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IT Matters, but Ideas Matter More

Richard D. Lang, EdD

In the May 2003 edition of the Harvard Business Review, Nicholas Carr stirred a nation of IT enthusiasts with his ringing admonition for businesses that rely on IT as a strategic imperative. Carr predicts that IT soon will become a commodity to be used as a utility in business, much like the “railroads and electricity.”

His premise is that once IT becomes prevalent, and everyone can deploy IT as a means to achieve the most efficient level of process, it is no longer strategic. In essence, if everyone can do it, there is no competitive advantage for using IT; there’s only a definite competitive disadvantage for not using it.

Most of us who have been toiling in this industry for the past two decades and more and have participated in its evolution, from the mighty monolithic iron-clad computer facilities to the latest state-of-the-art Internet-enabled personal micro-devices, may have had the same inkling as Mr. Carr but had never had the opportunity to express it in such a controversial manner. IT was never strategic—ideas are strategic!

Strategic ideas are not about technology. They are about solving business problems. It just so happens that we need IT to turn these ideas into reality. As technologists, our natural proclivity for gadgetry may have been our greatest impediment in achieving technological superiority in healthcare. Maybe we have been so enamored with technology that we have overlooked the ideas that spurred the very development of IT.

As we look forward to the future for our organizations, we might be more successful in implementing technology plans by first selling the idea, and then explaining how IT can make it happen.

Idea Number One—Ubiquitous Access

It would be great if all our customers could access any information that we process from any location in and out of our organizations. Physicians could access results from home and place orders accordingly. Suppliers could keep a close watch on critical supply levels and make proactive delivery schedules based on previously negotiated terms and conditions. Insurers could share critical information with providers, resulting in lower costs for back office billing and adjudication processes, as well as improved population-wide disease management programs and patient access. Patients could stay in touch with their care providers without having to schedule an office visit.

Internet technology has brought this idea to reality for many organizations. Technologies as simple as the Internet browser have enabled many organizations to morph legacy systems into Web-enabled, one-look, one-feel applications that are more intuitive to use. Web technology applications such as JAVA, XML, ASP, and Cold Fusion enable IT developers to link many disparate system databases together providing integrated access with a single Web-based query. VPNs, IP tunneling protocols and encryption routines enable customers to access privileged and sensitive information from outside the organization without compromising security.

The idea of ubiquitous access for better and more efficient decision-making is a strategic initiative that, if fully implemented, can improve an organization’s competitive advantage—with the help of IT.

Idea Number Two—Information Mobility

Healthcare organizations need to do more than just provide uniformed and ubiquitous IT access. The healthcare industry has one of the most mobile workforces in the country. Whether it involves the physician making rounds or the homecare nurse recording data from a visit, unthethered information processing is a key strategy for IT planners. The idea of mobile access is becoming more mature because of the continuous improvements in wireless networking technologies. With the introduction in 2000 of 802.11b as the standard wireless Ethernet networking technology, IT managers were able to expand the reach of mission-critical systems to mobile users at data transfer rates that are fast enough for most “character-based” applications.

As newer and faster protocols are developed, more bandwidth-intensive applications can be accessed by mobile users, and that ultimately will improve decision-making within organizations. In addition, IT managers are partnering with Internet Service Providers to expand wireless capabilities beyond the campus network to reach Internet-enabled PDAs and other mobile devices.

“Strategic ideas are not about technology. They are about solving business problems.”
However, wireless implementations do not come without challenges, with security being the main concern. Any wireless-ready device within range of an 802.11 access point can instantly connect with the network. Network planners must consider implementing wireless encryption protocol and other security mechanisms to secure the network. Nevertheless, organizations that combine the capabilities of wireless technology with sound policy and protection mechanisms can enable their mobile workforces to have unprecedented access to vital care data.

Idea Number Three—The Data Value Chain
Quick, efficient and timely data collection has long been a strategic priority for many industries. UPS, Wal-Mart and other companies owe much of their competitive superiority to their ability to track every transaction from its destination back to when and where it occurred.

Data loses value each second it goes unprocessed, and that’s particularly true in healthcare. Despite all the progress in systems integration and networking technologies, data collection has not significantly improved. For example, nurses still write vital signs and medication administration data by hand and save their notes for batch recording sessions—sometimes at the end of their shifts. Physicians still scribble orders and instructions on paper forms that are subsequently transferred to a more legible format for computer re-entry by nurses and clerks.

There are many reasons for the slow evolution of efficient and timely data collection. The sluggish development of intuitive and easy-to-use clinical software is one that comes to mind. But perhaps the most significant reason is that the IT industry hasn’t developed suitable and useable data collection devices near the point-of-entry. Bedside terminals, laptop cabinets and mobile PC carts have been deployed with varying success. All these devices require clinicians to use a keyboard, and many in the medical profession loathe typing. The IT industry has not done an adequate job in integrating voice and handwriting recognition into a uniformed lightweight data collection device that can be universally deployed in any care setting.

Although progress with bar code technology has become more pervasive, with the advent of the automated medication administration process, many more data-intensive modalities require improved data collection technology at the point of care. The introduction of tablet PCs and RFID technology, and the improvement of continuous speech recognition hold promise for the future. As the pen accuracy of the tablets improves, the cost of RFID tags declines and the voice-to-text error rate decreases, new data collection techniques inevitably will advance the value of information in healthcare.

The data value chain idea will become reality only when healthcare organizations demand that the IT industry develops integrated device technology that will suit the needs of all patient care professionals.

So Mr. Carr, in healthcare, IT still matters—and now more than ever. But it never mattered more than the ideas that provoked IT’s adoption. CEOs need to encourage more idea generation from the leaders in their organizations. They need to demand a
better explanation of why IT matters and how IT will bring these and other important ideas to reality.

The best ideas will drive the most interesting developments in IT. Healthcare leaders and government officials must continue to look for ways to provide better incentives for idea generation that promote IT as a way to create the most efficient and safe environment for patient care. That’s the best idea of all.

The Fall 2004 issue of the Journal of Healthcare Information Management (JHIM) contains a collection of special interest columns and articles that focus on New Technology Trends. In this issue, there are a number of examples, strategies, opinions and case studies that will be useful for organizations exploring how new technologies can solve critical business issues. Articles such as: The Power of Picture Archiving and Communication Systems: Strategic Hospital Considerations; Adding User-Friendliness and Ease of Implementation to Continuous Speech Recognition Technology; The Office of Advanced Technology: Providing Focus on the Piloting and Implementation of New Technology; and RFID & Bar Codes: Critical Importance in Enhancing Safe Patient Care provide useful knowledge about the development and application of new technology in healthcare.

In addition, special interest columns and articles offer the reader valuable information on the following topics: Information Security Strategies for Healthcare—Defining the Roadmap: Part 3: “New Stuff;” Physicians and Digital Medicine: Some Thoughts on the Future; JHIM Quick Study: Clinical Decision Support Systems; Pitfalls of Bar Code Medication Administration, as well as other original contributions.

Finally, I would like to thank the professional staff at HIMSS, the peer reviewers and the JHIM editorial review board for all the behind-the-scenes work that goes into producing each issue. JHIM continues to look for new ways to provide relevant, important, and useful information for healthcare professionals, academicians, and HIMSS members. If you have any comments or suggestions that could help us improve in any way, please feel free to e-mail me at: rdlang@know-power.com.

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New Stuff

Alton Brantley, MD, PhD

Edward de Bono, developer of lateral thinking, encourages stepping outside one’s present mindset to see alternatives. Technology offers many opportunities for such imaginings. However, it’s important that technology not become a solution in search of a problem. Looking at alternative technologies and applying them to current problems is an application of adoption and adaptation.

New technology generally has taken a decade to get from the laboratory to true first deployment. And generally, new technology’s cost is about five times that of the final market price. But there’s another kind of new technology development that has a shorter timeline and a lower cost. If technology has been developed according to the usual pattern in one field, the act of adoption and integration into a different field can be very quick and dramatic.

What follows are several developments that could be useful in healthcare delivery, along with scenarios for using them.

### Mesh networking

For the last decade, healthcare organizations have been deploying networks as a fixed communication technology because the standards were well-defined and the products sufficiently robust to use in critical situations. Because of high data volumes, fixed networks provide an essential backbone to information delivery. However, fixed networks are not sufficient in certain situations in which wireless networks are a better choice. For example, medical staff now can walk through hospital units, using portable computers with wireless cards to get access to medical information.

In some areas, however, such backbone networks may not be available, so an alternative would be useful. Adaptive on-demand networks and adaptive networking, known as AODV routing, assumes that each networked device will have the computing intelligence to find a device to talk to, and it uses that device as a relay to get to its final destination (see www.antd.nist.gov/wahn_home.shtml for more information). These networks dynamically adapt to load and to local resources to find ways to get information across a dynamically created set of points.

In a medical emergency such as a natural disaster, medical personnel can have equipment that is smart enough to connect dynamically to a network, enabling them to work as if they were linked via a more structured environment. This technology already is implemented and being used to provide network service in rural areas in England.

### Nanotechnology and nanomachines

Another outgrowth of the miniaturization efforts involving semiconductors has led to the development of smaller structures and potentially to the construction of useful devices at the microscopic level (see www.smalltimes.com). The construction of very small devices that become a “lab on a chip” and which can be mass-produced at low cost can revolutionize care, as it already has in some areas.
Diabetic care can be improved when patients get a home glucose monitoring system that enables them to measure their blood glucose, manage their medication and dietary adjustments, and notify their physician if problems occur. These devices have a simple disposable blood collection and reagent component that’s connected to a battery-powered special purpose computer and display.

The equivalent of a clinical laboratory on chips equipped with micromachines such as pumps, mixers and reagent containers specific to different studies could eliminate delays in completing laboratory studies. Deploying such devices would be valuable in emergency or rural settings, but hospitals also could achieve significant benefits, giving them an alternative to the expense of maintaining and staffing laboratories.

Motes

As semiconductor technology has advanced, it has focused on putting more power into each device and running faster. But there are interesting applications going in a different direction. Mote computing and “smart dust” use semiconductor technology to build small devices that have limited capabilities, use low power and can be deployed inexpensively.

Such devices now are inches in size and are shrinking to only a few millimeters square (see www.dust-inc.com). These small computers and radio transceivers consume miniscule amounts of power and are dedicated to particular functions. These devices already are being developed and deployed to monitor the environment and provide building security.

It’s not a great leap to think that these devices, coupled with the nanomachinery of a laboratory sensor, might become an implantable glucose monitor, able to periodically measure a patient’s glucose and communicate over a small local wireless network to an implanted infusion pump, which then could provide a controlled amount of infused insulin. By having the patient use a device connected to an external mesh network, the device can read the monitor’s history, and a record of the management can be obtained.

Electronic Ink

Today, some clinicians either carry laptop computers or first-generation tablet computers or push carts or rolling stands to which portable computers are attached. Even more prevalent are small handheld devices, such as personal digital assistants, or PDAs, that weigh no more than a few ounces and are capable of running for days to weeks before being recharged. But because of their small screen size, these handheld devices are not meeting clinicians’ needs.

For some time, MIT’s Media Laboratory has explored electronic ink, capable of producing high-resolution images on paper-thin surfaces (see www.eink.com). This technology now is beginning to appear in several settings, including handheld devices. Using electronic ink, handheld devices can be developed that have displays the size and resolution of a sheet of paper and yet are as light and inexpensive as a PDA. Because electronic ink consumes very little power, battery life will be far greater, and weight will be reduced.

A hospital could afford to buy a large number of these tablets and make them available to all caregivers for use as portable, rechargeable, wireless electronic medical charting devices. As clinicians leave for the day, they sign off and leave the devices to be recharged. Upon arrival, they pick up an available device, sign in and carry it throughout their shifts. Security devices would restrict their use to a single facility, minimizing loss through theft. Digital keys, with the public (known) key being installed in the device and the private (secret) key being provided to the facility, would provide HIPAA-compliant confidentiality and make the device useless if stolen.

Web Technology

Electronic ink, lightweight handheld technology, and mesh networking would provide a terminal device for clinical systems that deliver their information through Web technology. But Web technology has a lot of room to grow. Today’s client-server fat client applications are too maintenance-intensive, too inflexible and too impersonal to provide the ease of use and customization that an increasingly sophisticated professional clinical staff will accept.

