to collect and chart the data is greatly reduced.

In addition to the clinical and operational benefits of connected medical devices, new legislation, including the fiscal stimulus bill (ARRA/HITECH) and the healthcare reform bill (PPACA) promotes device connectivity. Stage One meaningful use requirements include the availability of electronic vital signs data, which can most easily be obtained through connected devices; Stage Three requirements are expected to explicitly include medical device interoperability[1].

Best practice in preventing hospital readmissions, to avoid the healthcare reform bill's upcoming financial penalties, includes the use of connected devices in post-acute facilities and patients' homes[2]. Also, growing numbers of new accountable care organizations (ACOs) will make use of remote device data to keep patients healthy and avoid expensive hospital care.

1 Medical Devices Landscape: Current and Future Adoption, Integration with EMRs, and Connectivity, HIMSS Analytics, 2010.

2 Klersy C, et.al., Economic Impact of Remote Patient Monitoring: An Integrated Economic Impact Model Derived from a Meta-Analysis of Randomized Controlled Trials in Heart Failure, Eur J Heart Fail (2010) doi: 10.1093/eurihf/hfq232

Medical Device Market Summary

Today most electronic medical devices are found in hospitals. The average hospital today uses almost 800 of the common devices, shown in Figure 1, below, with IV pumps, physiologic monitors and vital signs monitors making up 85 percent of that total. Hospitals also use dozens of other less common devices.

Figure 1, Number of Electronic Medical Devices in Hospitals[1]
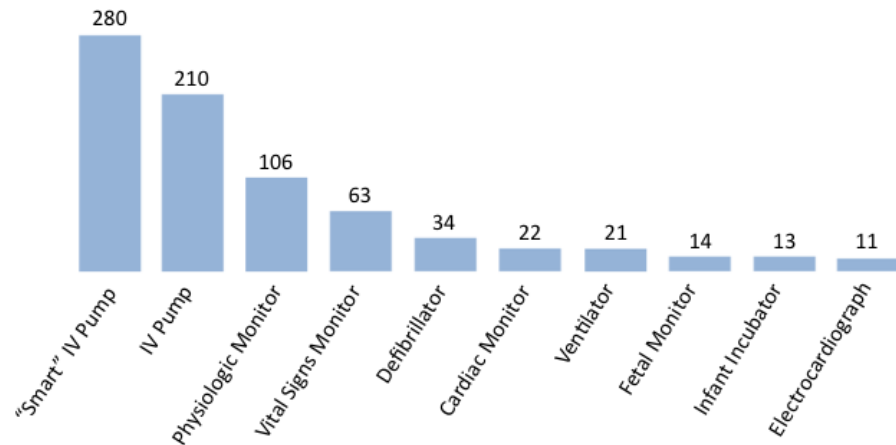
Very few of these devices are currently connected to a hospital network. As indicated in Figure 2, below, the number of connected medical devices in hospitals could easily grow by a factor of ten.

Figure 2, Percent of Hospital Devices Connected to an EMR[1]
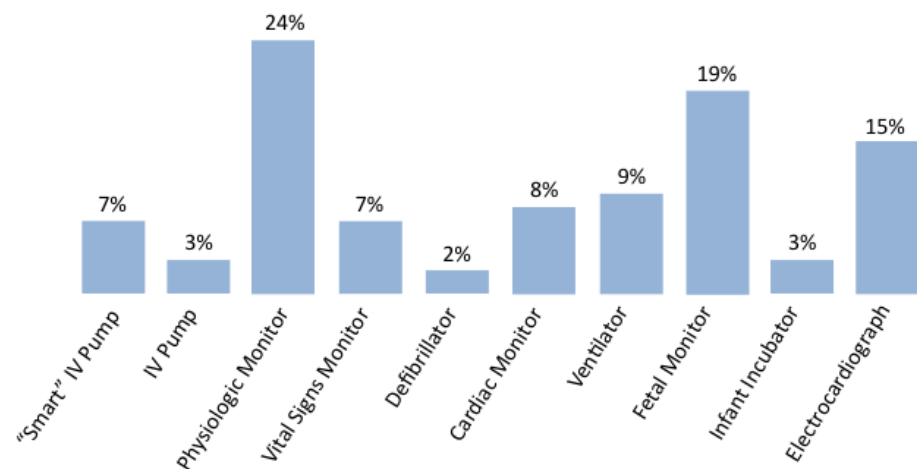
Reliable statistics are not available for the use of electronic medical devices outside hospitals, but their number is expected to grow even more dramatically. The need for more accurate, timely and efficiently collected data will increase use of CMDs in nursing homes, physician offices and other healthcare facilities. However, the greatest growth is expected to be in patients' homes and other locations outside of formal care environments, because potential

