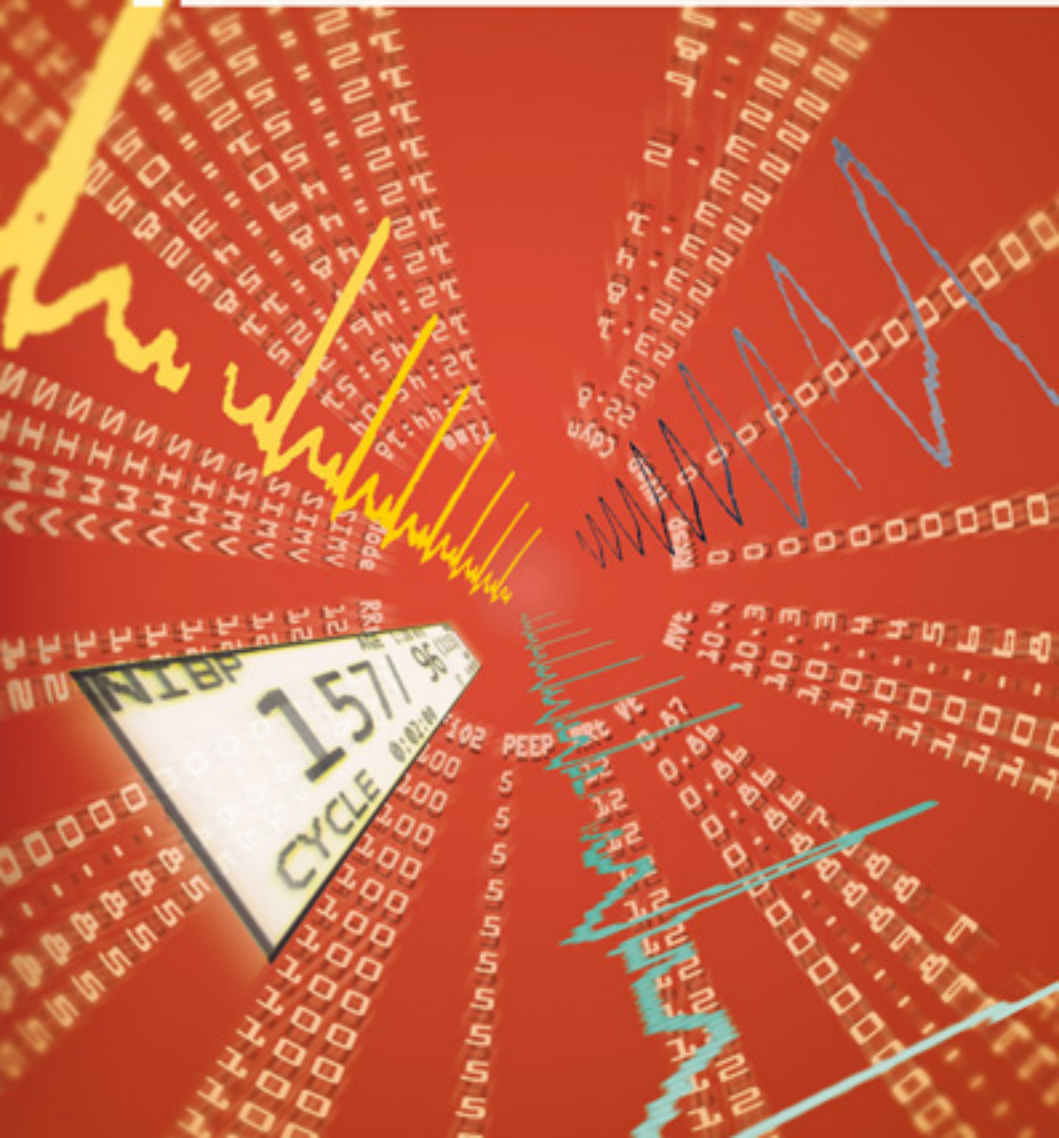
John R. Zaleski

Integrating Device Data into the Electronic Medical Record

A Developer's Guide to Design and a Practitioner's Guide to Application

SIEMENS



Zaleski Integrating Device Data into the Electronic Medical Record

The Author

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Preface

The idea to write a book on the subject of device integration occurred to me rather suddenly about a year ago. I have been involved in the field of medical information technology and medical integration for well over a decade now. I first cut my teeth interfacing medical devices to computers back in the mid 1990s during my doctoral research days, when it was necessary to collect data automatically from mechanical ventilators as part of my clinical studies. My study of the weaning behavior of coronary artery bypass grafting patients necessitated a complete and accurate record of patient respiratory data and such a complete record was available only through direct connection to the mechanical ventilators in surgical intensive care. As the years passed I became heavily involved in the interactions between electronic medical records and medical device technology—a necessary by-product of the roles I held. I have developed and continue to develop and manage products that support clinical workflow at the point of care, and these require interaction with medical devices. In my current role as product manager for a critical care product line at Siemens, I spend a considerable amount of time and energy in the fielding of medical devices in conjunction with electronic medical records. Therefore, the by-products of physiological measurement and monitoring are keys to assessing patient state. A recent Frost & Sullivan Market Insight article observed that the "most common problem with patient monitoring systems has always been their interoperability." [1]

In writing this text I struggled with the fact that there simply is too much to say on the topic in the limits of a single text to express all points of view, methods, testimonials from the field, and approaches.

As I complete this text efforts continue and evolve in the areas of medical device networking standardization. The proposed IEC 80001 standard, "Risk management of networks incorporating medical devices," is under development. This standard focuses on patient safety and connectivity within the healthcare enterprise networking infrastruc-

[1] Gideon V. Praveen Kumar, "Lack of Medical Device Interoperability – Is there a way out?," Frost & Sullivan Market Insight: 15 September 2008.

ture. Connectivity specialists, such as Tim Gee of Medical Connectivity Consulting, describe activities surrounding this standard and the implications for the healthcare enterprise.[2]

No doubt, critical review by those practitioners in the field will find areas requiring greater coverage or different approaches to similar topics based upon diverse experiences. To those critics let me simply say that any omissions were not intentional based on my belief that they were not important, but rather simply that space being limited, this represents in my judgment a first extensive treatment on the subject. I also struggled with single authorship. I imagine that some may suggest a broader array of authors may have provided for a more distilled, wider ranging treatment of the topic. I acknowledge this and humbly submit that I am not suggesting that I have "cornered the market" on intelligence in the area—simply that I believe a single point of view would make for a more homogeneous treatment—all the while recognizing that to the standard practitioner "your mileage may vary." I welcome differing viewpoints and hope to engage in a broader dialogue in the field. Improving our capabilities in this area as an industry will ultimately help every patient and every medical practitioner. Therefore, I see pursuit as a noble goal.

John R. Zaleski, Ph.D.
October 2008

[2] Tim Gee, Medical Device Connectivity Consulting, Inc.
http://medicalconnectivity.com/2008/05/26/iec-80001-an-introduction/

Contents

1 The Medical Device Integration Landscape

1.1 Introduction

Data inundate us.