Web technologies such as cascading style sheets, for example, enable the content of Web documents to be presented according to the needs and styles of individuals (for an example of their power, see www.csszengarden.com). The Document Object Model development standardization of javascript and java as
Universally available languages provide some local processing and user interface capabilities, but their distribution as Web services makes maintenance and upgrade issues evaporate.

**HDTV**

With the mandated market move to High Definition Television in the United States under way, the economics of high-resolution displays will rapidly improve. Soon, high-definition displays on large flat panels will be reasonably priced, and expensive displays or lower resolution video monitors will decline in use. For PACS systems, there will be no difference in what the radiologist views and what the clinician on the unit sees.

**One Possible Scenario**

The physician walks into the hospital, picks up an electronic ink tablet out of the rack in the doctor’s entryway, signs in with his retinal scan or fingerprint, registering the pad to him, and dons his radio frequency ID tag. This registration provides security for the device, enables secure communication, creates an electronic signature for the doctor and keeps it logged in under his name.

As he looks at the print resolution display, laid out in formats from his personal style sheet collection, he sees his patient information in a densely formatted but easily understood presentation. As he goes to the clinical unit, his location is noted electronically and a roster of his patients on that unit appears.

He enters one of his patient’s rooms and can view recent results from overnight monitoring, transmitted from various mote devices that measure physiologic and biochemical data. He requests some additional lab work, which will be performed by the nursing staff drawing blood and placing it on a slide that’s inserted into a handheld device she carries.

The results will be analyzed by the microlab on the slide and transmitted to the patient’s chart and to the doctor before he finishes rounds.

To view the patient’s films from that morning, the physician walks to a flat-panel display in the workroom, which senses the pad’s presence and offers to connect to it. The physician then calls up the films from the PACS system, using his pad as the control panel for the flat panel display connected to the PACS over the wired network. After the physician completes the review, he dictates a note into the pad, which is recorded and sent to a voice transcription server. It also is posted into the chart as a voice note until the physician reviews and signs the final note.

The advancement of medicine and medical technology can occur quickly if technology is adopted and incorporated in healthcare. Because these new technologies leverage developments that have other markets, they can provide improved care at a lower cost.

**About the Author**

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At my son's middle school, students sign on to their Citrix environment with a biometric (in this case, a thumb scan), even though most of our clinical applications use a simple username and password to authenticate users.

We all know the basics of AAA: authentication (who you are), as distinct from authorization (what you can do), supported by accounting (an audit trail and management of these rights and responsibilities). We all have memorized the levels of authentication as if they were mantras (what you know, such as a password; what you have, for example, a hardware token; what you are, such as a biometric). Many of us have struggled to make progress with proprietary technology and inadequate standards. And we all fear the legal, political, and societal implication of an inappropriate disclosure of information from one of our systems.

**Defining the Agenda**

My first column, in the Summer 2003 issue, identified a set of important information security realities for healthcare IT leaders. They are:

- Security starts with principles and policies.
- Continue your move to the Web.
- Keep your basic infrastructure healthy.
- If you’re not already doing so, start worrying about portable devices.
- In the end, it’s all about AAA (authentication, authorization, and accounting).

Last time, I talked about portable computing. In this column, I want to discuss the struggle with authentication, authorization and accounting.

**It's HIPAA, baby...**

The Spring 2004 JHIM had two wonderful articles about AAA and HIPAA. One described the Mayo Clinic’s struggle to deploy a single sign-on solution that did not unduly compromise the productivity of its workers while being unrealistically costly. The other reviewed key concepts about identity and access management, including the experience of Denver Health in securing its CPOE system.

Both articles chose to use HIPAA as the backdrop for these concerns, and rightly so. HIPAA legislation has not only pinpointed the exposure caused by these issues, but it has raised the stakes in terms of penalties for non-compliance and society’s sensitivity to inappropriate disclosure.

Although these issues existed long before HIPAA was born, the somewhat coincidental coming-of-age of the Internet and mass-consumption of computing in the United States has raised the level of risk to many organizations. Broadband access has lead to additional exposures because persistent connections enable the “bad guys” to automate attacks more readily while exposing inadequately protected homes and small business partners to intrusion. Broadband penetration in the US surged to more than 40 percent, according to the January 2004 issue of Broadband Report.1

**You think you've got it bad...**

In an earlier article in the Spring 2004 issue of JHIM, I tried to find some silver lining within the reality of heterogeneous computing environments within our organizations. A more heterogeneous computing environment enables us to distribute risk over a number of products and players, as long as we have the capability to make compatible choices.

While this pragmatism may not be an obstacle in developing and implementing an organization’s overall security architecture, uniformity leads to a more practical and supportable outcome when it comes to AAA. The more uniform the desktop, the more consistent the application architecture, and the more coherent the network, the easier it is to acquire and deploy an AAA solution.

Our concept of “user” is expanding rapidly. Hospitals are offering more online access to services, physicians, and specialties. Academic medical
centers are offering more educational content for aspiring health professionals and the public at large. Insurers aspire to be more efficient and customer-focused by providing access to information around-the-clock. But how do we incorporate these new, often transient users into our AAA plans?

There have been a number of efforts to provide more global AAA infrastructures, even though they have met with only limited success. Early adopters, especially in academic settings, looked to Kerberos as their standard, but it has yielded only a limited number of compatible applications and certainly is not for the meek. Public Key Infrastructure is touted as the underpinning of a pervasive authentication and authorization system, especially over the Internet. It has proven difficult to set up and costly to maintain and administer, and it has failed to provide a value proposition to certificate authorities and others who hoped to profit from its adoption and proliferation.

Other efforts aimed at developing the notion of a “federated identity” over the Internet also have had only very limited success (for a private sector example, check out the Liberty Alliance Project; to see what the government is up to, look at the Federal Bridge Project). Even Microsoft’s Passport initiative does not seem to have reached nearly as many users as they had hoped.

**Full steam ahead?**

So where do we go from here? **Pilot, pilot, pilot.** Healthcare organizations have to take this stuff for a test drive, simultaneously evaluating the robustness of the technology, the implications for administration, and end-users’ experiences. These three perspectives may be at odds with each other and represent tradeoffs to be managed. Findings should be documented and discussed carefully with users, management, and technical staff.

“**The more narrowly an organization defines its user population, the more success it will likely have in setting up a manageable implementation.**”

**Recognize the limitations.** Much of this technology is still in its infancy. The more narrowly an organization defines its user population, the more success it will likely have in setting up a manageable implementation.

Administrators can consult with industry analysts, but they can’t predict the future either.

**Look to traditional vendors, but keep an open mind.** While traditional Network Operating System (NOS), database or Web server vendors may offer compelling solutions, keep an open mind to alternatives that may interoperate better as pilot implementations expand to include other users and potentially other platforms.

This isn’t going to be easy. As we get more tangled in the Web, our users’ expectations for seamless integration increase, and mobility and wireless computing get more pervasive, but not necessarily more secure.

Sometimes, I try to gauge the future of technology through my 12-year-old’s eyes, and he’s usually on target: “Why can’t this stuff just work the same way every day?”; “Why do I have so many passwords?”; “Faster, faster, faster!” Our challenge as IT professionals is to make it all seem as effortless as my son expects it to be. Maybe one day, he’ll be there to help.

**About the Author**

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**References**

Back in 1991, the Institute of Medicine (IOM) issued a report suggesting that clinical decision support systems (or CDSS), as an element of the electronic medical record, would be universally adopted by the healthcare industry by 2001 (there’s no end to some people’s mad optimism). Last year, the IOM revisited that prediction and now estimates gradual adoption of CDSS by 2010.1 Not to be outdone in its timidity, the Bush Administration recently called for the creation of a universal electronic patient record by 2014. These targets indicate a far more modest expectation of EMR and CDSS proliferation, at least in the near term.

What has dampened the IOM, the Bush Administration, and the industry’s ardor to establish the EMR and CDSS as must-have clinical tools? It’s the usual suspects, mainly technology hurdles, physician pushback, data quality, and return on investment (ROI). Hopefully, the industry has pushed past the peak of the hype cycle and now can take a more realistic approach to designing and deploying these technologies.

CDSS consists of a variety of elements, ranging from simple alert systems to sophisticated longitudinal administrative and clinical reporting applications. In more advanced configurations, CDSS systems include additional functionality, such as ad hoc querying, diagnostic assistance, and therapy critiquing. But at a minimum, CDSS employs evidence-based or statistically significant best-practice guidelines and alerts to promote better clinical choices and outcomes.

Benefits of CDSS fall into three main categories: patient safety (reduced medical errors and improved ordering); quality of care (access to protocols and guidelines and up-to-date clinical evidence, and improved patient satisfaction); and workflow efficiencies (streamlined processes and reductions in duplication).2

There are two types of CDSS: rules-based and normative. Rules-based CDSS compares actual to evidence- or research-based best-practice data, said Kavah Safavi, medical director of Solucient Inc. Normative models compare actual to peer-group performance, where no accepted best-practice data is available, and employs expert systems to stratify results, for example, into different percentile levels. Put another way, the rules-based model relies on “if-then” type algorithms and associations referenced to a library of medical information; the normative model employs expert systems to make clinical inferences about the entire patient record.

Of the two models, evidence-based decision support applications are considered to be easier to design and deploy, although these tools are sometimes considered too rigid, too dated and non-intuitive. Neither methodology is the proven leader at this time, but as data capture in healthcare takes advantage of standard data formats and improved data access through system integration, evidence-based tools will grow in popularity, said Kevin Fickenscher, MD, National Director of CSC’s Clinical Transformation Practice. In addition to better-quality data, data mining tools tied to decision support will drive better decisions, better outcomes and improved synthesis of clinical information, he added.

Criticisms of CDSS

In theory, CDSS performs a vital service throughout the continuum of care, including screening and prevention; diagnosis and pre-diagnosis management; indications for use of procedures and interventions; appropriate use of technologies, tests, and medications; and care of specific clinical conditions.3 However, in the real world, CDSS hasn’t lived up to this billing, and in fact has been the subject of industry criticism for a variety of reasons.

For example, the rules-based model is only as effective as the relevance and frequency of the rules being triggered within the CDSS
system. Rules that have been over-designed actually can interfere with clinical processes, says Joe Poats, vice president and health technology leader for Cap Gemini. He notes that if CDSS is set up with too many rules, then alerts fire too frequently, ordering is delayed, and clinicians start looking for ways to work around the tool.

Clinicians complain that CDSS tools often are populated with general, textbook-type information that is not actionable, or contains too much information that distracts them and serves as a nuisance that actually interferes with clinical decision making, leading to non-compliance.

Finally, some CDSS systems simply don’t blend well into care processes and are perceived as a source of additional work by already busy clinicians. In some instances, the tools are so complicated that clinicians can’t use them effectively. Poor training is one culprit, but multi-layered, time-consuming input and query functions are also to blame.

There are additional technology and process obstacles. The CDSS are often hamstrung by a number of limiting factors, including inconsistent system architectures, insufficient bandwidth, non-standard deficient data, incompatible workflows, and a lack of user-friendliness. CDSS also have been the victim of flawed strategies and deployments. Too often, decision support has been architected and executed only partially, resulting in limited functionality and unmet expectations. Failing to adequately gain clinicians support—by addressing political, workflow, ROI and ease of use issues—practically guarantees failure.

**Ingredients for success**

For CDSS to truly work, three critical components must be in place, said Sumit Nagpal, president of Wellogic Inc. First, there must be a standardized, multi-sourced, persistent EHR. Second, data must be captured in real-time from all points within the healthcare continuum, such as the bedside, office, and lab. Finally, the data must be formatted in a user-friendly presentation structure, such as a dashboard.

Getting the right data into the right format at the right time is no small order and requires the convergence of a number of preconditions. Non-standard deficient data, incompatible workflows, and a lack of user-friendliness are also to blame.

There are additional technology and process obstacles. The CDSS are often hamstrung by a number of limiting factors, including inconsistent system architectures, insufficient bandwidth, non-standard deficient data, incompatible workflows, and a lack of user-friendliness. CDSS also have been the victim of flawed strategies and deployments. Too often, decision support has been architected and executed only partially, resulting in limited functionality and unmet expectations. Failing to adequately gain clinicians support—by addressing political, workflow, ROI and ease of use issues—practically guarantees failure.