improvements in data collection efficiency, cost and timeliness are greater outside of healthcare facilities, as illustrated in Figure 3, below.

Figure 3, Minutes to Obtain Vital Signs Data[3]
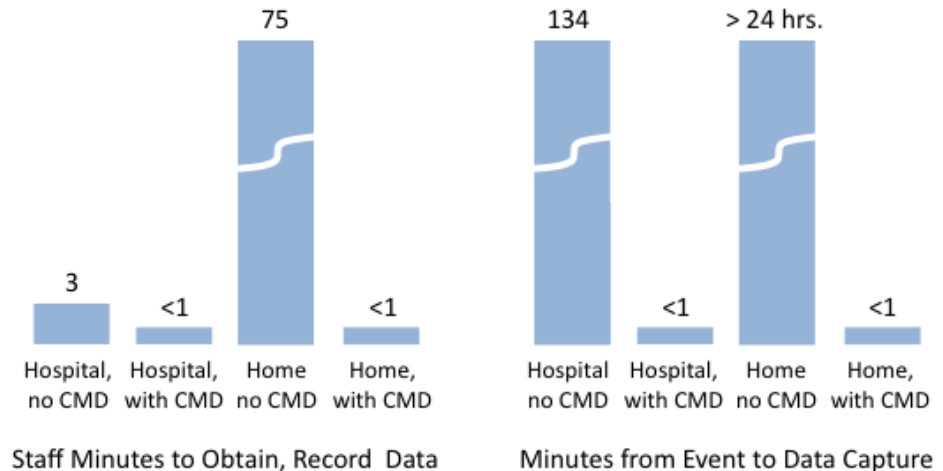
Note: Includes travel time

The Benefits of Hospital Device Connectivity

The benefits of connecting hospital devices that have historically been independent "islands" of functionality and data include:

- Improved data collection efficiency – Instead of nurses or other staff traveling from room to room or device to device, manually transcribing clinical information, device performance data, etc., this information can be remotely gathered, stored and displayed, saving staff time.
- Improved data collection quality – Transcription errors are eliminated with automated transmission and collection of remote device data.
- Improved data entry efficiency – In addition to time saved transcribing data from devices to paper, clinical staff also save time entering those data into an EMR or other data repository.
- Improved clinical decision support value – Continuously available, accurate, complete vital signs and other device data support more sophisticated and meaningful decision support applications (e.g., clinical protocols, infection surveillance).
- Improved analytical value – Data from networked devices can help a hospital better understand its patients, and the cost-effectiveness of current and proposed therapies.
- Increased nursing staff satisfaction – CMDs dramatically reduce charting time and free nurses to focus on patient care, greatly improving nurses' job satisfaction.

4 Hendrich A, Chow M, Skierczynski B, Lu Z, A 36-Hospital Time and Motion Study: How Do Medical-Surgical Nurses Spend Their Time? The Permanente Journal/ Summer 2008/ Volume 12 No. 3

5 Source: Black Box nursing and device manufacturer interviews.

Improved Data Collection Efficiency

Research shows[4] that nurses spend approximately 2½ hours per shift on documentation activities, reducing the amount of time they spend on direct patient care and increasing job stress. CMDs can automate a significant amount of nursing documentation.