More and more data are presented to us to review, analyze, and digest. We, in turn, generate data from those data in order to produce even more data that others must review, analyze, and digest. In short, we are a data-rich society made more so by ubiquitous computer and software programs. The benefits of data accessibility become obvious as insights drawn from its rapid access make plain in our everyday lives. Gone are the days of paper memoranda, paper facsimile, and even standard telephone calling. Today we have Internet-based communication, Web logs, remote meeting capabilities, and email. The need to be present at a vast majority of business meetings is mitigated by technology—a benefit that impacts other aspects of life and society, to include the ability to reside just about anywhere, thereby minimizing the need to commute to and from specific locations in our workaday lives.

Increasing healthcare costs are a factor in motivating this need. In the United States, national healthcare expenditures are anticipated to grow from just shy of 16.5% to approximately 19.5% (as a percentage of US Gross Domestic Product) in the 10 years from 2007 to 2017[1]. Clearly, providing greater automation and integration of healthcare data is consistent with the need to manage and mitigate these rising costs.

Patient data retrieved from medical devices at the point of care are an important subset of healthcare data. Automating medical device data collection is a logical extension for allied health professionals in that it can be brought to bear to assist in clinical decision making and assist in clinical workflow. However, the need to collect data is also

[1] Cinda Becker, "Slow: Budget Danger Ahead." Modern Healthcare. March 3rd, 2008. Pages 6-7.

consistent with the general direction the healthcare industry is taking towards globalizing the use of electronic medical records (EMRs).

What is an EMR? The National Alliance for Health Information Technology developed definitions for various terms, chronicled in its report titled "Defining Key Health Information Technology Terms." Healthcare IT News reported the definitions on several of these, including the EMR. As quoted from this source[2], here is the definition of the Electronic Medical Record as offered by The National Alliance for Health Information Technology:

"*Electronic Health Record:* An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one healthcare organization."

To be clear, in this book I address a specific class of medical devices and communicating their data to the EMR: those associated with vital signs, measurement, respiration, glucose, and general physiological function. Medical image data standards are well documented and are described elsewhere[3]. Data (or, perhaps more accurately, metadata) descriptive of medical imagery can be transmitted to EMRs using a Health Level Seven (HL7) Standard. Patient identification and admission, transfer, and discharge (ADT) messages can be associated with image metadata to enable linking to existing medical imagery. High-resolution medical imagery normally created using magnetic resonance imaging (MRI), X-Ray, or Computed Tomography (CT) equipment typically has very large data storage requirements (Gigabytes to Terabytes) and therefore cannot be practically stored within EMRs. Data about these images (i.e., *metadata*) can be stored but are normally text-based data that identify an image pointer together with patient identifying information.

The ability to access and make use of medical device data begets other uses that were not so obvious when the interest in and ability to retrieve it first became available more than 20 years ago. Such is the creativity, facility, and ingeniousness of the human mind. While aspects of society such as financial institutions, manufacturing, and service sectors have embraced the use of data, it is somewhat surprising that medicine is still in the early stages of implementation. This is

[2] Bernie Monegain, "Healthcare IT definitions are in." Healthcare IT News. 05/21/08. http://www.healthcareitnews.com/story.cms?id=9274&page=2

[3] Example: the DICOM Image Standard, available from http://medical.nema.org.

not to say that sophisticated software offerings do not take advantage of the ability to draw upon medical device data to better clinical care. Lags typically exist in the adoption of techniques by healthcare providers (hospital enterprises, physician offices, clinics, etc.) in the use of medical device data. Difficulties with data collection and the knowledge of how to do it is partly to blame. However, there are providers who have embraced and rolled out enterprise-wide software and computing solutions that take full advantage of medical device data collected from patients in the enterprise from the perspective of electronic medical record integration, computerized physician order entry (CPOE), laboratory information systems (LIS), and pharmacy (Rx) systems (to name a few). These individual subsystems, taken together in their collective whole, become what has been commonly referred to as a health information system (HIS) or computerized health record (CHR) that incorporates the sum total of all information available on any given patient within a health enterprise.

While critically important to patient care, these subsystems are not the primary focus of this book. Rather, my focus is to discuss medical device data, their measurement, and how their collection can be accomplished and used to assist in forming the basic understanding of patient state—i.e., the condition of the patient. Findings and measurements—how they are collected, displayed, used, and assessed—are key pieces of evidence for guiding the treatment of disease.

Before proceeding, definitions are necessary. The term electronic medical record, or EMR, is defined as a computerized repository of medical data consisting of patient findings, physiological information, identifying and demographic information, medications, diagnoses, orders, etc.

Definitions of EMR abound[4,5] which further qualify this definition based upon content and purpose. While these are recognized, the definition provided above will establish the basis for the analysis to follow and can be mapped into other definitions as need be. A drill-down into the details of the electronic medical record is the subject of Chapter 5.

In essence, the focus of this book is the mechanics of data acquisition, review, analysis, and presentation to the physician, nurse, and other

[4] Thomas J. Handler, M.D.,"Magic Quadrant for U.S. Enterprise CPRs, 2007," Gartner Industry Research ID Number G00152518; 31 October 2007.

[5] Wes Rishel, Thomas J. Handler, M.D., Jonathan Edwards, "A Clear Definition of the Electronic Health Record," Gartner Industry Research, ID Number G00130927, 4 October 2005.

allied health professionals (respiratory therapists, technicians, home health aides, etc.) who make up the team of care providers for any given patient. When I speak of medical device data I am referring primarily to that used in normal physiological measurement or assessments, such as blood pressure, temperature, pulse, etc., and on the periodic measurement and analysis of physiological parameters used in guiding patient care.

Gartner Industry Research[6] advises that medical device management & standardization currently reside (2007) at the peak of the industry hype cycle, and growth will occur in the field of medical device interface development and use in medicine as an important adjunct and enabler of clinical workflow and patient care management. Gartner further recognizes that the path ahead in the area of device integration is still not entirely clear in terms of the evolutionary roadmap. As a result, one of their key recommendations is to focus on interoperability as industry standards continue to evolve. This is an important point, because the lack of universal adoption of concise and clear standards is a key reason why medical device data collection is still not the norm in many, if not most, healthcare enterprises.

The use of medical device data for patient care is expanding as a result of the call to improve workflow in the clinical environment. Faster response to patient complaints, improved delivery of care, and reducing errors during treatment are but a few reasons why this value is recognized. The value proposition in medical device integration to the EMR is that it enables complex clinical workflow implementations, enhances patient care management, ensures data accuracy, and reduces the latency in recording data from devices when patients are in highly technologically dependent states, such as the case in intensive care units (ICUs).

Gartner also acknowledges the use of proprietary interface protocols between individual medical devices and the EMR. They suggest that medical device integration systems[7]:

"1) Provide physical or Internet Protocol-based connectivity to the instrument;

[6] Barry Runyon et al., "Hype Cycle for Healthcare Provider Technologies and Standards, 2007." Gartner Industry Research. ID Number: G00148328. Publication Date: 11 July 2007. Page 16.

[7] Barry Runyon et al., "Hype Cycle for Healthcare Provider Technologies and Standards, 2007." Gartner Industry Research. ID Number: G00148328. Publication Date: 11 July 2007. Page 36.

2) Map between the instrument proprietary data format and a format that works for the CPR [e.g. Health Level 7];
3) Provide a means to select representative data for charting;
4) Provide buffering to continue the data capture when the CPR is unavailable; and
5) Provide at least some support for adding patient ID information to the stream coming from the instrument."