**Ingredients for success**

For CDSS to truly work, three critical components must be in place, proprietary applications, systems integration, and standardized data structures are just a start. Organizations planning to implement CDSS need to go further and conceptualize the challenge from both a technical and clinical vantage point.

The impact of CDSS tools and systems on clinical quality, patient safety, and workflow efficiency is generally accepted, so the question of how do we reach the tipping point of CDSS adoption really depends on creating the environment in which data collection, interpretation, and distribution occur in the most rapid, transparent, and actionable ways.

To achieve the total integration of data envisioned by CDSS, data “feeder systems” must be vendor-neutral, with open architectures, and provide clinical content of all descriptions (including text, image, and voice). Protocols and guidelines, reports, test results, formularies, and more should be available to clinicians regardless of the systems they are running or the EMR and CDSS tools they have deployed.

Structured vocabularies and a common language will streamline the adoption of CDSS in multiple-vendor systems and remove the inherent issue of interoperability. That’s easier said than done; standards development is resource-intensive and can take years to complete. Of course, the common language issue immediately conjures an image of SNOMED or a similar universal terminology, but CDSS systems also must rely, for the foreseeable future anyway, on additional standards, such as HL7 (for data interchange) and DICOM (images) until language cross-mappings are fully completed.

To no small extent, the future of CDSS is intertwined with that of the EMR. As analytics supplant reporting as the marquee value proposition of the EMR, CDSS will become an intrinsic element of EMR systems.

Intuitive CDSS systems will trigger alerts and advice without prompting. For instance, tools may be activated within the EMR application and can be triggered automatically as data is entered into the electronic record. Artificial intelligence tools are being developed in tandem with CDSS to provide clinicians with alerts and advice concerning planned treatments and to alert clinicians about detected trends or indications consistent with a patient’s condition. The delicate balance that must be struck is between having the right data at the right time and structurally having too much data.
Step Approach

From a strategy standpoint, physician resistance and workflow disruption issues will be addressed by adopting a strategy that defines what is important to clinicians and by introducing tools that serve as the foundation of more ambitious, more robust CDSS.

As the urgency of standard nomenclatures, data formats, and language becomes more established and addressed, issues related to interoperability will recede. To remove the access and integration issues of data collection, CDSS are using browser technology to create a central hub for the collection of disparate data systems and then to create reports from the collective inventory of data elements. Likewise, as Web-based CDSS architectures introduce these tools to a wider audience, vendors will become more interested in conforming to neutral standards.

Clinical and financial alerts and recommendations will become increasingly intertwined, both as a reporting and monitoring tool and to support pay-for-performance reimbursement schemes and incentive programs.

Standardization of data sets and medical vocabularies is being actively pursued, and that will ultimately unify the source and output processing of CDSS information. Analytic tools such as artificial intelligence only now are being developed to refine the rules-setting process, establish better query and research parameters, and produce better outcomes analysis. With each of these instruments in development or already in play, it’s likely that the IOM prediction of “gradual CDSS adoption by 2010” may be unduly conservative.

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References
Hospitals seem to be leading the way toward the digital conversion of clinical process. There are many reasons for this: capital access, public visibility, management leadership, and IT infrastructure support.

However, as those that have reached the density of applications to permit computerized provider order entry (CPOE) have already learned, sooner or later, all hospitals and health systems need physician leadership and broad medical staff buy-in to successfully implement digital medicine. Achieving physician buy-in and penetrating the largely paper- and telephone-driven world of private physician practice are the twin constraints standing in the way of a seamless, paperless clinical environment.

With the exception of patients admitted for emergency care, the typical patient encounter with the health system begins and probably ends outside the hospital’s information domain—a physician’s office. Although a number of hospitals (governmental hospitals such as the Veterans Administration and Defense Department facilities) employ their physicians directly, the vast majority of facilities either rely on the patronage of tightly linked physician groups organized separate from the hospital (group-model health plans like Kaiser, faculty practice plans affiliated with teaching hospitals, and the like) or depend on the voluntary admitting behavior of physicians who practice privately.

The reason this is a constraint in a digital world is that vital information hospitals need about patients, such as their current medications and results of the diagnostic workup that preceded the patients’ referral to the hospital, remain in the physicians’ information domain, locked up in their paper record systems. If physicians cannot digitize this information in a form that can be accessed by and added into the hospital’s clinical information systems, it must be duplicatively gathered, either from patient memory or through costly retesting.

It is not impossible to envision a world in about 10 years where the hospital clinical information domain is almost completely digital, but the physician domain remains paper- and telephone-based, electronically inaccessible not only to hospitals but also to physicians who are away from their offices. Solving this problem requires thinking about a messy and complex issue: the boundaries between physician and hospital spheres and how it is likely to change in the ensuing decade.

Relationships at a Low Ebb

Hospital relations with physician practices have been exceptionally stormy during the past 10 years for multiple reasons. Among teaching facilities, hospitals have been under intense pressure to increase subsidies to medical schools to offset payment reductions from Medicare and Medicaid, and increasing numbers of patients whose care is uncompensated. In some cases, these pressures have been sufficiently intense to result in a switch in hospital affiliation and attendant mass disruption of referral patterns.

But in countless other instances, hospitals and health systems sought to use medical practice acquisition or captive group formation to consolidate ownership of physician practices to position themselves as sole-source contractors with health plans under capitation. Unfortunately, health plan growth did not reward this strategy. Growth in health plan enrollment tilted toward open access, broad network models such as PPOs and point-of-service plans and punished closed-access, captive physician network arrangements.

Although there have been a few examples of success, most of these efforts were both financial and political disasters for hospitals, resulting not only in huge economic losses but contentious relations with non-acquired physicians on the medical staff. Many physicians have
subsequently abandoned their hospitals emotionally or physically, seeking to build physician-owned or operated boutique ambulatory services or specialty hospitals.

Risks to Hospitals

Hospitals are profoundly at risk in the current medical practice climate. The 24-hour service obligations imposed on hospitals by the Emergency Medical Treatment and Active Labor Act (EMTALA) require hospitals to provide specialty physician coverage.

Specialists such as neurosurgeons and orthopedists who must provide call coverage to emergency departments are demanding huge practice subsidies from hospitals that are forced to do so to comply with EMTALA mandates. Radiology and anesthesia groups whose services are vital to core hospital services are requesting increased subsidies to enable them to recruit and retain young specialists. Hospitals are also being shaken down for increased practice subsidies by cardiologists and cardiac surgeons to prevent them from moving their practices to freestanding specialty hospitals.

Finally, to respond to pressures from health plans and employer groups such as The Leapfrog Group, an increasing number of hospitals are hiring full-time specialists not only to manage intensive care patients but also are employing intensivists and hospitalists to manage acute inpatients. Some CEOs believe that the cost of subsidies to physicians is their most rapidly growing and least controllable expense.

Where Is the Relationship Headed?

As an author, I often wrote articles opposing physician practice acquisitions by hospitals. In a 1993 article entitled “Driving the Nitroglycerin Truck,” I predicted both economic losses and political instability stemming from this approach. However, in light of the tight supply and prospective mass retirements of physician specialists in the coming decade, I see the division of labor between hospitals and physicians changing in the next decade, with profound implications for clinical IT.

For decades, the pediatric community has maintained a different relationship between physicians who cared for children and the children’s hospital. Specifically, most specialists such as pediatric oncologists, cardiologists, and others who render 24-hour-a-day care in children’s hospitals were employed by or practiced inside hospitals, while primary practicing pediatricians and family practitioners were in independent office-based practice. It’s possible to envision a similar division of labor in adult medicine, where primary-based practice and elective specialty care (plastic surgery, ophthalmology, sports medicine) is office-based, and critical care and 24-hour physician practice (intensive care medicine, cardiology, high-risk pediatrics and obstetrics, anesthesia, trauma surgery, intensivists, hospitalists, and the like) are hospital-based.

A couple of possible economic relationships may emerge in this critical care, 24-hour medicine world. One is outsourced relationships, in which hospitals enter contracts with national firms such as Pediatrix or Sheridan Healthcare to supply physician coverage. Another is an employment relationship in which the specialists are either employed by the hospital or work in hospital-owned physician groups. Either way, tighter linkages between physicians’ records and hospitals’ records will be essential to assuring seamless coordination of the care process.

CIO Planning Assumptions

Why is this of relevance to CIOs? Because the legacy of suspicion and mistrust from the unsuccessful invasion of the physician sphere in the last decade colors any strategic movement hospitals may make into the physician space. Physicians today are an angry lot—angry at health plans, plaintiffs’ attorneys, the government, and pharmaceutical companies, as well as hospitals. Many physicians more than 50-years-old are literally counting the months until they can retire, hoping that a sustained resurgence in equity markets will restore the value of their retirement accounts. It’s not a high priority for these physicians to renovate the information systems (and connectivity to hospitals) that undergird practices they plan to soon abandon.

The transition to a more tightly coordinated relationship with a hospital’s critical care services is likely to be painful, highly political, and highly individual to a given hospital or system and its community. To impose a template on this relationship
without considering local circumstances and personalities is to court a repetition of the 1990’s practice acquisition debacle.

However, CIOs contemplating physician connectivity strategies in relation to CPOE implementation should be aware that the ground might well shift underneath them in the five to seven years it will likely require to complete this transition. Designing compatible information systems will be easier for employed specialists than for freestanding independent practitioners. Coordination with hospitals’ senior management and medical staff leadership will be crucial to ensure that IT investments yield the anticipated improvement in information flow to support physician practice.

If hospitals have no choice but to subsidize independent physician practices, they should give some thought to requiring that physicians invest some of this hospital supplied cash flow in renovating their office-based clinical information systems and assuring two-way connection with the hospital’s digital clinical systems. Hospitals must explore how they can assist in this process without running afoul of Medicare fraud and abuse laws. If hospitals are required to subsidize private-practicing specialists, they should ask physicians, in return, to more tightly link their information domains with the hospital, so that vital information about their patients can move freely between office and hospital to assure safe patient care.

Hospitals must assume that physicians will require technical assistance in making the digital leap. To do this, they should design connectivity strategies that reward physicians willing to invest time and scarce capital in digitizing their office-based clinical operations. During the next 10 years, hospitals must work with their medical staffs to leverage information technology to make medical practice easier and safer.

Patients will notice a difference in reduced duplicative information requests and reduced duplication of tests, the cost of which they will bear in increasing amounts in future years.

About the Author

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Investing in bar coding systems to enable nurses to administer medications to patients in an inpatient setting is a proven, feasible way to decrease medication errors. On February 25, 2004, the FDA issued “Bar Code Label Requirements for Human Drug Products and Biological Products.” With the primary goal of improving patient safety at the point of care, the FDA estimates that “the bar-code rule, once implemented, will result in more than 500,000 fewer adverse events over the next 20 years, thereby reducing medical errors by 50 percent for an estimated grand total of $93 billion in savings.”

As of March 15, 2004, fewer than 2 percent of hospitals have implemented bedside bar coding systems; the predicted growth is 80 percent during the next three to five years. Those that have already implemented a bar coding system, such as the Department of Veterans Affairs, have credited the technology with a 74 percent reduction in problems caused by the wrong medication being administered and a 91 percent reduction in “wrong-patient” errors from 1998 to 2003.

The final report of the 2004 Annual HIMSS Leadership Survey placed a high priority, for the second year in a row, on the implementation of technology to reduce medical errors and promote patient safety. “Bar coded medication management was the IT application cited most frequently by survey respondents as being the healthcare application area they considered to be important to their organization in the next two years.”

Knowing this, CIOs at healthcare organizations may be anxious to recommend the purchase and implementation of bar code technology, and they may quickly get upper management’s unanimous approval. Problem solved.

Not so fast, oh ye of technological faith. There are many potential pitfalls a bar coding system may encounter. If these problems can be identified before implementation, they can be avoided, thereby increasing successful utilization of this technology and attaining a positive ROI, in terms of reducing medical errors.

Focus Areas

Here are several areas that need careful attention before implementation.

Workload. Hospitals are feeling the pinch of the budget crunch at the same time that they’re facing nursing staff shortages and high inpatient volumes. Ultimately, this leads to understaffed wards with overworked nurses. The last thing nurses want is another item to add to their “to-do” list. Additional unwelcome side effects related to this technology could include an eight- to 10-week learning curve, unwillingness to change, the lack of portability of the equipment, and IT glitches ranging from problems with hardware or software to poor wireless connectivity.