Figure 4, below, shows the estimated amount of time that could be saved by nurses in a typical hospital by automating charting from eight common medical devices, after subtracting the time spent reviewing the electronically collected data.

Figure 4, Potential Device Charting Nursing Time Savings[5]

	Net* Seconds Saved Each Time Charting	Daily # of Times Charted**	Total # Devices/ Hospital	Nursing Hours/Day Saved
Smart IV Pump	60	11	280	51
IV Pump	30-45	11	210	19-28
Physiologic Monitor	45-90	24	106	32-64
Vital Signs Monitor	30-60	9	63	5-9
Cardiac Monitor	60	13.5	24	5
Ventilator	30-60	8	21	1-3
Fetal Monitor	15	24	14	1
Infant Incubator	30	12	13	1
Total			774	115-162

* including data review ** average across ICU & M/S units

6 For example, CareTrends (Sensitron): El Camino Hospital, CA: Medical Surgical Benefits Study; 2006; and iSirona Case Study: Weiss Regional Health System, TX, 2009.

7 Stanton, MW, Hospital Nurse Staffing and Quality of Care, AHRQ Research in Action, Issue 14, 2010, accessed on March 8, 2011 at http://www.ahrq.gov/research/n ursestaffing/nursestaff.htm.

The annual value of the nursing time saved in a typical hospital is $1.8 – $2.5 million, but actual cost savings are much smaller. That's because even large time savings will not impact staffing levels and costs in ICUs due to mandated nurse staffing ratios. However, commercial studies[6] have shown a 1-1.5 hour time savings per nurse per shift on med/surg units from use of CMDs; on larger units that could be enough time to allow staffing adjustments. Even if CMDs cannot help reduce nurse staffing, they can help increase time devoted to patient care, which can improve patient outcomes[7].

Other studies summarized below have similar findings:

St. John's Medical Center in Jackson Hole, Wyoming, connected mobile and bedside vital signs monitors to their McKesson EMR. David Witton, St. John's Director of Information Systems says: "We

have seen a 60 percent time savings from importing rather than entering vital sign data, as well as...more thorough documentation."

Rice Memorial Hospital, a 122-bed hospital in Minnesota saved 25 minutes per ICU nurse, per shift in vital signs documentation time. Instead of entering up to 96 readings per patient per shift, vitals documentation now requires only on-screen approval before data are submitted to the EMR, saving more than five hours per day.

WellSpan Health in Pennsylvania implemented CMDs in their ICU, ED & PACU, saving an hour of Respiratory Therapist time and a half hour of nursing time per shift.

UAB Health System saved roughly 200 nursing staff minutes per shift in their high acuity ICUs and PACUs. It takes them 20 seconds to verify data vs. 4 minutes to enter data.

Improved Data Collection Quality

Figure 5, below, shows the number of errors CMDs can prevent every day in a typical hospital based on nurses documenting device data into an EMR; the number of errors prevented is about three times larger if the data are first recorded on paper and then transcribed into the EMR. Reduction in documentation errors prevents re-work, adverse events and unnecessary costs.

