Medical Device Networking for Smarter Healthcare: Part 2

Bridging the Gap Between Healthcare and Homecare
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Introduction

Healthcare providers are faced with a rapidly aging population, rising costs and an increase in the number of cases of chronic diseases ranging from diabetes to chronic heart failure (CHF), requiring more long-term care. Providers must tackle the challenge of meeting these growing demands as they deal with both acute shortages in physical floor space in hospitals and in the number of critical care professionals. In the U.S. alone, there may be a shortage of 200,000 physicians and 800,000 nurses by 2020, resulting in long wait times for routine healthcare, according to the Council on Physicians & Nurse Supply.

Home-based care is now considered an essential and relatively low-cost solution to effectively accommodate the shortage of space and healthcare professionals over the long term. This means that hospitals will need to more effectively use the patient data available to them by network enabling patient monitoring devices. In this way, hospitals will be able to provide more comprehensive, reliable and expedited care for their patients.

This paper discusses today’s industry trends and technology challenges of a hospital-based medical device networking infrastructure, and the necessity of enabling network access to all medical devices, both in a healthcare facility (e.g., hospital) and homecare environment.
Healthcare Today

The Hospital Environment

By connecting bedside monitors and laboratory equipment to a network, hospitals benefit in a variety of ways, ranging from reduced costs and increased productivity, to streamlined patient data collection and the reduction of medical errors. As an example, instead of nurses manually logging patient information in paper chart records and later transcribing the data into a computer, data including vital signs, blood work, and other test results can be automatically uploaded to the patient's electronic record, eliminating the possibility of human error, while reducing costs by eliminating time consuming administrative tasks.

Other associated real time benefits of automation include improved response to alarms reported from medical devices, finer detail in tracking patient data, and instant access to a patient's health status from any network connection. For longer term benefits, patient data can be easily stored for review and analysis, improving both patient care and satisfaction.

But to take advantage of medical device connectivity, hospitals and clinics will need to either retrofit or upgrade their medical equipment, enabling communication between devices or to a central processing system. This system would then be capable of maintaining health care records, forwarding alerts and in some cases automatically detecting anomalies. This requires an end-to-end connectivity solution and a high degree of automation.

The Homecare Environment

These technologies and skill sets can then be very easily replicated in a home care setting. Home care monitoring is considered to be the fastest growing segment in the medical device networking sector, benefiting health care service providers including hospitals, medical centers and doctors' offices.

By monitoring patients with chronic conditions remotely, health care providers can free up space in the hospital or medical care facility. Blood sugar levels, heart rates and other values can be monitored in the home, and transmitted wirelessly at regularly established intervals via a patient's home network connection or cell phone at a relatively low cost. Monitoring can also improve care for patients who have been released from hospitals but need to have certain parameters monitored during the recovery period at home.
Technology Challenges

Healthcare information technology (HIT) departments are faced with several challenges when integrating these medical devices in different applications. Some challenges include medical device interoperability, safety mechanisms and implementation issues, all of which can vary depending on the area of deployment, such as in an emergency room (ER) or intensive care unit (ICU).

Minimum requirements have been established for the collection of patient health data and a secure national network infrastructure. These requirements protect electronic health records (EHRs) and related patient data by making them indecipherable to unauthorized persons when transmitted over a wired or wireless network.

Today, the healthcare industry is currently working to solve several technology issues centered on interoperability, safety mechanisms and implementation.

- Medical device interoperability: There are many standard and non-standard methods in which medical devices can interconnect to software systems that will ultimately provide the clinical efficiencies that are expected. In the U.S., these standards bodies are:
  - Integrating the Health Environment - Patient Care Devices Domain (IHE-PCD)
  - The Continua Medical Alliance
  - The American Society for Testing and Materials – Integrating the Clinical Environment (ASTM-ICE)
  - The Health Information Technology Standards Panel (HITSP).

- Fail-safe mechanisms: Medical devices must include built-in fail-safe mechanisms, including those for physical safety such as EN 60601 for patients who may be in contact with medical devices. Other software-based safety mechanisms ensure that the medical device data is accurately matched with a patient ID.

- Easy implementation: The networking of medical device data is a complex electronic transaction. The incorporation of ease-of-use software, helping to monitor data flow and troubleshooting when problems occur, will greatly improve the adoption of these systems.

The technology portion of patient monitoring is being addressed on multiple fronts with standards bodies and industry consortia. Medical devices are not only becoming more accurate and precise in their measurement capabilities but are also being designed “interoperability ready.” Patient monitoring will be driven by market and government forces that cannot avoid addressing an aging population with a growing list of chronic diseases, who will become the leading consumers of health care services. This growing population is expected to drive the need for highly accessible, high-quality, safe, economical and sustainable remote health care.
Real-world Scenarios and Data Quality

The Impact of Data Quality

Despite the fact that medical diagnostic and lab equipment deliver high-quality results that physicians and surgeons rely on for determining the type of care provided to patients, data transmission, data retrieval and data interpretation is not yet being adequately addressed by this equipment.