Danville (VA) Regional Health System was an early beta test site for a bar coding medication administration product. In reporting on the experience in October 2000, senior clinical analyst Patsy Sublett, MSN, said, “The biggest hurdle for many nurses was getting into the habit of wheeling the wireless computers into their patients’ rooms every time they administered medication. Ultimately, there was only an eight- to 10-week learning curve for the nursing staff to become comfortable with the system, thanks to ongoing training and an atmosphere of candid dialogue among nurses and managers.”

Complexity. To make these systems both portable and able to work on a wireless network, they typically involve a rolling kiosk mounted with a PC, monitor, battery, wireless network capability, locked drawers for medications, and a wireless bar code scanner. The portability enables the nursing staff to move from room to room, dispensing the medications with instant medical record updates after the patient’s bar code and the medication are scanned.

While this sounds simple enough,
the kiosks are usually large and physically cumbersome to move around when nurses are rushing from room to room. The more drawers, medications and battery packs are stored in the kiosks, the heavier they become. Additionally, IT glitches, such as problems with battery life, wireless connectivity, dead zones within wireless access points, and PC hardware or software malfunctions are serious concerns, because a problem with any of these will make the kiosk non-functional. Furthermore, never underestimate the power of a disgruntled user to sabotage the kiosks so they can’t be used.

**Operations.** Clearly, pharmacy departments play a huge role in the bar coding workflow. The type of pharmacy dispensing system an organization has in place will greatly dictate how the inpatient wards receive the medication for their patients on a daily basis.

In an ideal scenario, the pharmacy department would deliver the trays for the kiosk—already stocked with the patients’ daily medications—to each floor. Nurses then would arrive ready to start seeing patients.

Another scenario that doesn’t work well is when a pharmacy department advances medication dispensing technology to the point where inpatient nurses wind up taking on the tasks that pharmacists used to perform, such as taking the medications out of the medication dispensing system on their floor and then equipping the trays before loading them into the kiosk. This can create a workflow bottleneck if nurses have to wait their turn in line at the dispensing station to receive the medication stock.

The directors of both nursing and pharmacy must be aware of these potential scenarios when working with IT to evaluate systems and how they will work together.

**Beating the System**

Nurses know that medications must be delivered in a timely manner throughout the course of the day. Regardless of the medium in which the medications are delivered to the patients’ rooms, the whole objective is to get the right medication and the right dosage to the right patient at the right time.

> The type of pharmacy dispensing system an organization has in place will greatly dictate how the inpatient wards receive the medication for their patients on a daily basis.

Nurses don’t welcome the additional hurdle of changing to a new system that causes them to do more work and become less efficient throughout their workday. To maintain their efficiency and avoid a poor performance evaluation, some nurses may be tempted to look for alternative ways to keep the system updated and the patients medicated.

A workaround scenario might involve a nurse scanning all the medications into the system at the nurses’ station, giving the appearance that the right drug has been administered to the right patient. In addition, nurses may be able to print duplicate bar coded wristbands at the nurses’ station and scan them just as they would if they were with the patient at the bedside.

In fact, the nurse can avoid the scanner all together by manually entering both the medication’s internal entry number (IEN) and the patient’s social security number or unique patient identifier. After the pre-scans or manual entries of both the medications and wristbands are complete, the nurse then walks down the hall and administers the medications to the patient without ever touching the kiosk or scanning a patient’s wristband at the bedside.

These and other potential workaround scenarios defeat the whole purpose of bar coding medication administration, which is to reduce medical errors. The abuse of the system and failure to properly use bar coding technology can lead to more medication errors than not using it.

For example, if a medication is late, the bar coding system may force a nurse to enter an explanation for the delay. After taking time to enter this information, the nurse then is even further behind schedule. This additional problem, coupled with workaround tactics, could trap the nurse in an endless cycle of playing catch-up, and mistakes could occur as a result of implementing a bar coding system that wouldn’t have occurred otherwise. Thus, the organization’s ROI is tremendously skewed and utterly destroyed as a result of operational issues coupled with users’ non-acceptance of the proper utilization of the technology.

Finally, it’s difficult to discover when such workarounds are being used unless an obvious significant instance, such as a medical error, is directly linked to a specific event that clearly would have been prevented had the system been used properly.
Currently, the best way to discover the abuse is to actually observe it and report it to the nurse manager on the floor. Most bar code software isn’t programmed to detect workarounds and doesn’t have the ability to easily provide information, in terms of performing audits focusing on multiple patients being administered multiple medications within time frames that are not humanly possible. While audits can be conducted at the database level to identify individuals who use workarounds, they can be very time- and labor-intensive, in terms of manpower, as well as a burden on system resources that must support the rest of the hospital.

Administrative actions that may encourage discovery would be to implement hospital policies that mandate nursing services operate using the bar coding technology appropriately. In addition, the chief of nursing services must instill this concept in nurse managers. The direct-line nurse managers in turn can educate, provide proper training and tie proper utilization of the bar coding system into the nursing performance appraisal, taking into consideration operational workflow conditions. Tracking medication errors and tracing them back to the nurse who signed for the medications is another possible checkpoint; however, this would have to be accomplished retrospectively.

**Summary**

Beating the system to maximize efficiency will yield no positive return on a bar code investment, in terms of reducing medical errors. The critical success factor in the bar coding scenario is that of operational effectiveness. By shifting the nurses’ focus from that of efficiency to that of operational effectiveness, the use of bar coding medication technology will reduce medication errors.

CIOs looking for a quick fix to reducing medication errors through the use of bar coding technology need to understand that the technology alone won’t solve their problem. Rather, it’s the balance between operational efficiency and effectiveness among multiple departments working together, both vertically and horizontally, which will yield the greatest ROI.

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**References**


The Power of Picture Archiving and Communication Systems: Strategic Hospital Considerations

Carole L. Brown, MS, MBA, and Sophie Paule Howarth, MS, MBA

ABSTRACT

As healthcare information becomes more digitized, hospitals are adopting critical diagnostic tools to improve patient care decisions, while reducing errors and increasing overall efficiency. According to Radiology (2000), 75 percent of the imaging procedures performed in 1995 used devices that were not available in 1970. Today, imaging applications continue to move from research and development into common use each year. With regard to digital imaging, Picture Archiving and Communication Systems (PACS) perhaps have changed radiology more than any other application in the past few decades. Once regarded as “nice-to-have-but-too-expensive” devices, PACS are rapidly moving into the mainstream of “must-have” solutions for quality-conscious and forward-thinking hospital CEOs. However, before widespread implementation of PACS can occur, several critical factors should be taken into consideration.

KEYWORDS

- Radiology information systems
- Competitive bidding
- Organizational culture
- Competitive bidding
- Diffusion of innovation
- Hospital information systems
- Confidentiality
- System integration
- Computer security
- Multidisciplinary management teams

Introduction

While consumers enjoy the highest-quality medical care in the world, the statistics surrounding patient safety are still beyond belief. Last year, risk managers surveyed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in 2001 reported that about 70 percent of hospitals have increased the number of medical error disclosures in the past two years.

Despite the media attention received from this report, diagnostic and technical errors continue to account for a disturbing percentage of medical errors. For example, according to the Institute of Medicine, oversight or delay in diagnosis, failure to employ indicated tests, use of outdated tests or therapy, and equipment and systems failure remain among the most recognizable category of medical errors reported in U.S. hospitals.

Innovative PACS Imperatives

In 2001, the Institute of Medicine published its second report on quality in the nation’s healthcare system, entitled “Crossing the Quality Chasm—A New Health System for the 21st Century.” Its study indicated that the “development and
application of more sophisticated information technology systems are essential to enhance quality and improve efficiency of current IT infrastructure capable of supporting all facets of healthcare delivery. Fueled by the desire to reduce medical errors and improve clinical work processes, the healthcare information technology market has increased considerably in the past decade. According to the 2003 Dorenfest Integrated Health Care Delivery System Database, patient safety issues are paramount in the minds of senior management teams. Dorenfest’s data collection method consisted of demographic information prepared by its market research associates, who used the data to telephone vice presidents of marketing or planning and CEOs at various health delivery systems around the country. Patient safety issues led executives to resort to IT software solutions to help reduce medical errors throughout their hospitals.

The results concluded that picture archiving communication systems have shown the most dramatic growth of more than 30 percent of the hospitals interviewed, and more than half of these hospitals purchased PACS within the past two years. According to Dorenfest, during the next two years, another 40 percent of the nation’s hospitals will be purchasing PACS. Although this study supports the benefits of PACS, there are several factors that should be taken into consideration before hospital executives decide on the role PACS will play in realizing their strategic initiatives.

PACS are electronic and ideally filmless information systems for acquiring, sorting, transporting, storing, and electronically displaying medical images. Its acronym can be more clearly defined as:

- **Picture** viewing at diagnostic, reporting, consulting and remote workstations.
- **Archiving** on magnetic media or spinning disk, using short- or long-term storage devices.
- **Communications** using local or wide area networks or public communication services.
- **Systems** that include modality interfaces and gateways to healthcare facility and departmental information systems, offering an integrated system to the user.

Implementing a PACS generally involves the integration of a Radiology Information System (RIS) and Hospital Information System (HIS). A PACS is deployed to give simultaneous access to diagnostic images without regard to the viewer’s geographic location. Physicians make orders on a workstation and can acquire clinical data of patients anytime.

A PACS is an important part of the HIS. Through the interconnection between the PACS and workstation, radiologists may acquire the basic information about patients from a workstation; at the same time, physicians will view the medical images and diagnosis reports of these patients.

By strict control of license permission, information from the PACS may be shared at different levels by every physician. Limited access in the sharing of patient records is allowed through a password-activated user profile. This approach determines what information is displayed on a monitor and what work lists may be accessed by a user. For example, the profiles of referring physicians may restrict them to seeing only a database subset of their own patients.

Regulations outlined in the Health Insurance Portability and Accountability Act (HIPAA) require that records and the equipment housing patient records be physically safeguarded, that the network and computer security measures protect electronic files, and that administrative procedures to guard confidentiality of these records be implemented.

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FOCUS: New Technology Trends

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One company, EMed Technologies Corp., delivers X-ray images and reports from hospitals to radiologists. To comply with HIPAA, and it built an eMed.net system with federal regulations in mind. The corporation recently hired a security services company to analyze the system’s access control, data encryption, password management, and record-keeping capabilities. The new PACS hold great promise for improving speed and accuracy and maintaining confidentiality in hospitals. However, system planning must extend throughout the environment of information to realize these gains.

PACS Whys and Wherefores

A clear, high-level understanding of why a PACS project is being undertaken is critical. By creating a mission statement, the team will have an ongoing benchmark by which to evaluate all possible add-ons for fit with the major objectives for implementing PACS. In addition, the crafting of a PACS mission statement offers the first opportunity to build the consensus necessary for a process that will affect the hospital’s clinical and operational processes.

The guiding principles for deploying a radiology information system might cover integrity, quality, respect, security, and creation of a culture of safety. Statement essentials for understanding the hospital’s mission, vision, and values for implementing a PACS can encompass:

…”the crafting of a PACS mission statement offers the first opportunity to build the consensus necessary for a process that will affect the hospital’s clinical and operational processes.”
• Improving the health of individuals and the community at large.
• Advocating and ensuring the latest expertise in high-quality healthcare services.
• Establishing a recognized progressive information technology network, linking all constituents to communicate, educate, and facilitate the transfer of information.
• Offering value-added services for clinical improvement in achieving the unique mission of each constituent.
• Promoting access to the most advanced facility.
• Providing the most accessible and effective services necessary to reflect the needs of the 21st century.

Shifting—A Clinical and Cultural Climate

The culture of hospitals greatly influences the quality of care. Major gains in the prevention of medical errors cannot be achieved until the organizational culture changes. Innovativeness relates to the extent to which health systems encourage exploration and adoption of new practices.

Hospitals can lag in the clinical application of PACS for a variety of reasons. Medical professionals may be slow to adapt to any technology when capital is in short supply, and underdeveloped standards for interoperability may lead a conservative community hospital community to proceed with caution.

Despite such barriers, integrated digital systems are fast replacing most paper-based systems and components. Benefits such as single point of entry, intelligent systems support, and standardized vocabularies and phraseology are expected to improve patient safety and treatment quality and reduce overall cost.