The need for seamless and straightforward medical device data integration will grow as the population ages. Patients with chronic illnesses will of necessity require devices to assist in managing diabetes, chronic obstructive pulmonary disease (COPD), heart disease, cancer, and others. The aging population will require and benefit more fully from the ability to monitor and manage chronic health problems from the comfort of home. Indeed, devices that measure basic physiological parameters necessary for diagnostics and therapeutics provide invaluable data for management, prevention, and monitoring of disease. Specific measurement instruments that are often used for home health monitoring include flow meters, glucometers, blood pressure and pulse oximetry monitors, medication tracking meters, and cholesterol monitors[8].

In addition, medical device integration into the EMR provides other benefits, including simplifying analysis and clinical decision support assessments, automated charting, and, as we will see later on in Chapter 10, establishing the basic foundation for automatic control of medical equipment at the bedside and simplifying clinical documentation and charting. Some of these functions, and strategic as well as tactical benefits, have been described in the literature of the American College of Clinical Engineering[9]. Medical device integration is receiving much more attention within senior management in healthcare enterprises. Indeed, Gartner[10] suggests that

> *"…the CIO will take on more responsibility for medical device oversight and ultimately will bring the associated biomedical engineering staff under the office of the CIO."*

[8] Shekar Rao, "Prognosis for Medical Electronics—Growth and Technology Convergence," 9th Texas Instruments Developer Conference India, 30 Nov – 1 Dec 2006, Bangalore.

[9] Stephen L. Grimes, "Convergence of Clinical Engineering and Information Technology," College of Healthcare Information Management Executives, August 24th, 2006. Pages 9, 35.

[10] Barry Runyon, et al. "Hype Cycle for Healthcare Provider Applications and Systems, 2007." Gartner Industry Research. ID Number: G00148329. 11 July 2007. Page 25.

Furthermore, technological advances in networking, improvements in positive patient identification, and the uses of barcodes and radio frequency identification (RFID) will further enhance automated data collection as they will enable near error-free association of patient data with patient identity, thereby facilitating automatic data capture.

Positive patient identification is a subject that will be addressed more fully in Chapter 8, where methods and technologies will be discussed.

The Joint Commission Perspectives on Patient Safety reported that "incorrect patient identification was involved in 13% of surgical errors and 67% of transfusion errors."[11] Gartner reported a study at a single Florida hospital in which an error rate of 4.4% was associated with transcribing vitals parameters data into the EMR[12].

1.2 Medical Device Integration Landscape

Medical devices for vitals measurement span the range from single value to multi-measurement, network-enabled machines. Figure 1-1, influenced by the work of Norgall[13], illustrates medical device technology dimensions along three axes each representing the evolving states of connectivity, access to data, and device complexity. The simplest of devices and interfaces are those shown closest to the origin, with increasing complexity further out along the axes.

Three key features of any medical device are

- the type of device and the complexity of the measurements it produces, and
- the data it measures and transmits externally,
- the method by which it communicates to external systems.

These are reflected in the three axes of Figure 1-1: Data, Device, and Connectivity Technology.

Beginning with the Data axis, the simplest of measurement devices, such as home-care meters including glucometers, stethoscopes, or

[11] "Technology in Patient Safety: Using Identification Bands to Reduce Patient Identification Errors." Joint Commission Perspectives on Patient Safety, April 2005, Volume 5, Issue 4. Page 1.

[12] Wes Rishel, "The Evolving Market for Universal Medical Device Busses." Gartner Industry Research. ID Number: G00149688. 26 June 2007. Page 2.

[13] Thomas Norgall, "Interoperability and Medical Device Communication Standardization," Fraunhofer-Institut fuer Integrierte Schaltungen—Angewandte Elektronik; Erlangen, Germany; 10-12 October 2002; Slide 3.

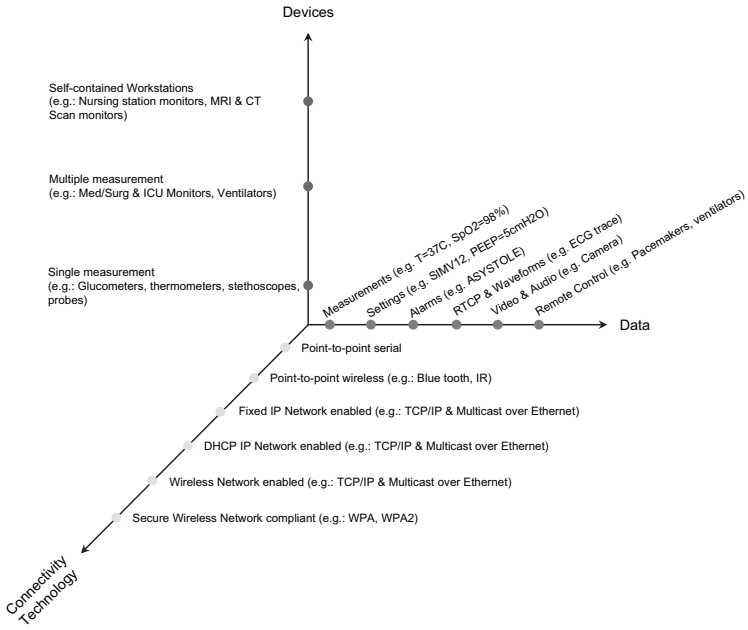

Figure 1-1 Medical device domain with ever increasing complexity

simple non-invasive blood pressure measurement cuffs, all measure one or two parameters discretely. The parameters typically will not contain personal identifying information and some of the data that are measured may not even have time or date stamps. These are the most basic of measurement devices.

Moving further along the axis we arrive at devices that accept specific settings, including thresholds. Some of the more sophisticated glucometers and multi-parameter measurement devices (cholesterol meters, blood pressure cuffs) fall into this category.

Next, devices that sound and transmit alarms are indicated. These devices typically produce an alert when a specific user-defined threshold is exceeded. Devices residing within this class of medical device can include ad hoc point of care monitors. The measurements obtained from these devices may be queried continuously.

Moving further out we arrive at devices that support real-time streaming protocol (RTSP) transactions. ICU monitors, mechanical ventilators, and infusion pumps are in this category. Continuous waveforms are produced and transmitted using a proprietary protocol along a high-speed network to a nursing station or other end-user

device that displays results, waveforms, and alarms that can indicate life-threatening problems.

Live video and audio communication can be included within the realm of real-time communication, together with the real-time control of medical devices from a remote location. Although automatic control system theory is used internally to medical devices in the management of systems vital to patients, generally available forms of external automatic control, whereby medical devices are controlled remotely and automatically in response to user input, are still a long way away. For example, automatically controlled weaning algorithms that can be adjusted by allied health professionals from afar (possibly through a Web portal over a hospital enterprise network). The use of such methodologies are beginning to be considered for the monitoring and maintenance of patients in a controlled environment, such as ventilated patients being weaned according to a specific protocol. Such functionality would reside within the realm of expert systems. In the future, routine or redundant activities may be automated as the level of acceptability and confidence in such systems grows through continued use, validated through extensive clinical trials.

Certain implantable pacemakers allow for bi-directional communication in which pacemaker settings can be adjusted using an external device that communicates transdermally. Data can also be downloaded from these devices.