Figure 5, Daily Errors Prevented in Charting Device Data[8]
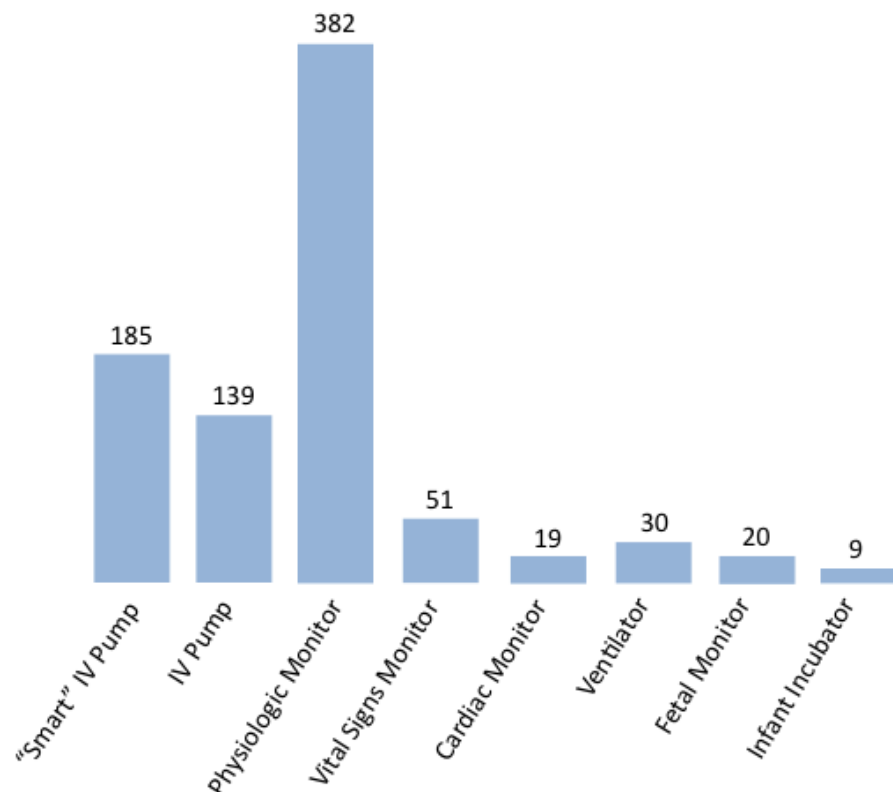
8 Black Box estimates based on Smith LB, Banner L, Lozano D, Olney CM, Friedman B. Connected care: reducing errors through automated vital signs data upload. Comput Inform Nurs. 2009 Sep-Oct;27(5):318-23. Estimates also based on expert nurse interviews and device data quoted above.

Device	Errors Prevented
"Smart" IV Pump	185
IV Pump	139
Physiologic Monitor	382
Vital Signs Monitor	51
Cardiac Monitor	19
Ventilator	30
Fetal Monitor	20
Infant Incubator	9

Note: Represents reduction to a 1% error rate

Improved Data Entry Efficiency

In addition to the time clinicians now spend charting device data on paper, CMD's can save the time required to enter those data into an EMR. It takes up to a minute longer for a nurse to open the EMR's documentation module, find the location to chart all data values, complete the charting, and close the EMR than it does to chart on paper. However, nurses typically chart multiple items in the same EMR documentation event, so the additional time spent electronic-ally documenting from any single device is not that great.

Improved Clinical Decision Support Value

Clinical decision support (CDS) capabilities are the #1 source of value from EMR systems[9]. Basic CDS includes such things as drug selection and dosing alerts, electronic order sets, and duplicate lab test alerts. Beyond these basics lies a world of value, much of which requires more detailed data, collected more frequently than most hospitals are able to afford.

Emerging, high-value CDS applications include clinical surveillance systems that can review large volumes of clinical data and highlight patient risks when they occur, to guide real-time changes in care. CMDs can dramatically reduce the cost of data collection for these systems, making them a practical alternative for more hospitals.

Another of the CDS capabilities made possible by CMDs is global alerts for each type of device. For example, networking older IV pumps without safety alerts could allow hospitals to create their own real-time alerts based on current data, which could be sent to nurses in time to avoid dangerous and costly errors – making "smart pumps" out of "dumb" pumps. Potential candidates for this type of CDS include IV pumps, ventilators and cardiac monitors.

Improved Analytical Value

Devices that connect to the network add analytical value. If all of a hospital's smart pumps are connected to the network, then pump data can be aggregated to show trends in unsafe pump programming, which nurses need to be trained, whether certain times of day see greater numbers of errors, etc.

Electronic medical devices are not reimbursed separately, but many of them are associated with procedures which do have separate charges. Accurate, complete, timely data on device use can be part of an audit to identify and capture missed procedure charges.

Increased Nursing Satisfaction

9 Thompson DI, Classen DC, Haug PJ, EMRs in the fourth stage: the future of electronic medical records based on the experience at Intermountain Health Care. J Healthc Inf Manag. 2007 Summer;21(3):49-60.