In a real-world example, a group of health care providers relied on the result of a digital glucometer to determine the dosage of insulin for a patient. When the dose was administered, it proved to be fatal. The root cause of the problem was a faulty LCD display segment, where the decimal point failed to light on the device's liquid crystal display (LCD).

Now, suppose this glucometer could be retrofitted with some form of communications mechanism, so that in addition to displaying the test result on the LCD, it also communicated the result to a central system that could advise the care provider of the appropriate dosage based on specific rules. If this scenario was deployed in the case above, the health care provider would have immediately noticed the discrepancy between the readout on the LCD and the advised dosage.

In effect, this would have created a fault tolerant system, which in this case would have proven to be a life-saving system. If we take this one step further, the central intelligent unit could then become an integral part of the dispensing process to ensure the correct dosage. The Institute of Medicine of the National Academies, in a 2000 report, "To Err is Human: Building a Safer Health System," estimates that medication errors account for more than 7,000 deaths annually.

In another real-world scenario, a routine checkup resulted in a four-day nightmare for one patient due to a test result error. It was determined that the mistake was the result of human error in reading and/or recording the test results. These types of errors could be significantly decreased by changing how data is recorded and retrieved. As an example, if the blood sample analyzer could directly store results in a central computer, which could later be retrieved by the physician or nurse practitioner over a network, this patient could have been spared from four days of worry.

Medical errors are also costly in terms of dollars spent to repeat diagnostic tests or to counteract adverse drug events, according to the Institute of Medicine's 2000 report. It also leads to patient dissatisfaction and a loss of morale for health-care professionals, who are frustrated by not being able to provide better care for patients.
Medical Device Connectivity

The key word here is "connectivity." These highly reliable and expensive medical devices have left a gaping hole in the way care is provided today. Several medical devices are incapable of communicating with each other, or alternately talking to a single central intelligence unit. While new medical equipment under development today will provide some form of network interface, the devices already deployed in the field will need to be intelligently retrofitted, primarily because of their long lifecycle of about 15 to 20 years.

In basic terms, medical device connectivity entails getting that data onto some type of network so that it can be integrated with an electronic medical record (EMR) system and other critical health IT systems in a hospital or clinic. In the case of older equipment, this will likely be accomplished via the addition of adapters on the serial output port. Making hardware changes to existing equipment from the factory is typically not considered because it will require months to get approval from the U.S. Food and Drug Administration (FDA).

Retrofitting, generally speaking, is tantamount to opening a can of worms. Each time you take care of one problem, the next one appears. The typical problems associated with any retrofit technology also apply to the healthcare environment. For example, rewiring an older health care IT infrastructure may be limited in the way the new wiring is configured. In many cases, older wiring closets in hospitals lacks the ability to support increased bandwidth needs provided by Gigabit Ethernet to support large data transfers including EMRs and imaging, along with supporting requirements for LAN, Internet access and WLAN.

Available infrastructure, health-care facility layout and budget allocation, will all be major factors that influence retrofit decisions. The general layout of a health care facility, in terms of the location of the ER, ICU and lab, and available electrical outlets may sometimes pose a challenge. Adding new electrical/electronic equipment and the location of the nurses' stations may dictate the choice in wired versus wireless connections. The physical wiring distance from the lab or a patient ward to the central computer room or nurses' station may pose additional challenges for ensuring data integrity over long wire lengths. Lack of access to the existing wiring infrastructure also may restrict the deployment of additional cables (Ethernet, serial, etc.).

In addition, proximity to patients in a controlled environment also should be addressed at the definition phase. There are several regulations that require certain device specifications for devices in close proximity to the patient (Ex. EN60601). These regulations affect the form factor, electrical isolation and enclosures of these products.

Building an Intelligent Health-Care Network

Proximity to the patient and point of care are perhaps the biggest influencing factors in determining form, function and certification of a medical product. Enclosed or
boxed products that will be in proximity to a patient and health-care provider must adhere to a set regulations noted earlier. However, embedded networking products or modules that will be enclosed in larger pieces of equipment may not be subject to the more stringent regulatory standards.

The most basic need for patient satisfaction is receiving reliable and timely care, but also, and most importantly, receiving feedback. Therefore, we'll breakdown the problem into two fundamental pieces – care provisioning at a medical facility and care provisioning at home.