Proceeding along the Device axis we evolve from discrete single measurements through multiple measurements and to self-contained workstations. Single measurement devices are those that are designed for a specific, single task (temperature, glucose, etc.) Multiple measurement devices provide a collection, or vector, of measurements that describe many aspects of the patient state. Critical care telemetry monitors, mechanical ventilators, and infusion pumps typically fall into this category. Surgical monitors can also be considered as a multi-measurement device.

Beyond this realm lies the region of self-contained workstations: devices that can collect measurements and also perform on-line analysis of measurement data. Nursing workstations, MRI and CT Scan systems populate this region. However, telemetry monitors are moving into this area as their level of sophistication advances.

In terms of the level of sophistication associated with connectivity technology, these have evolved, as well.

Looking at the Connectivity axis of Figure 1-1 we see the evolution from simple point-to-point communication using a physical serial interface up through network-enabled technology. Whether wired or wireless technology is used for point-to-point communication, such as infrared (IR) communication devices or Bluetooth, these communication technologies are differentiated from large-scale networking protocols in that they support communication of (primarily) one device to one computing client and checks on data integrity are performed to ensure data integrity.

True data redundancy and delivery checking occurs once we enter the domain of Ethernet via Transmission Control Protocol / Internet Protocol (TCP/IP) communication. Here, TCP/IP is the preferred protocol due to its verified delivery mechanism. Many medical monitors communicate patient critical information to nursing stations using TCP/IP but use a less reliable mechanism, such as User Datagram Protocol (UDP), which I refer to as "fire and forget." This form of transmission does not verify packet delivery. Oftentimes multicast transmission is used as a broadcast mechanism within a networking subnet to enable devices to communicate with each other.

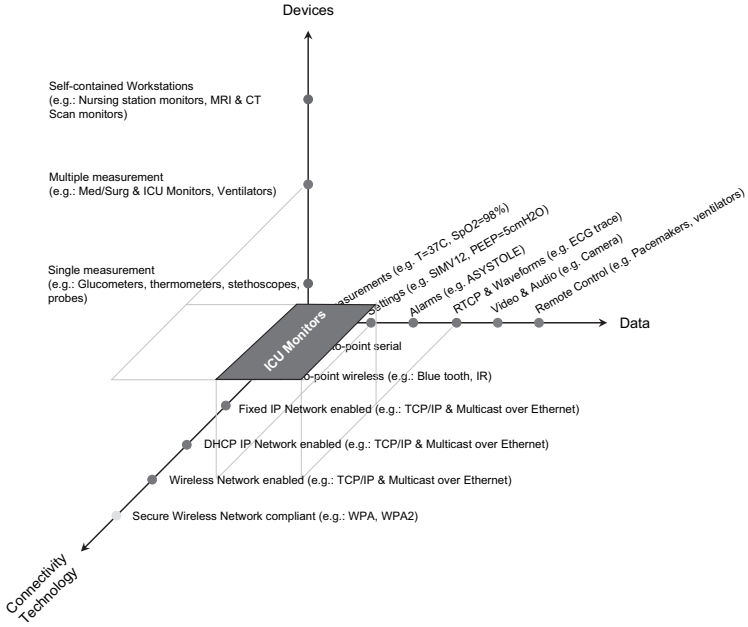

Figure 1-2 Range of technologies and measurements represented by typical ICU monitors

Most of the sophisticated telemetry monitors today communicate via wired or wireless TCP/IP over Ethernet. They do so using fixed or static Internet Protocol (IP) addressing.

Figure 1-2 illustrates the span or range of technologies typically associated with critical care telemetry monitors.

Critical care telemetry monitors collect a wide range of measurements (i.e., multi-measurement devices) and provide the capability to set thresholds which establish acceptable range limits corresponding to alarm triggers. The range of communication technologies span fixed IP wired to fixed IP wireless communication. By contrast, we can compare a typical single-parameter measurement device, such as a glucometer, with the ICU monitor. This is illustrated in Figure 1-3.

A limitation of these simple devices is their native inability to be networked within a large enterprise—this severely limits widespread and standardized data integration with the EMR. The scalability of devices having only point-to-point connectivity can be extended by bringing in third-party network extenders. One such example is the Moxa Tech-

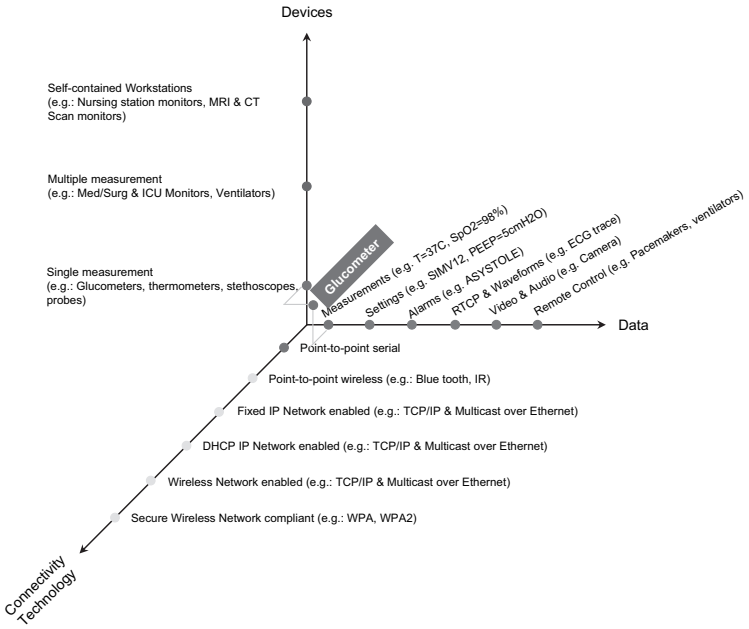

Figure 1-3 Single parameter measurement device using point-to-point communication

Figure 1-4
Moxa Technologies NPort W2150 Wireless 802.11g to Serial adapter (Courtesy Moxa Technologies, used with permission)

nologies *Airworks* device illustrated in Figure 1-4. I will cover devices such as these in Chapters 2 and 3.

In the case of point-to-point devices that employ serial communication interfaces, these can be extended to attach to existing (standard) Ethernet networks using a device like the one shown in Figure 1-4. The state of this technology is such that communications can be supported in an 802.11 wireless environment and serial devices—those normally isolated to lab or small networks—can now be accessed throughout the enterprise remotely.

In reviewing the current and future needs of medical device measurement technologies, Figure 1-5 (via the arrows) provides a high-level assessment of where the industry should focus. The arrows in the diagram identify the gaps in current technology but also show areas of needed future focus.

The use of single, multiple, and workstation data collection and measurement devices will and must continue in order to meet future patient care management needs. Advances in the complexity and sophistication of data analysis, clinical decision support, and workflow methods will also require seamless, automated, and continuous data integration to the EMR, thus motivating more rapid integration solutions.