Nurses don't like transcribing data from medical devices – it's tedious, error-prone work, and it takes their attention away from patient care. Hospitals that have implemented CMDs have found that their nursing staff greatly prefers reviewing imported data to transcribing them directly. St. John's Medical Center's David Whitton says of their CMDs "This application is the only time I have seen a nurse hugging an information systems employee."

Out-of-Hospital Benefits of Device Connectivity

In this section of the report we use the term "remote patient monitoring" (RPM) for devices designed to operate outside a traditional healthcare setting and transmit data to clinical users at a distance.

As stated earlier, the operational benefits of device connectivity are greater outside of hospitals. That's because physician offices, post-acute and long term care facilities, and especially the patient's home are not only less "wired" than hospitals, but have fewer staff available to collect data manually. So, it's more challenging to manually collect device data outside the hospital without remote patient monitoring (RPM) devices.

The out-of hospital benefits of device connectivity are also greater from a clinical and strategic standpoint. *Health information exchanges* (HIEs), *Medical Homes*, *Accountable Care Organizations* (ACOs), and *hospital penalties for readmissions* are important future considerations that require or encourage RPM.

- HIEs allow participating providers to share patient information across organizational boundaries to improve the safety, coordination, efficiency and quality of care. More advanced HIE systems are able to accept data from RPM devices.
- Medical Homes are a method of providing comprehensive primary care to patients in which primary care providers work closely with patients and their families. RPM is an important part of the latest thinking about Medical Homes[10].
- ACOs are groups of providers that band together to take responsibility for all of the care provided to a group of patients -including hospital, preventive, chronic, post-acute, and long-term care. ACOs are one of the only ways for healthcare providers to actually increase revenues under new healthcare reform regulations, so most American hospitals are investigating or planning to become part of an ACO. ACOs will need the inexpensive, accurate remote data collection capabilities of RPM to efficiently manage their patients across the continuum of care.
- Under healthcare reform provisions hospitals will also be penalized if their patients are readmitted. Many of the most effective readmission prevention strategies involve the use of RPM devices to monitor patients' conditions and compliance with dietary requirements and medications.

Some experts estimate that RPM devices could cut U.S. healthcare costs by $200 billion over the next 25 years by improving chronic

10 Adam Darkins, Patricia Ryan, Rita Kobb, Linda Foster, Ellen Edmonson, Bonnie Wakefield, Anne E. Lancaster. Telemedicine and e-Health. December 2008, 14(10): 1118-1126.

11 See The Center for Technology and Aging's recently released report, "Technologies for Remote Patient Monitoring in Older Adults," available at www.techandaging.org.

care and preventing hospital readmissions[11]. This conclusion is supported by a recent literature review of heart failure management methods[12]. The review found that RPM use was associated with a significantly lower number of hospitalizations and a cost savings of between $500 and $1,500 per hospitalization. The authors concluded that "…RPM is a 'dominant' technology over existing standard care."

Another environmental factor driving RPM adoption is the national nursing shortage. If current trends continue the United States will lack 20 percent of the nurses it needs by 2015, as shown in Figure 6 below, three times larger than any shortage in the past 50 years.

Figure 6, Expected US Nursing Shortage, 2000 - 2020[13]

12 Klersy C, et.al., Economic impact of remote patient monitoring: an integrated economic model derived from a meta-analysis of randomized controlled trials in heart failure, Eur J Heart Fail (2010). doi: 10.1093/eurjhf/hfq232 First published online: December 29, 2010.

13 Based on: Toward a Method for Identifying Facilities and Communities with Shortages of Nurses, Summary Report, HRSA, Accessed on March 8, 2011 at http://bhpr.hrsa.gov/healthworkforce/nursingshortage/default.htm.

RPM devices will help mitigate the increasing need for nurses outside the hospital environment by automating data collection and reducing the number of home visits required.