Successfully implementing PACS presents a fundamentally different challenge to hospital IT departments used to managing business systems. PACS implementation requires the leadership of physicians and upper-level administration and demands significant cultural and process changes. Thus, acceptance is a required level of commitment by the clinical staff, and it is essential to develop strategies to facilitate physician adoption and utilization of the new technologies.

If CEOs, physicians, and clinicians are expected to adopt PACS, some of the key buy-in concepts could be considered enticing:
• Faster patient treatment and diagnosis, which leads to short waiting times and enhanced patient care.
• Increased departmental productivity and competitiveness.
• Reduced or optimized staffing.
• Increased speed and HIPAA-secure exam access across the enterprise.
• Reduced report turnaround time and labor costs.
• Integrated legacy information systems (HIS/RIS/EMR).
• Minimized film use across the enterprise.

• Eliminated use of development chemicals (for traditional X-ray), thus increasing environmental benefits.
• Reduced patient exposure by eliminating re-exams.
• Reduced storage space and fewer instances of lost films.
• Eliminated patient transport because of lack of timely interpretation.
• Increased recruitment efforts, while minimizing radiologist and technologist attrition.
• Reduced disposable waste (film, film printers, and chemical solutions), leading to lower waste treatment costs.
• Improved collaboration between medical professionals.

Before interviewing vendors, hospitals should consider creating a multi-disciplinary team to develop a list of requirements for its PACS.”

There are five identified characteristics of innovations that influence the likelihood of PACS adoption. Relative advantage is the extent to which an innovation is perceived to be superior to the current solution. Compatibility is the extent to which an innovation is perceived as being consistent with the existing values and needs of potential adopters. Complexity is the extent to which an innovation is perceived as being difficult to understand and use. Trialability is the extent to which an innovation may be examined on a limited basis. Observability is the extent to which the results of an innovation are visible to others. Innovations that are perceived by individuals as having greater relative advantage, compatibility, trialability, observability, and less complexity will be adopted more quickly.

The culture of medicine embraces tradition and approaches new ideas with caution; thus, achieving widespread adoption of new ideas like PACS can take several years. When it comes to technology adoption, physicians usually fit into one of five categories: innovators, early adopters, early majority adopters, late majority adopters, and laggards. Each group requires a different approach to achieve acceptance of the innovation.

• Innovators require no additional motivation, but in fact may require a degree of restraint so they do not try to accomplish changes that require too severe (and thus unachievable) cultural or process changes.
• Early adopters possess the greatest degree of opinion leadership in most social systems. They are also most likely to respond to a cognitive approach involving education; regarding costs and benefits of the new
technology; and frequently become champions within peer groups, helping to increase the rate of adoption.

- Early majority adopters require a combination of cognitive and motivational emphasis.
- Late majority adopters may respond best to motivational emphasis accompanied by peer pressure and identification of barriers.
- Laggards require not only identification of barriers, but also removal of those barriers. Laggards may need the motivation of mandatory adoption, coupled with a high degree of training and support.

Hospitals that engage the key members of the medical staff early in the clinical transformation process will significantly improve their chances of a successful PACS implementation. They also will be more likely to realize the clinical improvement goals that lead to the implementation decision.

**Creating Collaborative Efforts**

With many errors associated with a lack of access to radiology information and inefficient coordination among team members, interventions are clearly desirable. A needs assessment is a collaborative process, which results in definition of project objectives and goals, consensus on imaging modalities to be included, and a timetable for installation of the PACS, priorities and information system initiatives.

Performing a needs assessment of a PACS can provide the hospital executives with useful data. In some cases, hospitals will learn that a department’s system does not really meet their information needs. In other instances, users may be dissatisfied with their system because they are not taking advantage of its full capabilities. They may inform those assessing the need for PACS that the current system cannot do certain things—when, in actuality, it can. Obviously more training may be required under these circumstances. However, this need may never have been identified without a thorough needs assessment process.

JCAHO does not specify exactly how it wants hospitals to do their needs assessments. Many approaches are acceptable, provided a sincere attempt is made to assess the needs of information system users throughout the hospital to improve the quality of patient care.

The format of a needs assessment can vary. Generally, an assessment is conducted as a survey. However, questions can be developed and conducted as individual interviews or focus groups. Hospitals also can collect and analyze performance data to determine common needs. They will explore these areas through the use of personal observations; additional assessments may include on-site observation, testing, and assessment departments.

Hospital departmental observations should be conducted by individuals who are experienced and knowledgeable in performing a task analysis of the PACS work processes, procedures, methods, and practices being observed. These individuals are referred to as subject matter experts. Typically, these experts are individuals who once worked in the position and have the in-depth knowledge of the hospital PACS concepts and processes. Subject matter experts offer the troubleshooting information required to determine whether additional training is needed or if the situation is indicative of a needed intervention.

If the hospital plans to use testing and assessment centers, they may want to check into validation and reliability studies to ensure compliance with HIPAA, JCAHO, DICOM, and legal requirements.

**Multi-disciplinary Teams**

Before interviewing vendors, hospitals should consider creating a multi-disciplinary team to develop a list of requirements for its PACS.

PACS hardware and software dramatically change business processes and hospital workflow. As the hospital establishes needs, goals, objectives, and strategies, it must realize in tandem both challenges and opportunities in undertaking the transition from analog to digital radiology. It will be imperative that the business be driven by building on the new capabilities to secure a new dimension in maximizing quality patient care, more efficient operations, enhanced productivity, value-added services to physician practices and, ultimately, return on investment.

The team should be formed by the hospital leaders and consist of information systems technologists, radiologists, clinicians, and support staff to foster a shared vision of implementation of PACS.

It is critical that each individual comprising the management team fully understand their part in the infrastructure of the department. They must possess the current departmental processes and workflow knowledge and be able to link that knowledge with the PACS. PACS must be regarded as the tool by which the processes and workflow become more efficient and people more productive, not as the new process itself.

Management’s responsibility will be to communicate the need for the IT effort, build commitment, generate changes in thinking and behavior, and align encouragement and rewards. Just as important, they will need to define job descriptions, match resources, train staff, and be resolute in hiring new personnel. As technology changes faster than people can respond, shortages in skills are inevitable. New skill sets are not only required, but management must note the reason why people are learning less quickly than ever before; therefore, the success in fully utilizing PACS will fall on training, support, hiring, and retaining.

A variety of people from all parts of the hospital should be appointed to gather the required information for PACS planning. Radiologists in various subspecialty areas can collaborate with clinicians from those areas within the
hospital to gain an understanding of their needs and interest levels. Vendors can take an active role in performing evaluation of PACS through site visits and meetings with the hospital. Purchasing and finance personnel are heavily involved in developing the financial model and capital discussions for the PACS implementation.

Members of the information systems and hospital departments convene to discuss the required networks, construction schedules, and space and planning requirements. Another can be involved in working on and preparing the Request for Proposal (RFP), while yet another evaluates responses to the RFP. Radiology administrative teams often join forces with the leaders of hospital divisions to explain the benefits and economics of PACS. Effective strategies can be developed to indicate the ways in which PACS could effectively assist in minimizing medical errors and bring success to the hospital's priority areas within its overall corporate plan. Thus, the culmination of these efforts can lay the groundwork for the approval of a favorable PACS plan.

**PACS Specifications**

Emarking on a PACS installation is an expensive and potentially risky venture for any hospital. Often, the larger the hospital, the greater the expense and risk. However, after a hospital has decided to introduce PACS, it must decide on a process of implementation.

Several methods exist for implementing PACS, which are highlighted in Figure 1. However, there are arguments that incremental "mini-PACS" or "big bang" are the most favorable approaches considered in the decision-making process. If a hospital is brand new, the big bang approach is very effective. However, most hospitals chose a more incremental approach, such as starting with a mini-PACS, then deploying it to a full-scale PACS over a comparatively short time span.

A rationale for deciding to use a big bang approach is related to the fact that a phased PACS introduction would require that the two systems (digital and conventional) operate in parallel. Some hospitals consider a complete switchover to avoid such "double duty."

The incremental approach or phasing of PACS provides many advantages unless the hospital is building an infrastructure from the ground up. The primary element defining the mini-PACS approach is its dependence on manual intervention as well as a relatively small scale in the number of modalities, viewing systems, and archival elements.

The mini-PACS is a perfect first step for a small diagnostic center interested in reducing film costs. Likewise, a hospital would consider using this approach based on cost issues. If the entire mini-PACS system is scalable, components may be added as needed and desired. With a minimal investment, a hospital could install a viewing system and DICOM archive server. As the hospital grows, it can add archive space, viewing components, enterprise automation, radiology information systems, paper printing, and other components.

A mini-PACS environment includes a manual as opposed to automated archive and image tracking mechanisms. In the mini-PACS environment, an administrator will typically manually assign images to a diagnostic reading station in the hospital and move images onto a long-term archive as desired and necessary. While most mini-PACS environments do not have a radiology information system component, that is not always the case. In addition, most mini-PACS systems are single site environments with one or two modalities and viewing stations.7

### TYPES OF PACS

- Big Bang approach
- Phased approach (incremental)
- Vertical vs. Horizontal
- Fee-Per-Use (Off balance sheet, operating budget)
- Wide-area distribution first
- New low-cost Web based systems

**Obtaining a Competitive Bid**

The main purpose of a hospital's RFP is to give vendors maximum latitude in design and development; delineate project requirements; standardize requirements among vendors to enable comparison and selection; and act as a basis for acceptance testing, performance guarantees and a subsequent contract.

Specific requirements of an RFP include on-site inspection assuring infrastructure and physical facilities adequate to support the vendor; installation time line and planning, acceptance testing, training, quality assurance, HIPAA compliance, on-site vendor support, warranty and maintenance, remote monitoring, obsolescence protection, itemized pricing, statement of inclusion and non-inclusion, and disaster recovery.

Several key criteria should be used to narrow down the final selection of potential vendors. Ease of use may be a key factor, depending on the number of physicians the systems will be required to support and when going filmless must be absolutely simple for them to make the transition. Manageability, scalability, and reliability with an unbeatable uptime guarantee, with penalties and a performance guarantee of specific timelines, also might be key considerations. Reliability means the hospital cannot afford to have system downtime.
In writing the RFP, the hospital should understand the nature and limitations of the vendor's response. Large PACS companies have two to four staff members, often experienced professional engineers, who prepare RFP responses. In preparing RFP responses, vendors' staff call on the expertise of project managers, development engineers, computer programmers, network analysts, re-engineering specialists, information systems integration specialists, installation specialists, and service managers.

Because of the resources expended in preparing a response, some vendors (particularly smaller ones) may decline to respond with RFPs if they think they will not lead to contracts. If an RFP is extremely complex, vendors may spend as much as 200 hours in preparing a response, and it may take several weeks for the preparer to obtain the specific information that is needed. For this reason, response deadlines of less than 60 days may be unrealistic.

A useful RFP seeks to present a solution to the hospital’s problems, and it should specify the reasons for acquiring PACS and how the system will be used. Only a detailed understanding of the purpose of the PACS will permit the vendor to propose the best possible system for a given hospital. While some vendors are willing to help a hospital evaluate its current procedures or determine the needed number and placement of workstations, others consider these tasks to be the territory of consultants; in either case, such steps should be taken not through the RFP, but before it is written.

If a hospital is to gain maximal benefit from its RFP process, there are several pitfalls to avoid. The RFP should be double-checked to ensure that duplicate questions are removed; depending on the structure of the document, these may inadvertently be asked in different sections of the RFP, leading to longer response and evaluation times.

For the same reasons, questions answered by information widely available to the public should be deleted. The hospital should, for example, avoid asking vendors how they entered the PACS industry and how long they have been in the business; company histories can easily be found elsewhere.

The issuance of an RFP that is actually a filled-in template from another source also may be detrimental to implementing a PACS project. Documents of this type, which now may constitute 30 percent to 40 percent of RFPs, cannot address the place of PACS in the hospital’s strategic plans or the buyer’s implementation objectives. An unclear RFP will garner imprecise responses that are difficult to compare.

To facilitate vendors’ prompt responses, the hospital should make the document available in an electronic format. Those compiling the RFP also should ensure that it presents enough information about the hospital’s existing imaging equipment, information systems, staffing, procedural volumes, and workflow patterns to permit the construction of an informed, detailed proposal.