The ability to both receive data and to control medical devices will continue. This will occur both organically and out of business need: medical hardware and software manufacturers recognize this today and collaboration between hardware manufacturers and software developers will increase as the solution will involve both—the soft-

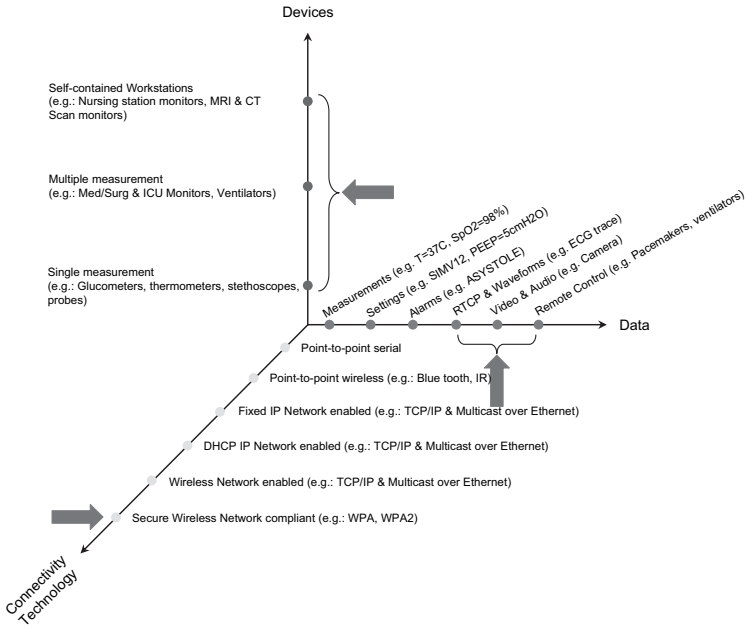

Figure 1-5 Areas of future technology capability and growth for measurement devices

ware will become integrated and fully coupled with the medical device. Stethoscopes, glucometers, ventilators, and similar devices are already migrating in this direction.

To ensure data integrity and security, medical device manufacturers will need to evolve their physical communication standards to align more with those of the communication & networking industry. The FDA[14] has already weighed in on this subject with a draft guideline focusing specifically on wireless technology and the need for standardization requirements that must be met as part of the regulatory evaluation and certification process of medical devices that rely on this technology.

Finally, standards-based application-level communication such as HL7 will continue to grow and become the common "language" by which medical device manufacturers enable transaction exchange between device level "gateways" and existing clinical repositories.

[14] "Draft Guidance for Industry and FDA Staff—Radio-Frequency Wireless Technology in Medical Devices," http://www.fda.gov/cdrh/osel/guidance/1618.html

Future areas of monitoring can include noninvasive ischemic stroke monitoring, prosthetic monitoring, monitoring for congestive heart failure, bed monitoring for patient movement, weight, and fowler angle, infusion pumps, intra-arterial balloon pumps, and beyond[15]. A discussion, along with examples of the details of device communication, is the subject of Chapter 2.

1.3 Evolving Standards in Medical Device Communication (IEEE/ISO & MD PnP™)

Standards and working groups focusing on medical device interface standardization have been in existence for years and have endeavored to establish a common architectural, data, application, and communication framework for device connectivity with computer-based information systems and with each other.

The challenge remains to enable common interfaces to secure information while protecting it from unauthorized or hostile access. The Workgroup on Electronic Data Interchange (WEDI) and other standards-setting organizations such as X12, Health Level 7 (HL7), the American Society for Testing and Materials (ASTM), the National Institute for Standards and Technology (NIST), the Computer-based Patient Record Institute (CPRI); and various associations such as Healthcare Financial Management Association (HFMA) and the Association for Electronic Health Care Transactions (AFEHCT) are involved in establishing standards both for data interchange between and among different systems and also the security policies associated with protecting those data. Independent researchers and academic institutions are also engaged in research to align on common standards[16,17,18]. While manufacturers of medical hardware and software are engaged in the production of next-generation technologies to support and enhance clinical diagnosis and treatment, they must also dedicate time and effort to enabling their systems to communicate according to these new standards.

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[15] Shekar Rao, "Prognosis for Medical Electronics—Growth and Technology Convergence," 9th Texas Instruments Developer Conference India, 30 Nov – 1 Dec 2006, Bangalore.

[16] Richard Schrenker and Todd Cooper, "Building the Foundation for Medical Device Plug-and-Play Interoperability." Medical Electronics Manufacturing. April 2001.

[17] http://mdpnp.org

[18] Richard A. Schrenker, "Software Engineering for Future Healthcare and Clinical Systems." Computer, Published by the IEEE Computer Society. April 2006.

The Institute of Electrical and Electronics Engineers (IEEE) along with the International Standards Organization (ISO) have proffered standards and working groups that are investigating and evolving the area of universal interoperability. The IEEE 1073 standard which has essentially been supplanted by the IEEE/ISO 11073/20601 standards have made important strides towards achieving this standardization. The Medical Device "Plug-and-Play" Interoperability Program is pursuing open standards leading to seamless, universal connectivity among medical devices and systems[19]. MD PnP™ was initiated by Massachusetts General Hospital and the Center for Integration of Medicine & Innovative Technology (CIMIT)[20]. This is an interdisciplinary program focusing on medical device interoperability to improve patient safety and workflow-related efficiency. In short, the MD PnP™ program is championing standards adoption, positing the regulatory path to facilitate adoption by the larger manufacturing community, among others, and working towards providing a proof-of-principle laboratory for demonstrating and eliciting requirements related to medical device connectivity.

In the area of Connectivity Technology, I have combined two concepts together: that of physical connectivity and data integrity. At its most basic, data are collected typically via serial connection according to specific standards ("Standard for Medical Device Communications—Transport Profile—IrDA Based—Cable Connected", IEEE 1073.3.2, for example). These are point-to-point connections with no verification of transmission beyond the basic hardware layer and no validation of role or data integrity.

The IEEE 11073 standards provide for an evolving framework around the enablement of medical device communication with computer-based health information systems. The goals, as enunciated in the standards, are[21]:

1) Provide real-time plug-and-play interoperability for patient-connected medical devices; and,
2) Facilitate the efficient exchange of vital signs and medical device data, acquired at the point-of-care, in all health care environments.

Versions of these standards in draft form are in review and date as recently as February 2008. These standards describe recommended

[19] Information available at http://mdpnp.org/Home_Page.html

[20] Information available at http://www.cimit.org

[21] International Standard ISO/IEEE 11073, Health Informatics—Point-of-care medical device communication—parts 10101, 10201, 20101, 30200, 30300; First Edition 2004-12-15

communication mechanisms associated with cable-connected devices, infrared (IrDA) devices, and interconnectivity speeds (e.g.: baud rates, stop bits, link disconnect timing, etc.)

The primary collection of these standards is described briefly below:

- ISO/IEEE 11073-10101 standard describes common nomenclature, syntax, and terminology for identifying findings and vitals parameters. This standard describes the nomenclature architecture for medical device communication at-point-of-care (APOC);[22]
- ISO/IEEE 11073-10201 standard proposes a domain information model describing medical device data attributes and their structure for communicating with external systems[23];
- ISO/IEEE 11073-20101 standard proposes application-level communication profiles including medical device encoding rules (MDER), allocation of object identifiers, time synchronization protocols, state transition, and some sample code segments for implementing these[24];
- ISO/IEEE 11073-30200 standard describes suggested connectivity for cable connected communication, including RS-232, RJ45, and others[25]. This standard discusses details such as medical information bus (MIB) cable lengths using CAT-5 cable[26]. Signaling speeds are suggested relating to serial transport, both through cables and via infrared; for example, signaling speeds of 9600 bits per second, data size in any received frame of 64 octets, and link disconnect times of 3 seconds[27]; and finally
- ISO/IEEE 11073-30300 focuses on infrared wireless connectivity. The IrDA physical communication and architecture are described here[28].