As important as the clinical and operational benefits, and regulatory mandates are, the long-term driver of RPM device adoption is likely to be direct consumer demand. A recent study[14] found that 40% of American consumers would be willing to pay for a remote monitoring device, such as a scale, blood pressure cuff, glucose meter or heart-rate monitor. The study estimates the annual market for such devices is $7.7 to $43 billion.

14 Healthcare unwired: New business models delivering care anywhere, Price Waterhouse Coopers, 2010.

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Meeting the Challenges of Device Connectivity

In spite of the substantial benefits of CMDs there is a great deal of frustration among hospitals and medical device vendors over the technical and operational challenges of connecting their devices. The key challenges include *translation of device data* from numerous proprietary device formats into something that can be read and understood by EMRs and other information systems, supporting industry standard *wireless networking security protocols*, supporting *dual band wireless communications*, supporting *multiple interfaces* in addition to serial connections, and *minimizing the burden of testing* to ensure that devices are compatible. Device manufacturers must also balance their need for stable product designs that can last many years to earn back the high costs of device development, with the rapid evolution of technical capabilities and standards.

Data Translation

The primary reason for increased interest in CMDs in hospitals is the need to incorporate device data into EMRs to create a more complete and accurate picture of patients' conditions and enhance clinical decision support and analytics capabilities to improve care processes and patient outcomes. Most hospitals have dealt with this issue one device at a time, since each device vendor has their own proprietary data format. Given the increasing data volumes and the growing number of networkable devices, this is becoming more difficult. In a recent focus group[15] hospital administrators and IT staff commented on the difficulty in designing gateways and interface capabilities to EMRs.

Some device connectivity vendors are designing translation software into their modules, to take the burden off device manufacturers and individual hospitals. These solutions can translate data into HL7 and other standard formats.

Wireless Network Security

Cisco is the dominant infrastructure provider in hospitals and is known for providing very secure wireless access points. Cisco initially developed the LEAP standard, which was designed to provide increased security; their latest standard is EAP. It's important that device manufacturers support a hospital's preferred security protocol (likely LEAP or EAP) to avoid costly work-arounds. In many cases work-arounds are not feasible and the hospital will instead select another, compliant device vendor.

Support for EAP and other common wireless networking security protocols requires that wireless networking vendors add special software, memory to store and run the software, and additional processing power.

[15] Focus group findings presented at TCBI's second annual Medical Device Connectivity Conference and Exhibition.

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The focus group research findings for hospital administrators and IT staff included:

- Providers are frustrated at medical device manufacturers' inability to conform to their IT networking standards
- Providers often incur additional costs when trying to accommodate medical device manufacturers that do not meet their networking standard and configuration requirements.
- Many providers said that if a medical device manufacturer can't make their device fit and work within their existing network, then they "simply won't do business with them."

Dual Band Communications

The most commonly used wireless band is 2.4 GHz, which doesn't require a specific FCC license. The 5 GHz band, which was formerly restricted to government and military uses, is now an emerging standard for hospital device use, given its superior performance in an environment with lots of potential interference.

During the transition from 2.4 to 5 GHz device connectivity modules must include the RF chips and firmware to support both bands.

Focus group findings included:

- Instances of "dead spots" and users carrying too many devices are common.
- Some participants felt apprehensive about wireless devices as they believe they are "the least reliable piece" of their networks.

Multiple Interfaces

Serial UART is the traditional and stable network standard but serial ports are very slow, and have been largely replaced on many common devices by USB ports, which are faster and smaller. Other common interface options include SPI, which is faster still, and I2c. Some devices, such as EKGs require the faster SPI interface to accommodate the high volume of data available from the device.

Device manufacturers must support all common network interfaces to avoid costly work-arounds and sub-optimal performance (inability to send all required data in a timely manner).

Testing Requirements

Hospitals assume that CMD vendors have tested the compatibility of their devices with all common wireless configurations; however, such testing requires expertise that most device manufacturers do not have. One alternative is to engage a specialized testing company to do detailed and specific testing, but this can be quite costly. Alternatively, the device manufacturer can incorporate a third-party wireless module into their device and rely on the module

manufacturer's testing processes, which are typically robust.