Whether the PACS is to be purchased from a single vendor or assembled by using components from multiple vendors, the RFP should contain a clause that defines the responsibilities of each party. An errors-and-omissions clause is mandatory, and any facility-specific contract language should be placed at the end of the RFP.

The RFP and its response should be treated as communication tools subject to refinement through discussion. The RFP should indicate who will be available to answer vendors’ questions and how that individual can be reached. Vendors should be treated as potential partners, not adversaries.

When it comes to PACS selection, hospitals and vendors have a mutual interest in improving the RFP process. The understanding of a hospital’s needs, both by the hospital itself and by interested vendors, is of paramount importance. Open, informal communication and in-depth discussion are the best tools through which both buyers and vendors can prepare themselves for successfully using the RFP process (see Figure 2).

### PACS Vendors List

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Vendor</th>
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</thead>
<tbody>
<tr>
<td>Acuson</td>
<td>Commedica</td>
</tr>
<tr>
<td>Agfa</td>
<td>Philips</td>
</tr>
<tr>
<td>Ali</td>
<td>Sectra</td>
</tr>
<tr>
<td>Brit Systems</td>
<td>Siemens Medical Solutions</td>
</tr>
<tr>
<td>Dicomit</td>
<td>Philips Medical Systems</td>
</tr>
<tr>
<td>Ge Healthcare</td>
<td>Amicas</td>
</tr>
<tr>
<td>Cemax-Icon (Kodak)</td>
<td>Eastman Kodak Co.</td>
</tr>
<tr>
<td>Image Devices</td>
<td>Marconi</td>
</tr>
<tr>
<td>Sectra</td>
<td>Mckesson/ Camtronics</td>
</tr>
<tr>
<td>Scimage</td>
<td>Medical Systems/ Medical Imaging Group</td>
</tr>
<tr>
<td>Fujifilm Medical Systems/ Heartlab</td>
<td>Canon</td>
</tr>
</tbody>
</table>

*Figure 2*
Standardization and Confidentiality

From a CIO’s perspective, it is easy to fall into a mindset that compliance is a regulatory requirement that can be solved with technology. The integration of digital image management systems as a component of a computerized medical records system enables hospitals to maintain the integrity of patients’ radiology images more securely than can ever be achieved with film. The beauty behind PACS technology is that diagnostic exams maintained in an electronic archive do not get lost the way that films can; they are not dispersed throughout a hospital, and no medically interesting films are inadvertently borrowed and never returned.

PACS are designed for the explicit purpose of managing diagnostic image storage, distribution, and display. When images are digitally archived, lost or misplaced files become a non-issue. Access to images can be limited to specific users. Automated electronic auditing can track viewing activity on an image-by-image basis. Daily system backups minimize the risk of destruction of records caused by hardware or software failure. Thus, PACS are an important tool in a hospital’s security initiative.

Installation of PACS does not automatically guarantee security of radiology records. Computerized medical records of any type are more vulnerable to tampering than paper and film-based ones. Computer hackers are not a threat to a film file room, but they can create havoc with digital or electronic images, for example, by modifying the contents of a computer database or destroying records altogether.

Maintaining the security and integrity of PACS is a joint collaboration of the vendor, the hospital’s information systems department, the system administrator, and the users themselves. The components of a PACS infrastructure always should be placed in a secure room, and the network on which the system operates should be protected by the hospital’s firewall. It is important not to assume that precautionary measures will take care of themselves because of the usage of an information system.

When selecting PACS, it is important that hospital security managers be involved in the evaluation team. They are the most qualified individuals to assess the scope and depth of the security mechanisms designed into the system and to evaluate the capability of the vendor’s own security initiatives.

In Consideration of Standards

In 1996, the government enacted HIPAA to mandate the standardization of methods by which medical information about patients is exchanged. This regulation spans corporate privacy and information-security policies and corresponding business workflows, right down to communicating with and training business and clinical users. Compliance involves improving the quality of patient care and system usability by clinicians rather than simply meeting the privacy and security requirements outlined in HIPAA.9

The challenge facing radiology departments is to determine what activities and workflow modifications need to be implemented to be HIPAA-compliant without compromising patient care. Currently acceptable standards for medical professionals who need to access patient records are undergoing radical change.

The impact of these regulations undoubtedly will have a global impact and is expected to change the way many radiology departments function. For example, HIPAA requires that records and the equipment housing those records be physically safeguarded, that network and computer security measures protect electronic files, and that administrative procedures to guard confidentiality and availability of these patient records be implemented. Comprehensive records of all measures undertaken must be maintained, including the logs showing proof of consistent monitoring.

“T he incremental approach or phasing of PACS provides many advantages unless the hospital is building an infrastructure from the ground up.”

Information technology is replete with standards. Among the most recognizable are Digital Imaging and Communication in Medicine, or DICOM, the image exchange standard for networked devices, and Health Level Seven, or HL7, the data exchange protocol for healthcare messaging.10

PACS consist of several components that are required to meet clinical and international imaging standards. They include acquisition devices such as CT, MR, CR, NM, and endoscopy; networks; display devices; image servers or image archives, and storage devices. As a result, DICOM support is critical. A PACS vendor should not be held responsible for the level of DICOM support offered by the modality manufacturer. Serious consideration should be given when spending money to make devices DICOM-compliant, because the software upgrade cost alone can easily exceed the value of the modality. The pre-windowed and leveled video data can be captured from the display console of the modality (called frame grabbing), but the value of this is limited in clinical applications and does not allow nearly the flexibility that data in a DICOM file format does.

HL-7 compatibility is handled by virtually all vendors the same way—using a gateway (or broker) to make the
interface between the hospital or radiology information systems and the PACS or, longer term, between the PACS and other clinical systems in facilities that plan to develop a longitudinal clinical patient record. Planning should include determining which clinical systems will require upgrades in the future.

Wireless networks associated with PACS are governed by the Institute of Electrical and Electronics Engineers (IEEE) standards 802.11 (a-g); short-range, device-based wireless generally adheres to the Bluetooth standard. The Wireless Medical Telemetry Standard (WMTS) defines the frequency band allocation for medical telemetry, with the American Society for Healthcare Engineering (ASHE) serving as the national WMTS frequency coordinator.

As the number of digital systems began to proliferate, it became apparent that there was little, if any, standardization for communicating digital information between different modalities or systems. The standards created an infrastructure but not the phraseology and syntax required for a common clinical information transfer language. As a consequence, two major professional societies, the Radiological Society of North America and the Healthcare Information and Management Systems Society used their combined influence to establish a project called “Integrating the Healthcare Enterprise” (IHE). Since 1999, IHE has brought together more than 30 vendors of imaging systems to help improve the way computer systems in healthcare share information. IHE promotes coordinated use of established communication standards, such as DICOM and HL7, to address specific clinical needs in a vendor-neutral environment.10

Conclusion
PACS are a powerful tool to help hospital departments achieve radiology objectives without boundaries. However, planning for PACS must be made within a framework of informed decisions. A multidisciplinary team is recommended for hospital PACS installation and is obligatory for enterprise-wide planning. Hospitals should incorporate a dose of goal-oriented enthusiasm and the desire to beneficially harness new information technologies, blended with the expertise of knowledgeable vendor partners. Facilities should formulate a solid strategic hospital business plan and implementation model if success is to be achieved.

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References
The Office of Advanced Technology: Providing Focus on the Piloting and Implementation of New Technology

Kenneth G. Bobis, PhD, John K. Camoriano, MD, and Mary J. Wright, MN, RN, BC

ABSTRACT

Rarely does an organization have the luxury of employing full-time staff whose sole purpose is to seek out, select, pilot, and recommend new technology. If such an effort is not a dedicated activity, an organization will have a hard time keeping abreast of technological development with an eye towards successful deployment to the benefit of the business. This paper summarizes the role and activities of the Office of Advanced Technology (OAT) at the Mayo Clinic in Scottsdale, AZ. The OAT has been in existence since 2001 and is staffed on a part-time basis by three individuals: a member of the physician consulting staff, a nurse informaticist, and a member of the allied health Information Technology staff. The office has successfully conducted pilot projects in several new technology areas, advocating the adoption of some technologies and deferring on others. Moreover, they have been instrumental serving as a spokesperson and single point of contact for all new technology initiatives of this multi-specialty practice.

KEYWORDS

- Technology
- Advanced technology
- Emerging technology
- New technology
- Informatics
- Pilot project

Introduction and Background

"...It is better to think and sometimes think wrong than not to think at all." William J. Mayo MD, 1935

Mayo Clinic has three group practice operations in Rochester, MN, Jacksonville, FL, and Scottsdale, AZ. While the organizational structure is similar to that in a typical corporation, the legal entity that controls centralized functions is the Mayo Foundation. While the operations in Jacksonville and Scottsdale are dwarfed by those in Rochester, their technology needs are comparable. Each of the three sites has a burgeoning electronic medical record, with computerization across major departments. The success of this automation to the delivery of patient care has created an ongoing need to ensure the efficient and effective use of technology across the entire foundation.¹

The Need for the Office

Scottsdale experienced major growth in 1998 when it opened its new 178-bed Mayo Clinic Hospital in Phoenix, AZ. At that time, 34 computer systems were installed to both upgrade existing clinic systems and automate the new hospital. Since that time, the computing environment has been meeting the needs of the practice, but the organization has committed more focus to the importance of
information technology as a factor in the strategic decision-making process. This action was a concern to senior IT management because there was no formal, disciplined mechanism for evaluating newer technology.

Scottsdale administrators knew that the manner in which Scottsdale IT investigated, selected, and implemented advanced information technology would be critical to the success of the organization in achieving its mission. Another contributing factor was that both Rochester and Jacksonville had groups dedicated to the evaluation of emerging technologies. Rochester has an Information Management Technology Committee, while Jacksonville uses a Department of Applied Informatics.

The solution proposed for Scottsdale was the establishment of a formal function with responsibility for assessing emerging technologies and determining their roles in meeting the Mayo mission. This group was the Office of Advanced Technology (OAT), which began operations in the fall of 2001. Initially, OAT members included a physician consultant and an allied health Information Technology staff member. Two years later, a nurse informaticist was added to the group to increase its awareness of technology issues and their implications in the hospital setting.

Governance Structure

Mayo Clinic is a physician-led organization as specified in the Mayo Model of Care. As such, all major clinical and administrative functions are under the oversight of a committee or subcommittee. Each of these governing bodies is composed of representatives of Mayo’s “Three Shields” of Patient Care, Research, and Education, as well as the Department of Administration.

The Scottsdale Division of Information Technology is under the control of the Information Systems Steering Committee (ISSC). In turn, the ISSC has three subcommittees that have oversight, respectively, for project request prioritization, security, and Internet and intranet activities.

Because the original concept behind the OAT was to establish a group that was nimble in its reaction to technological advances, OAT was organized as an Office and not a subcommittee.

To provide an environment of success for this new endeavor, a charge, vision and mission were drafted. Moreover, strategic objectives were developed to organize its ongoing operations.

The charge of the OAT is to serve the Mayo Clinic in Scottsdale in discovery, evaluation, and recommendation of new information technologies in the support of medical practice, research, and education. It is also to serve as a resource and sounding board for administrative and medical staff that have information technology ideas, questions, or proposals that warrant evaluation. Vision and mission statements also were developed for OAT (see Table 1).

The objectives of the Scottsdale OAT were aligned with

### Table 1. Vision and Mission of the Scottsdale Office of Advanced Technology.

1. **Vision:** To be the Acknowledged Leader in the Identification and Application of Information Technology to the Practice and Business of Medicine
2. **Mission:** To anticipate the value of new technologies to the Practice, Education, and Research and proactively champion their adoption.