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[22] International Standard ISO/IEEE 11073-10101; Health Informatics—Point-of-care medical device communication—Part 10101: Nomenclature. First Edition 2004-12-15

[23] International Standard ISO/IEEE 11073-10201; Health Informatics—Point-of-care medical device communication—Part 10201: Domain Information Model. First Edition 2004-12-15

[24] International Standard ISO/IEEE 11073-20101; Health informatics—Point-of-care medical device communication—Part 20101: Application profiles—Base standard. First edition 2004-12-15

[25] International Standard ISO/IEEE 11073-30200; Health informatics—Point-of-care medical device communication—Part 30200: Transport profile—Cable connected. First edition 2004-12-15

[26] Ibid.

[27] Ibid.

[28] International Standard ISO/IEEE 11073-30300; Health informatics—Point-of-care medical device communication—Part 30300: Transport profile—Infrared wireless

Since the medical device plug-and-play initiative was launched, the focus of MD PnP™ has been on integrating these devices into a clinical environment in the context of use cases that are specific to application at the point-of-care. An important extension of this vision is that of enabling individual medical devices to seamlessly communicate with one another[29].

The work in the standards arena is extremely important and must continue. Enabling seamless communication among medical devices is a noble goal. Pragmatically, though, the state of the situation as it exists today is far from being standardized. This is one reason I decided to write this book. The fact today is that the standards related to electrical connectivity, networking, suggested data modeling, and nomenclature are necessary components relating to the overall goal of achieving universal medical device communication. But adoption aside, the details of the data content, and the query-response mechanisms of the health information systems that retrieve the data and validate for the purposes of storage within the EMR, have practical business implications in terms of costs to implement. The adoption, recognition, and creation of common data communications software and models will require extensive development efforts; the modification of medical hardware and firmware to conform to these standards must occur; and alignment between industry and healthcare enterprises on the specific needs and content of the interface specifications must occur. All of these can happen, and will happen eventually. But in the meantime, the problem of medical device data integration into an EMR remains. Participation in the standards organizations and working towards an accepted and sufficiently-detailed standard must occur in parallel with pragmatic device integration. For the present, the 'sub-optimal' methods for data integration using third-party software and hardware must still be used to achieve the end result in the operational environment. This work cannot stop while a standard is being developed, balloted, approved, and adopted.

While standards are necessary for assuring continuity and consistency, the use of common data models by manufacturers for extracting data from medical devices must also evolve towards consistency. As I will show in Chapter 2, devices performing the same functions may even have different data definitions and some medical devices may not even produce the same results (that is, may produce variants of the same data or additional data that are not produced by medical

[29] "'Plug and Play' Connectivity Initiative Launched." AAMI News. Vol. 40, No. 1 January 2005.

devices even supporting similar functions). For instance, two mechanical ventilators may be queried for values related to respiratory rate. One ventilator may provide an inspiratory and expiratory value while another may only provide an average between the two values. The aforementioned standards describe recommended communications mechanisms and data models for medical devices. Yet, currently, devices specify differing syntax, communication rate, and even physical access mechanisms.

1.4 Data Integration: A First Look

Figure 1-6 illustrates the process flow involved in the basic storage of medical device data as they are collected manually by a clinician. This process flow is oftentimes referred to as a scenario—a descriptive sequence of events that capture the steps involved in achieving the goals of a use case, which can be described as an overall model of system and user interaction to achieve a specific goal.[30,31] While greatly simplified, the essence of the process is as follows.

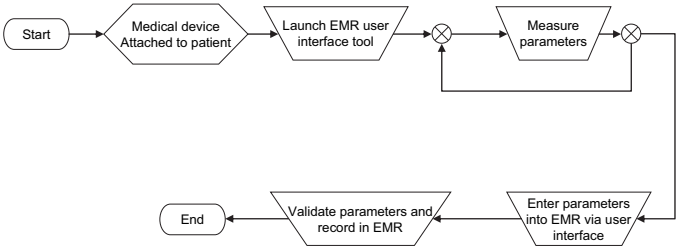

Figure 1-6 A simple functional representation of the manual data entry and EMR storage processes

In the example provided, an EMR tool—such as a system involving a user interface that allows on-line, manual interaction—provides the means for an allied health professional (typically, a physician, nurse, respiratory therapist, or technician) to enter data measurements obtained from a patient. For example, a user interface as part of a

[30] Allen Holub, "OO design process: Use cases, an introduction," IBM on-line article, 01 Dec 2000, http://www.ibm.com/developerworks/java/library/co-design5.html.

[31] http://en.wikipedia.org/wiki/Use_case.

medical application operating on a laptop computer would provide data entry fields for blood pressure, temperature, and pulse. The user "attaches" a medical device to a patient (such as a blood pressure cuff), launches an EMR user interface tool into which data can be manually entered, measures and reads the parameter using the medical device, enters the parameter into the user interface, validates the parameter to affirm that it is a true recording of the measurement from the medical device, and then transmits the newly measured value to the EMR for storage and later retrieval and review.

Within Figure 1-6, the summing junction is added to indicate that more than one parameter can be measured. Once all parameters are collected they are transmitted together as a finding to the EMR. In our simple example of blood pressure, pulse, and temperature, these three values, taken together, comprise the finding. They become part of the patient medical record once validated by a health professional. They define specific, quantitative physiological measurements of patient state at the time of measurement.

The finding establishes what I will refer to as a data "vector" of patient physiological findings, otherwise termed "vitals" measured on a particular date and at a particular time, *t*:

$$FindingsVector(t) = \{BP, HR, T, \cdots, t\}$$

where *BP* is patient blood pressure typically represented as the ratio of systolic and diastolic components (usually measured in millimeters of mercury—mmHg), *HR* is pulse or heart rate (measured in beats per minute), *T* is temperature (measured in either Celsius or Fahrenheit), and *t* is the date/time stamp of the measurements. Each value can be compared with normally accepted ranges to determine their compliance.

The process of measuring and reviewing these findings is part of findings validation—the process by which measurements are determined to be accurate, true, and representative of the patient physiological state at the time of measurement. The validation process is critical as it affirms the confidence in the validity of the measurements. Thus, while physiological measurement data are necessary, bad data are useless: a blood pressure measurement taken while a patient is moving about or agitated is not indicative of a resting value and is not a valid indicator of true resting blood pressure. This also applies to pulse measurement (unless a patient is undergoing a stress test). Hence, the patient's environment and status is important as it estab-

lishes the context in which the finding was measured. The user interface to the EMR is illustrated in the notional diagram of Figure 1-7.

The notional diagram depicts several user interface "tabs" located vertically on the left side of the user interface. This serves to illustrate that different forms of data may be stored in the EMR. Those shown are examples and include laboratory data (e.g., complete blood count or blood gas information) and patient medications.