**Level of care provided at a healthcare facility.** When a patient is asked to undergo additional tests at detached facilities, which often are composed of disparate systems, it results in a paper trail of the patient’s record. These records now need to be physically shipped across facilities/buildings in order to ensure that the patient is receiving the right treatment. While the process may not be the most efficient, and perhaps is a bit time consuming, the patient is able to receive direct feedback from the healthcare provider in person.

If all the healthcare provisioning facilities were networked, test results could directly be fed into and retrieved from a central location. This would not only eliminate the paper method, but also greatly speed up the process and reduce human intervention in administrative-type functions.

In the case of providing care at the patient's home, one or several devices may be connected to a patient, but the patient cannot be made responsible for logging data and transmitting them either physically and/or electronically to his or her care provider. Therefore, a certain degree of automation as well as a communications method needs to be deployed along with home-care devices. Whether a single medical device or several are in use, data would need to be collected and transmitted to the health care provider, who would then use this data to provide relevant feedback either electronically or by voice.

Physical proximity to the patient, therefore, does pose a few challenges in providing care. In essence, we would need to bring together all monitoring devices, immaterial of the location where they provide care, into a common network. For this to work, they would need some degree of interoperability. The first issue that needs to be addressed is communications, which can be achieved either in a wired network setup, such as those supported by LAN/WAN, broadband, etc., or alternately through a wireless network such a Wi-Fi, cellular, etc.

An associated benefit to a connected hospital would be an intelligent prescription/surgical storage unit that can help in efficient inventory management. But the real beauty of this system is that once we have an established medical device network connectivity system in a hospital, it can be very easily adapted in a home-care environment.
Emerging Trends in Communications for Remote Patient Monitoring

Since cellular technology is already widely deployed, it has the inherent advantage of reaching a larger patient base. This technology can easily be used for remote patient monitoring, alarm forwarding, prescription dosage administration, and voice communications.

However, there are several different connection options available including Wi-Fi, Bluetooth or Zigbee, each with their own set of trade-offs. For example, Zigbee and Bluetooth are considered to be very easy to use and offer reliable home area network connections, while Wi-Fi delivers a greater range and data speeds than other types of wireless connections, although much more difficult to implement in home networks due to security settings.

**Wireless Technologies**

Wi-Fi and Bluetooth technologies are advancing quickly for use in Personal Area Networks (PANs). Using this technology to aggregate data and then transmit over broadband and/or cellular is a very viable option for both hospital and in-home based care. Most mobile devices and portable computers already incorporate Bluetooth, which will enable them to aggregate data from network-ready medical devices in a general vicinity while transmitting the data electronically.

The biggest limitation of portable medical devices is battery life. Even if they use rechargeable batteries, these devices operate for a pre-determined number of hours (anywhere between four and eight hours) between charges. This translates into a low-power requirement for the devices. While both Wi-Fi and Bluetooth offer their own benefits and disadvantages in terms of how much power they consume, another factor that is equally important to consider is distance range that these devices would need to be able to transmit over. Based on this metric, Wi-Fi is the clear winner. But this does not mean that Wi-Fi is the technology of choice.

With wireless radios now becoming available in very compact form factors and at prices that are even more compelling, provisioning for both technologies would be the best option since both have a very strong ecosystem in place. ZigBee, despite its somewhat lower adoption rate in this field, is perhaps the most promising low-power wireless technology available today.

**Cellular or Broadband?**

This argument is really academic in nature. If patients who require in-home care do not have broadband availability in their neighborhoods, then this decision is already made for them. But in the case that they already have broadband, then the question is
would they rather have the cost of transmitting data bundled into their broadband service or would they choose to have it sent over their cellular network?

Other questions that need to be answered include what happens if there is a service outage either over broadband or cellular, should networking gear be embedded into Class 3 medical devices, and if this is the case, fail-safe provisioning would become mandatory. Given the state of options that are currently in play, an Ethernet device with an option to switch to cellular may be the best fit for remote monitoring applications.

The bottom line is that wireless technology offers plenty of cost-effective and power-efficient solutions today. The advantages of building such basic blocks -- i.e., retrofitting older devices with communication mechanisms that streamline data flow in a HIT environment and eventually lead to secure access of data anytime and anywhere within the HIT network -- provide options for several technologies which include the following:

1. They can be deployed in hospitals and in a patient's home with minimal to no changes to equipment.
2. They are interoperable.
3. They have a high degree of built in fail-safe mechanisms.
4. They can be used in all types of patient ID systems, including those that use bar codes, RFID or biometrics.
5. All networking technologies will always remain backwards and forward compatible.

**Conclusion**

The daily needs and complexities of providing complete patient care, in a hospital and at home, is continually growing and continues to remain the biggest bottleneck in transitioning from patient care to preventive care.

The projected shortage of general practitioners also is contributing to the challenge. While technology is no substitute for human intelligence, it can definitely aid in delivering a high-level of care to a larger number of patients efficiently.