### Table 2. Guiding Principles of the Mayo Clinic in Scottsdale OAT

1. Look for opportunities to integrate or leverage existing systems rather than to create new infrastructure.
2. Look for opportunities to integrate Foundation systems into local use.
3. Mayo Clinic in Scottsdale will not be “early adopters” of a new technological trend.
4. Technology must support the Patient Care, Education, Research, or Business Goals of Mayo Clinic in Scottsdale.
5. Technology must provide a Return on Investment.
6. Technology must result in a positive Benefit to Cost ratio.
7. Technology must be cost-effective, reliable, accurate, & timely.
8. Technology must reduce administration costs, reduce staffing costs, be necessary to meet regulatory requirements or increase the flow of information to management.
10. Will not seek champions or generate implementation projects.
the IT and Organizational Strategic Plan. Objectives of the OAT are for it to:

- Evaluate and propose new applications of information technology in the delivery of clinical care as they relate to the long-term strategies of the organization.
- Maintain a practical knowledge base of emerging information technologies with potential benefit to Mayo Clinic in Scottsdale, keeping the list prioritized for potential adoption based on the potential of the technologies to solve problems in business processes.
- Be a resource for others in the institution who request information or insight into information technology.
- Anticipate new information technologies and forecast their value and application to the practice and business of healthcare delivery.
- Provide an open forum for the discussion of the applications of information technology.
- Maintain a “technology timeline” of leading technologies and a proposed schedule for “proof of concept” pilot projects and possible adoption.
- Provide internal education through ISSC briefings, IT staff “brown bag” lunches, and medical staff “grand rounds” talks.
- Conduct pilot projects on new technology.
- Develop and maintain metrics to show its effectiveness in meeting its charge.
- Become a self-sustaining entity, funded by research and education grants, as well as providing a proven return on investment.
- Represent the Mayo Clinic in Scottsdale through the publication of scholarly papers and national presentations.
- Partner with the education committee to develop the area of informatics as an academic and scholarly entity.

Several responsibilities were intentionally excluded from the purview of this group. For example, the OAT will not run technology implementation projects; instead, technologies would be made available to established project teams for production implementation after they were proven to be effective in pilot projects. Also, the OAT was not designed to be the chief proponent of any technology, nor is it to serve as the research arm of the organization.

Several informal guiding principles were established as core tenets for the OAT (see Table 2).

### Table 3. OAT Pilot Project Methodology

- Perform a feasibility study based on viability of the technology as noted in the literature.
- Review the use of the technology across Mayo Foundation to avoid duplicate efforts.
- Obtain pilot approval to proceed from the ISSC.
- Create vision / scope document.
- Develop requirements document (2 week iterative cycle).
- Compile critical success factors.
- Perform vendor identification and selection.
- Design pilot.
- Conduct pilot.
- Assess pilot.
- Make recommendations.
- Perform a security risk assessment.
- Summarize lessons learned.
- Make “Go-No Go” decision on appropriateness for project use.
- Write white paper, including recommendations and financial effect analysis for full production deployment.
- Hand-off technology to project team for implementation.

Several responsibilities were intentionally excluded from the purview of this group. For example, the OAT will not run technology implementation projects; instead, technologies would be made available to established project teams for production implementation after they were proven to be effective in pilot projects. Also, the OAT was not designed to be the chief proponent of any technology, nor is it to serve as the research arm of the organization.

Several informal guiding principles were established as core tenets for the OAT (see Table 2).

> The solution proposed for Scottsdale was the establishment of a formal function with responsibility for assessing emerging technologies and determining their roles in meeting the Mayo mission.

### Methodology

The primary activity of the OAT is to organize and conduct proof-of-concept pilot projects. Within the existing Scottsdale governance structure, the only groups that can authorize such projects are the ISSC, Information Technology Advisory Prioritization Review Subcommittee (ITAPRS), and IT Management Team (ITMT). This “check and balance” ensures that proponent groups would not use the OAT to fund and run an initiative that could not gain institutional support.

Any of these groups can authorize a pilot test of a new technology without a clearly defined business need. This is because one of the deliverables of an OAT pilot project is
a white paper that includes the business value and an estimate of the costs and benefits of a full rollout of a technology.

In addition to stand-alone pilot projects, often the first phase of an officially sanctioned project would make use of a pilot in the vendor-selection process. In such a situation, the project manager would ask the OAT for assistance in organizing and executing the first or pilot phase of the project.

Before the OAT was established, pilot projects at Scottsdale did not have clearly defined success criteria and typically had no scheduled completion date. The findings of the pilots were generally not published or available for review by local and Foundation groups. Because pilot projects were not conducted within specific timeframes, the technology under study often was declared "de facto" production," leading user communities to believe that the technology had production status even though it did not have official IT support.

To alleviate this situation, a customizable methodology was implemented. The basic methodology uses an "expedited waterfall" approach (see Table 3). It requires a maximum 90-day pilot project period and a published white paper summary at the completion of the pilot. White papers provide an estimate of the cost involved in a full production deployment of the technology under consideration.

The most important document in this methodology is the vision and scope document (see Table 4). In the pilot project process, a lot of attention is paid to ensure that all decisions related to the pilot are documented and agreed to by the pilot sponsors.

### Table 4. OAT Vision and Scope Document

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Introduction</td>
<td>Contains the purpose and structure of the scope document.</td>
</tr>
<tr>
<td>2</td>
<td>Problem Statement</td>
<td>Provides a description of the problem or opportunity to be solved by the project team and customer.</td>
</tr>
<tr>
<td>3</td>
<td>Objectives</td>
<td>Identifies the project objectives that must be met for the project to be considered a success, along with exit criteria and success criteria for the project.</td>
</tr>
<tr>
<td>4</td>
<td>Vision Statement</td>
<td>Describes how the customer and users envision the solution in the long-term, including how it will be used in the Scottsdale environment, who will use it, and how it will meet the needs of Scottsdale. This section also identifies the owner of the need the pilot is designed to meet.</td>
</tr>
<tr>
<td>5</td>
<td>Scope</td>
<td>Describes the initial high-level boundaries of the solution in terms of business or medical functions affected.</td>
</tr>
<tr>
<td>6</td>
<td>Assumptions</td>
<td>Describes the assumptions made concerning the pilot project.</td>
</tr>
<tr>
<td>7</td>
<td>Issues</td>
<td>Contains issues that must be resolved before the start of the pilot project.</td>
</tr>
<tr>
<td>8</td>
<td>Resource Requirements</td>
<td>Identifies the resources, including human, hardware, and software, required to conduct the pilot project. Specific names and the roles served are listed.</td>
</tr>
<tr>
<td>9</td>
<td>Solution Concept</td>
<td>Describes the general design of the solution in terms of technology, workflow processes, and criteria for a successful solution to the problem from the user's perspective.</td>
</tr>
<tr>
<td>10</td>
<td>Estimated Budget</td>
<td>Identify the budget required to conduct this project.</td>
</tr>
<tr>
<td>11</td>
<td>Timeframes</td>
<td>Identify a high-level schedule for the pilot project.</td>
</tr>
<tr>
<td>Appendix A</td>
<td>Abbreviations and Definitions</td>
<td>Contains the definitions of any abbreviations or acronyms used in this document.</td>
</tr>
<tr>
<td>Appendix B</td>
<td>High Level Capital Expense Analysis</td>
<td>This section contains a high-level analysis of the Capital and Operating Expenses involved with a full production deployment of this technology in Scottsdale.</td>
</tr>
</tbody>
</table>

Pilot Projects

Scottsdale IT considers pilot projects to be proof-of-concept activities generally performed as the first step in an established project or to determine if a project should be initiated. It is not conducted simply as "technology for technology's sake," but rather a pilot project must be
supported by a business sponsor and be intended for a verifiable business or medical need.

Table 5 contains a list of the pilot projects that have been conducted by the OAT since its inception.

**Cross-site Interaction**

Since 2000, Mayo Foundation IT has been moving toward increased centralization of common functions in an effort to increase operational efficiency. While much progress had been made on implementing this strategy, the exploration of advanced technology remains the responsibility of each individual Mayo Clinic site.

As with most major organizations that feature a distributed IT function, it was common to find two or more Mayo Clinic sites investigating the same new technology. In some cases, the same products and vendors were being considered and even the same problems being studied. This disjointed approach to advanced technology was not only a nuisance, but it could have major financial implications because of the costs involved in conducting pilot projects.

Additionally, Mayo Foundation did not have a single view of how emerging technologies could support the missions of practice, research and education for the next decade and beyond.

<table>
<thead>
<tr>
<th>Pilot Project Name</th>
<th>Problem Statement Under Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wireless at Mayo Clinic Hospital</td>
<td>Can mobile wireless PC devices, instead of stationary wired ones, be used at the Mayo Clinic in Scottsdale Hospital, by physicians, nurses, and physician / nurse extenders, without a loss of effectiveness in patient care or timeliness of data retrieval?</td>
</tr>
<tr>
<td>Tablet PCs</td>
<td>1. Can mobile Tablet PC devices be a cost-effective replacement for traditional stationary computers at the Mayo Clinic Hospital and Mayo Clinic in Scottsdale, by physicians, nurses, and physician / nurse extenders with an improvement (rather than a decrease) in efficiency of workflow and satisfaction?</td>
</tr>
<tr>
<td></td>
<td>2. Can those who deliver clinical care to patients in the clinic and hospital increase their job effectiveness and satisfaction through the availability of clinical information systems from locations remote from the worksite such as home or while traveling?</td>
</tr>
<tr>
<td>PDA Support</td>
<td>What effect does PDA deployment in Scottsdale have on Information Technology Support costs?</td>
</tr>
<tr>
<td>Physician Quality of Life</td>
<td>Will the ability to access the Scottsdale computing environment while off campus increase the satisfaction of the consulting staff?</td>
</tr>
<tr>
<td>PDA in Transplant</td>
<td>What effect would PDA deployment in Scottsdale have on Information Technology hardware, software and support costs and what Practice benefits can be measured using centralized, server-based integration of PDAs with existing Mayo office applications and Outlook?</td>
</tr>
<tr>
<td>Portable Video Conferencing</td>
<td>Can portable, IP-based video conferencing equipment be used to provide an effective alternative to the Mayo Foundation teleconference network for meetings held between the Clinic in Scottsdale and the Hospital in Phoenix?</td>
</tr>
<tr>
<td>Telemedicine with Mexico</td>
<td>Can the Mayo Foundation teleconferencing network be used to conduct extended educational sessions with medical facilities in Hermosillo, Mexico?</td>
</tr>
<tr>
<td>Distance Learning</td>
<td>Can intranet-based virtual classroom tools be effective in delivering education to Scottsdale IT staff?</td>
</tr>
</tbody>
</table>
This led to the development of a MGP Advanced Technology Workgroup, established as a separate group that has the freedom to proactively discuss, explore, and pilot new technologies. Modeled after the Scottsdale OAT, the MGP Workgroup shares the same vision and mission statement as the Scottsdale group.

As the foundation workgroup matures, the vision is for it to conduct distributed pilot projects, attempting to explore the same technology across sites, possibly for different business reasons. While the management of such activities adds another layer of complexity, many believe that the new organization will provide a variety of efficiencies.

Future of OAT
The Scottsdale Office of Advanced Technology will remain a viable organizational entity for the foreseeable future. It will build on the experiences of its previous pilot projects to hone its methodology, thus gaining more efficiency in its operations. It also will attempt to secure dedicated resources for its future pilot projects to help ensure compliance with its expedited methodology and continued operational success.

About the Authors
Kenneth G. Bobis, PhD, is the CTO and director of development and software engineering at the Mayo Clinic in Scottsdale. He also serves on the adjunct faculty at Arizona State University, the University of Illinois-Chicago and the University of Phoenix.

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Mary J. Wright, MN, RN, BC, is the manager of nursing informatics at Mayo Clinic in Scottsdale. She serves on the adjunct faculty at the University of Phoenix.

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4. According to the Merriam-Webster Dictionary of Law, an “office” is “a special administrative department or unit.”
Focus: New Technology Trends

RFID and Bar Codes—Critical Importance in Enhancing Safe Patient Care

Richard A. Perrin and Ned Simpson, FHIMSS

Abstract

Medication administration recording and supply management are complex and interrelated processes. The integration of bar codes and radio frequency identification tags are viewed as critical in achieving effective and safe patient care. However, these systems are complex; all parts need to be aligned, and the systems must work together to produce the desired outcomes. In healthcare, automation using bar coding and RFID capabilities is of growing importance because of the Institutes of Medicine study and the integrated electronic medical record. Healthcare systems today are increasingly complex, and while bar codes and RFID technologies provide opportunities for enhanced patient care, systems using these capabilities must be carefully planned to achieve optimal outcomes.

Keywords

- Radio frequency identification
- Bar codes
- Electronic medical records

Introduction

Healthcare providers continue to struggle with rising healthcare costs and the need to provide dwindling numbers of healthcare professionals with resources and systems designed to ensure the most efficient, effective, and safest means of providing care. Healthcare providers are facing rising costs, burgeoning care needs for an aging population, and shrinking numbers of healthcare professionals.