The user interface is the entry point for findings. The clinician, via this point of entry, validates the findings. Once the clinician enters parameter values a method of entry and transmission is then provided ("Enter" button) to cause the results to be written to the EMR. Because the finding is entered manually, the health professional is afforded the opportunity to correct parameters as necessary in the event of error or changes to physiological state should invalidate a particular measurement.

Once the "Enter" button is pressed the process of storing the finding occurs when the data are transmitted to the EMR for storage and later retrieval and review. This completes the simple process of storage within the electronic medical record. Although greatly simplified,

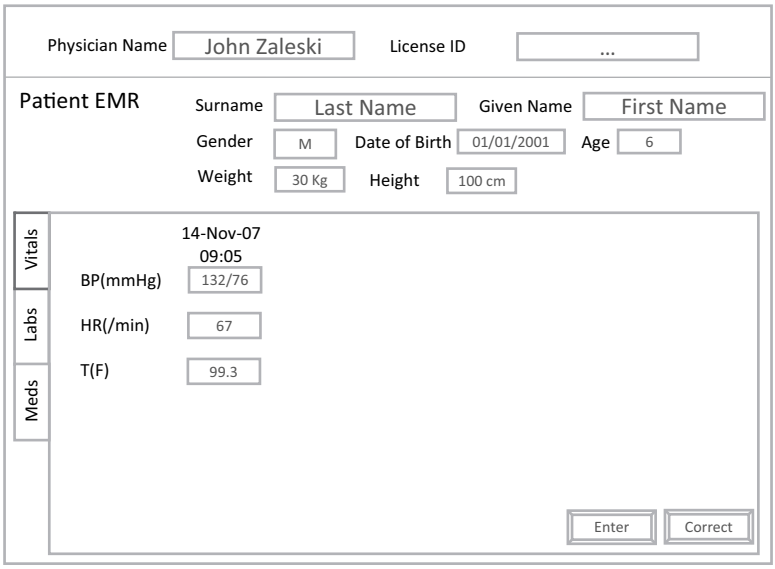

Figure 1-7 A notional depiction of a generic EMR user interface display into which parameters are entered manually by a health professional

this process serves to illustrate the essentials of data retrieval. Most electronic medical records and health information systems provide for much more complicated functionality.[32]

Various developers of electronic medical records and health information systems today provide the essential features described in the example here.[33] Accurate and timely medical record data recording is essential to clinical decision making. Hence, mechanisms for medical device data measurement and storage within the electronic medical record enable a better longitudinal understanding of a patient's state.

The process for viewing already-existing information within the clinical record in much simplified form is illustrated in Figure 1-8.

Figure 1-8 A simple functional diagram representing the process for retrieving patient findings from the EMR

A user interface tool provides the health professional with the ability to select a patient of interest from those within the EMR. The patient is selected and the findings are retrieved and displayed. Details have been left out of this process flow, including user authentication, which are necessary but outside the scope of this current discussion. Rather, this process is taken up at the point where the user has "logged" into the EMR system. Authentication and role-based access are assumed.

Once authenticated, the user may be provided with a census list of patients for whom the health professional is authorized to review. The user then selects one particular patient from within the census list. This triggers the retrieval of that particular patient's EMR. The medical record might depict the information in Figure 1-9 together with older results that can be reviewed in comparison, just as in the case of legacy paper charting of medical records. Figure 1-9 shows the comparison with a previously measured finding. The health professional can view the data historically and comparatively so as to obtain a view

[32] For example: Siemens Soarian® Clinicals Health Information System.

[33] Examples of developers of health information systems that feature robust electronic medical records include Cerner, Epic, GE, McKesson, Meditech and Siemens.

Figure 1-9 Update showing prior data stored in the EMR

of patient "state" change over time. In the instance shown here this patient's blood pressure rose over a period of approximately 5 weeks.

The purpose in showing this example is to establish a common basis for understanding the underlying processes and work flows inherent in measurement and recording of findings. The primary differences between paper chart recording and electronic recording has been reduced to the medium used for the task—that is, paper versus a virtual user interface and computer database access application. While paper charting has worked for decades as the standard for clinical charting, in the age of electronic media the process of automating the collection of medical device data is a natural extension.

In the case of simple medical charting in which discrete findings are recorded during the course of a patient visit, the data comprise only a small portion of the patient EMR. Recording such values manually becomes a trivial undertaking. In non-emergent environments in which patient findings need be recorded only on an ad-hoc basis and in limited quantity, entering measurements into an EMR for later retrieval and analysis is straightforward and demands very little time or effort on the part of the clinician either to enter parameter values initially or to retrieve and review them. The benefits of automating the process of findings collection become apparent when the scale is increased in terms of quantities of measurements and number of

parameters in a finding. Improved data security and accuracy are also realized by automating the medical device data collection process.

Consider the sampling of patient findings in Table 1-1. While not a complete list, these parameters make up a subset of those patient

Table 1-1 Sample patient findings recorded by health professional during a typical stay in an ICU

Finding Name	Symbol	Description	Typical Values (adults)
Systolic Pressure	SP	Arterial pressure measured during contraction	120-140 mmHg
Diastolic Pressure	DP	Arterial pressure measured at the end of the cardiac cycle	80-95 mmHg
Mean Arterial Pressure	MAP	Mean component of blood pressure, estimated as DP + 0.333 x (SP - DP)	90-110 mmHg
Stroke Volume	SV	Volume of blood pumped by heart in one contraction	40-70 ml/m^2
Cardiac Output	Q	Volume of blood pumped by heart in one minute	2.4-4 liters/ minute
Respiratory Rate	Resp	Quantity of inhalations and exhalations per minute	12-20 /min
Pulse	HR	Quantity of left ventricular contractions per minute	60-100 /min
Arterial pH	pH	Blood acidity / alkalinity index	7.33-7.49
Temperature	T	Body Temperature	36-38C
Inspired O2 Fraction	FiO2	Fraction of O2 contained in inspired gas (ventilated or masked patients)	21-100%
Tidal Volume	Vt	Volume of gas inspired in a single breath	5-7 ml/Kg
Minute Volume	Ve	Volume of gas inspired in a single minute	5-7 liters/ minute
O2 Saturation	SpO2, SaO2	Percentage of oxygenated hemoglobin, measured via pulse oximetry or blood gas	>95%
Positive End-Expiratory Pressure	PEEP	Residual pressure maintained in lungs at the end of spontaneous expiration, typically employed as a technique to maintain gas in lungs at end of expiration	5-10 cmH2O
End Tidal CO2	etCo2	Measure of carbon dioxide determined on the expiratory side of intubated and non-intubated patients (for instance) correlated to changes in cardiac output and used to estimate low cardiac output or to establish a measure of respiratory viability in mechanically ventilated patients.	35-45 mmHg

parameters monitored during a stay in an intensive care unit (ICU). These represent only the key cardiovascular and respiratory findings that are typically available from in-room patient monitors.[34]

Other findings include laboratory data, infusion pump data, patient intake and output fluid data (intake being partially comprised of infusion data), and notes recorded by allied health professionals (e.g.: physicians, nurses, respiratory therapists). In the past, findings were recorded in a paper flow sheet in the ICU. The process of recording patient vitals consumes a large quantity of nursing time as they are updated many times per hour. Standard nursing care involves monitoring devices for the purpose of collection, identification, assessment, and treatment of the patient. This can be a daunting task. A seemingly obvious answer to capturing the readily available data is to automate its collection by providing a means to transmit it directly into the electronic medical record. The quantity of data recorded becomes obvious especially as data collection frequency increases. This is apparent from Figure 1-10 in which the quantity of findings is shown parametrically against the data collection frequency, assuming the simple list of 15 findings shown in Table 1-1 is the base set of those to be recorded over a 24 hour period.