Focus group findings included:

- Providers purchase equipment from one vendor only to have it conflict with other equipment, resulting in considerable frustration and expense.
- Test and (re)certification of provider networks at installation of many medical device systems is a necessity to ensure they work properly and don't conflict with other devices.
- Most estimated that it costs their hospital hundreds of thousands of dollars to participate in testing and certification.

These technical challenges are far from insurmountable. Device networking experts have identified optimal solutions that address each of these provider concerns. However, device manufacturers who are not experienced in providing wireless network connectivity and implementing connected devices in a complex hospital environment should seek expert partners to avoid compromising patient health and customer relationships.

Device Life

One other consideration for device manufacturers is device life. Medical device models, which take much longer to get to market, and have a more costly development cycle, need a longer life than consumer devices which are replaced yearly. It is very difficult for device manufacturers to go directly to RF chip vendors to get the chips they need in the relatively small quantities they need. In addition, these chips are updated every year or two, and a medical device vendor can't afford to revise their hardware that often. The component isn't guaranteed for the long life of the device, and frequent software changes require costly chip modifications. Purchasing and integrating a third-party networking module mitigates these issues because the connection from the device to the module does not change – the required changes are made inside the module.

Recommendations for Device Manufacturers

- Fully understand the regulatory and strategic issues that promote wireless device connectivity, and how they affect your devices specifically.
- Fully understand the secondary uses of the data from your devices, and the potential business value of these data.
- Quantify the business benefits of wireless networking of your device – what's the financial, clinical, operational value add?
- Fully understand the technical issues and costs associated with adding wireless connectivity to your devices.

- Quantify the tradeoffs of buying vs. building wireless connectivity into your devices.
- Develop a formal plan, budget and timeframes for executing the plan, and assign it to one of your best project managers.

Recommendations for Hospital Executives

- Document the amount of time required to collect and enter medical device data in your hospital ICUs and Med/Surg units.
- Document or estimate your current error rate for manual device data transcription.
- Determine which devices require the greatest amount of charting time and which have the highest error rates.
- Estimate the hard benefits of CMDs, starting with those described in this report.
- Calculate the cost of purchasing new connected devices to replace the most costly and error prone device types, or connecting existing devices via standalone serial port device servers.
- Develop a business case based on your unique costs and benefits to support the purchase and implementation of CMDs.

Black Box SME is a professional services firm dedicated to improving the realized value of healthcare technology. BBSME has worked for many of the largest and best-known healthcare IT vendors in the world, as well as many established niche players and startup firms. Using the Product Value Analysis methodology and tools, BBSME quantifies and describes the business value of a product from its buyer's perspective.

Douglas Ivan Thompson, MBA, FHIMSS, the author of this report, is a nationally recognized expert on the business value of healthcare technologies. He has worked with over 100 hospitals to plan for, realize and measure the benefits of clinical information systems, and chaired HIMSS' CIS Benefits Task Force. Mr. Thompson has published numerous articles about the role of information technology in clinical quality improvement & measurement, and is a frequent speaker to business and professional audiences.

Lantronix, Inc. is a global leader of secure communication technologies that simplify remote access, management and control of any electronic device. With over 650 hospital and medical manufacturer customers worldwide, along with a dedicated health care team, we are committed to enabling safer, higher quality care delivery. Easy to integrate and deploy, Lantronix products remotely connect and control electronic equipment via the Internet, provide secure remote access to firewall-protected equipment, and enable remote management of IT equipment over the Internet. Lantronix serves some of the largest medical, security, industrial and building automation, transportation, retail/POS, financial, government, consumer electronics/appliances, IT/data center and pro-AV/signage entities in the world. Since 1989, we have connected over 3 million devices across 10,000+ customers globally – every 1 minute of the work day, Lantronix enables another device on the network. The company's headquarters are located in Irvine, Calif. For more information, visit www.lantronix.com.