The amount of data that must be recorded becomes time consuming, requiring the complete attention of the health professional, even to the point of possibly impacting patient care. The frequency of data collection causes the nurse to focus on the role of a scribe for informa-

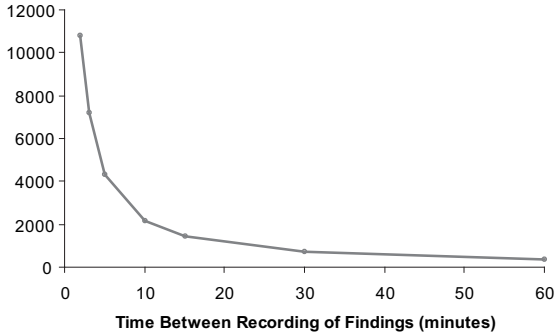

Figure 1-10 Quantity of findings recorded in the medical record over a 24 hour period as a function of collection frequency

[34] Paul L. Marino, The ICU Book, 2nd Edition, Williams & Wilkins, 1998; Pages 4, 271, 367, 470, 876.

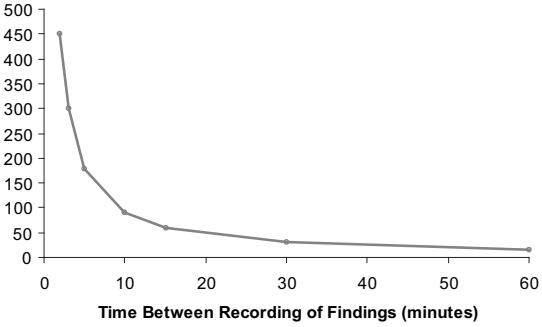

Figure 1-11 Data recorded on a typical patient over one hour (with 15 findings per entry)

tion readily available from bedside telemetry monitors, laboratory data, and ancillary equipment. Because this places a burden on the health professional, a balance must be achieved in the frequency with which data are recorded without dominating the valuable time which must be devoted to patient care. Typical data recording intervals are approximately once every 15 minutes, or 4 findings entries per hour. The quantity of data recorded in a single hour is shown in Figure 1-11.

Concerns also exist with recording accuracy. Erroneous recording of data, while unfortunate, does occur.

In a typical ICU, the process of recording findings occurs around the clock. Because of the manual interaction and the intensity of the ICU environment it becomes inevitable that errors can and do occur, especially in the process of transcribing findings from bedside monitors to paper records or an EMR. A hypothetical assessment of the number of errors in the recording of findings during a 24 hour stay in the ICU is illustrated by Figure 1-12. Given a 1% likelihood of recording a finding in error (i.e., a nurse records findings correctly and accurately 99% of the time) the number of errors expected to be recorded within the medical record is approximately 15. If, instead, a 5% likelihood of recording an error is the norm (i.e., a nurse records findings correctly and accurately 95% of the time) the number of errors expected to be recorded within the medical record is approximately 72. Mathematically, these may be expressed as:

$$E\{error = 1\% \mid 24hours\} = 14.4$$

$$E\{error = 5\% \mid 24hours\} = 72$$

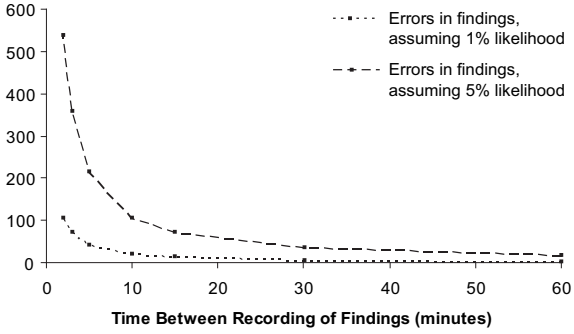

Figure 1-12 Expected error rate over a 24 hour period associated with the recording of findings versus recording interval

Neither of these expected values is necessarily an indication of what will absolutely occur, but rather what may occur in a typical encounter within the ICU with a patient over a normal 24 hour period. Of course, this is an estimate of error rate based only on the recording of findings. This does not take into account medication errors and other errors that may be independent of the analysis above—but which also have some correlation to errors in recording of medical device parameter data. The accurate recording of information is recognized in the industry and has been codified. Items 9 and 14 of the 30 safe practices[35] for improved healthcare identify explicitly under the subsection for Facilitating Information Transfer and Clear Communication state that:

> "...care information, especially changes in orders and new diagnostic information, [must be] transmitted in a timely and clearly understandable form to all of the patient's current health care providers who need that information to provide care..." and

> "...standardized protocols to prevent the occurrence of wrong-site or wrong-patient procedures [should be implemented]."

Errors can cost lives and money. The Institute of Medicine (IOM) report estimated the total cost of preventable adverse events to be approximately $17 billion[36]. These represented between 2% and 4%

[35] Agency for Healthcare Research and Quality, "30 Safe Practices for Better Health Care." AHRQ Publication No. 05-P007. Current as of March 2005.

[36] Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, editors, "To Err Is Human: Building a Safer Health System (2000)," Institute of Medicine & National Academy Press. Page 41.

of U.S. national health expenditures in 1996[37]. The report refers to a study of 1,047 patients admitted to two intensive care units at large teaching hospitals where 45.8% were "identified as having an adverse event" related to or defined as "situations in which an inappropriate decision was made when, at the time, [an] appropriate alternative could have been chosen."[38]

While the bulk of these errors are related to artifacts surrounding medication error administration, a subcategory within these was identified as inadequate monitoring and documenting patient information, such as findings and responses[39]. The point must be underscored that the root cause of errors being projected here is not only because of incorrect recording of data, but rather the entire process, or system, for monitoring the patient in general. Health professionals can be notified more rapidly when clinical information is available for analysis within the EMR. More timely, complete, and accurate information can translate into notifications to clinicians of adverse events whereby multiple care providers can review and be made cognizant of patient status. Such information has historically remained within the "data island" of the monitoring device or the subsystem responsible for directly interacting with the patient (e.g.: infusion pumps, bedside vitals monitors and mechanical ventilators, etc.).

Once data from these devices can be made available within the EMR, then care providers have a means of accessing this information from anywhere within the health enterprise, thereby enabling more thorough and complete review by individuals spanning the spectrum of care for any given patient (i.e., therapists, nurses, physicians). The need for device-level data integration becomes obvious especially in large healthcare enterprises wherein health professionals may be widely distributed and unable to be present at the bedside of a patient for extended periods of time. Intensive care units, medical/surgical wards, post-operative acute care units, operating theatres, emergency departments, and in certain situations, home-health environments all can benefit from medical device integration for these reasons.

The challenge remains taking information at the point of care and developing a universal mechanism for migrating it into the EMR, as illustrated in Figure 1-13. Many devices provide information (data)

[37] Ibid. Page 27.

[38] Ibid., page 31.

[39] Ibid., pages 36, 38.