In this environment, providers need to make careful strategic choices about the acquisition, implementation, and effective use of information technologies. Information technologies, in integrated systems coupled with redesigned workflows, can make a significant contribution to safe and efficient healthcare and ultimately will result in reduced costs. Auto-ID technologies, encompassing both radio frequency identification (RFID) tags and bar codes, have been recognized for their potential to radically improve patient safety, especially for medication administration and healthcare operations.

For hospital-based patient care activities, automated systems using bar coding and RFID capabilities are of growing importance because of the Institutes of Medicine (IOM) study.1 The report by the Institutes of Medicine provided an in-depth review of the issues, and the results indicate healthcare providers are lagging behind other industries in the adoption of safe practices and quality assurance methods through the use of automated systems.

The Institute of Medicine Report stated that “as many as 44,000 to 98,000 people die in hospitals each year as the result of medical errors,” with an estimated 7,000 of these deaths related to medication errors.2 This bellwether report on medical errors and the need for enhanced patient safety indicated that many medication errors are not a result of
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**Integrated Medication Administration**

![Diagram of integrated medication administration system](image)

**Figure 1.**

individual performance but rather occur because providers fail to incorporate systems that could be designed to prevent such mishaps and tragedies.

In responding to the findings published by the IOM, the Agency for Healthcare Research and Quality (AHRQ) said providers need to focus on making systems improvements and not simply blame caregivers for medical errors. “Healthcare professionals are simply human and, like everyone else, they make mistakes. But research has shown that system improvements can reduce the error rates and improve the quality of healthcare.”

**Issues to Consider in Systems Design**

The industry has been galvanized by the extent, magnitude, and cost of medical errors in our delivery system. The findings are forcing healthcare providers to focus on applying the principles of error analysis and elimination. Although not all errors cause injury, accidental injury can result from error.

Focusing on the root of the problem, errors are either the failure of a planned action to be completed as intended or the use of the wrong plan to achieve an aim or desired outcome.

In healthcare, assuring that a planned medical action is without error means assuring the accuracy of medication prescription and administration, which to date has been a very labor-intensive manual process that does lead to occasional medication errors. Medication errors are particularly prevalent in our delivery system and have received the most focus in discussions of bar code technology. Every nurse (and a host of other healthcare providers) knows about the “Five Rights” of medication administration.

For medication administration to be considered error-free involves a number of “right interventions” in addition to ascertaining the right patient and right time. The drug, the dose, and the route of administration all must be correct to qualify as the “right intervention.” Using bar codes for automated data capture of the patient, medication, and nurse identities has been shown to radically reduce medication administration errors.

Auto-ID/Bar Code Enabled Medication Administration, or ABMA, systems have delivered enormous value to early adopters. With a much smaller investment than that required for fully integrated computerized provider order entry (CPOE) or electronic health records systems, ABMA systems should be considered for implementation as a key strategy to enhance the quality of the patient care medication administration process.

The relationship of the ABMA system as part of integrated medication administration systems, including CPOE, patient accounting/management, pharmacy, and materials management information systems (MMIS) or enterprise resource planning (ERP) systems, is shown in Figure 1.

In relation to the capabilities typical in hospitals’ information systems strategic plans, ABMA systems are the fastest to implement and offer the least expensive but highest return on investment for patient safety. However, they are not without challenges. The major areas of challenge include:

- Application integration with patient management, order communication (CPOE), pharmacy, and other systems.
- Bar code labeling of all medications at the unit-of-use level.
- Process and workflow changes.

While each of these challenges deserves considerable discussion, this article focuses on the dimensions that tie ABMA systems for point-of-care activities to the pharmaceutical and medical device supply chain. With very few exceptions for hospitals, supply-chain management begins with purchasing and ends at the receiving dock and storeroom. At the same time, information systems addressing medication ordering, distribution, and administration address different details and share only a subset of the information processed.

A typical scenario highlights the challenge. A physician medication order may have very basic information. The hospital’s policy, procedure, or customs dictate requirements to the nurses and pharmacist who know what to do with such an order. For example, at a particular hospital, the Q4D may translate to specific times each day. When the order is received in the pharmacy, many translations and perhaps substitutions may be made. Two 100mg tablets may be used for a 200mg order. A standard generic substitution may be made if the order was not DAW (dispense as written). In some cases, the pharmacist may contact the ordering physician to request authorization for a therapeutic substitution.

The architecture of most hospitals’ information systems...
has inherent separation between systems such as order communication and the pharmacy (see Figure 1). Thus, the scenarios described above will not be processed through the information systems. In our example, the order communication system would show the 200mg brand name drug while the pharmacy system might show two 100mg tablets of the generic version of the drug. Moving to the actual administration of the drug, the situation can become even more complicated.

ABMA systems require that each medication have a bar code or RFID tag at the unit-of-use level. Until recently, bar-coded unit-of-use medications were not readily available. As a result, hospitals would not invest in markedly safer medication administration because bar coded medications were not available, and pharmaceutical manufacturers and distributors would not invest in putting bar codes on unit-of-use medications because hospitals did not have systems to read them and were unwilling to pay extra for bar coded medications.

A secondary issue is the format of the bar codes used to mark medications. The diversity of existing bar code formats is illustrated in Figure 2. It shows several different standards that may be used, all of which have different requirements for hardware and software to read and interpret the bar coded information.

RFID tags now are starting to appear at the manufacturing and wholesale distribution levels of the supply chain because of the emphasis on efficiency in wholesale distribution and the interests of pharmaceutical manufacturers to reduce and eliminate drug counterfeiting. Adaptation of RFID tags at the patient bedside is most likely years away, although early trials are under way focusing on use of this evolving technology to automatically link the correct patient with the supplies being provided. As with barcodes, RFID tags have a variety of standards that are evolving, presenting challenges to manufacturers and distributors in the short term and to healthcare providers in the future.

FDA Regulations

The Food and Drug Administration stepped in to break the bar code dilemma by issuing a Bar Code Rule for human drugs, blood, and blood products. The Food and Drug Administration’s February 25, 2004, bar code rule is the first step in facilitating the implementation of bar coding systems to automate hospital pharmacies and improve hospital supply chain efficiency. This rule requires manufacturers, repackers, and relabelers to apply bar codes containing products’ National Drug Code (NDC) numbers to the immediate package of most prescription drug products, including biological products.

While this is a tremendous step forward, the FDA’s role as a public health agency limited the scope of its rule making. The rule imposes no requirements on hospitals and does not require unit of use or unit dose bar coding. Putting these systems in place is complex, and hospitals implementing bar code-enabled medication administration have many decisions that must be considered in the design and structure for the use of bar codes in their patient care information systems (see Table 1).

The earliest adopters of ABMA systems had to apply bar codes to all their medications. Internal hospital identifying numbers—such as the charge master numbers—were used. As unit-dose medications become available with NDC bar codes, hospitals’ ABMA systems had to accommodate both internal and manufacturer applied NDC numbers. However, NDC numbers can be very different for the same medication. Table 2 provides an example of how the same drug/dose/tablet can have multiple NDC numbers.

Connecting the Point of Care

The challenge is having an ABMA system that is exact and precise enough to accommodate all the obvious and subtle variations of the “simple” medication administration process.

When the bar code scanner or RFID reader returns a character string, a computer application will have to parse out the NDC number and verify that it is the Right Drug, Right Dose, and Right Route. A rather brute-force approach to accomplish this is to dedicate staff to table maintenance. But this compromises the premise that eliminating manual steps and using electronic auto identification systems reduce errors and saves money.

The safer approach and far more cost-effective approach is to use supply chain EDI or XML transaction sets that move information all the way to the ABMA system. When hospitals require that deliveries of pharmaceuticals be preceded by an EDI Advance Shipment Notification (ANSI X12 Set 856), the NDC codes of the actual medications shipped and delivered can be captured in the provider’s ERP/MMIS and pharmacy information management systems. This captured information must go beyond the receiving dock and purchasing and accounts payable by moving the knowledge of the NDC
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numbers for drugs “in-stock” to the ABMA system. Thus, integrating the systems will result in moving supply chain management capabilities to the point of care.

Systems Complexity and Patient Safety

Healthcare information systems today are increasingly complex, and while bar codes and RFID technologies provide opportunities for enhanced patient care, systems using these capabilities must be carefully planned to achieve optimum outcomes.

Before the advent of automated systems, hospitals used myriad manual paper-intensive processes to order, track, and bill for supplies and medications. During the past few years, there has been increasing emphasis on integrating these activities by using information systems designed to automate order processing, data capture, and supply consumption for patient charging.

CPOE, materials management information systems or enterprise resource planning, and pharmacy information management systems all benefit from efficiencies that result from use of automated identification technologies.

This is especially true for ABMA systems built on the premise of using bar coding or other auto-ID technologies to automate data capture and record medication administration transactions. Systems designed to incorporate ABMA will provide significant benefits to providers, both financial through more efficient patient care, reduced litigation and insurance costs, and in terms of improved quality of patient care.

Thus, the strategic focus for healthcare providers should include implementation capabilities designed to make effective use of ABMA systems at the point-of-care. Patient care quality benefits will accrue mostly through ensuring the five rights of medication administration are adhered to in the patient care process. These include the right medication, the right dose, the right time, the right patient,

<table>
<thead>
<tr>
<th>Applications</th>
<th>Structure &amp; Symbology determined by</th>
<th>Standardized Structure and Symbology</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Medication purchased with bar code on unit-of-use</td>
<td>FDA Rule</td>
<td>EAN.UCC or HIBCC “Linear”</td>
</tr>
<tr>
<td>A. NDC Code</td>
<td>Mfg. - Packager Choice</td>
<td>EAN.UCC: 2D Composite Component</td>
</tr>
<tr>
<td>B. Lot &amp; Expiry</td>
<td></td>
<td>HIBCC: Separate Code 128</td>
</tr>
<tr>
<td>2. Hospital bar coded Unit-of-use medication</td>
<td>Hospital Choice</td>
<td>Mfg using non std micro PDF &amp; Data Matrix</td>
</tr>
<tr>
<td>3. Blood and Blood products</td>
<td>FDA Rule</td>
<td>EAN.UCC or HIBCC if hospital subscribes HIBC PAS</td>
</tr>
<tr>
<td>4. Hospital prepared IV mixes</td>
<td>Hospital Choice</td>
<td>Codabar or ISBT 128</td>
</tr>
<tr>
<td>5. Patient ID Band</td>
<td>Hospital Choice</td>
<td>HIBC PAS</td>
</tr>
<tr>
<td>6. Employee ID</td>
<td>Hospital Choice</td>
<td>Implementing proprietary content &amp; format</td>
</tr>
<tr>
<td>7. Specimen Container</td>
<td>Hospital Choice</td>
<td>HIBC PAS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Implementing proprietary content &amp; format</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NCCLS</td>
</tr>
</tbody>
</table>

Table 1 – Structure & Use of Barcode Applications for Medications
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Table 2. NDC code and labeler information.

<table>
<thead>
<tr>
<th>Description</th>
<th>Unit</th>
<th>Qty in Package</th>
<th>NDC Code</th>
<th>NDC Labeler</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vicodin</strong>®</td>
<td>Bottle</td>
<td>500</td>
<td>00044-0727-03</td>
<td>Knoll Laboratories Div Knoll Pharmaceutical Co.</td>
</tr>
<tr>
<td><strong>Vicodin</strong>®</td>
<td>Bottle</td>
<td>100</td>
<td>00044-0727-02</td>
<td>Knoll Laboratories Div Knoll Pharmaceutical Co.</td>
</tr>
<tr>
<td><strong>Vicodin</strong>®</td>
<td>Unit dose</td>
<td>00044-0727-41</td>
<td>Knoll Laboratories Div Knoll Pharmaceutical Co.</td>
<td></td>
</tr>
<tr>
<td><strong>Lortab</strong>®</td>
<td>Bottle</td>
<td>100</td>
<td>62584-0023-00</td>
<td>Amerisource Health Services Corp</td>
</tr>
<tr>
<td><strong>Lortab</strong>®</td>
<td>Bottle</td>
<td>500</td>
<td>0756-0186-50</td>
<td>D M Graham Laboratories Div</td>
</tr>
<tr>
<td><strong>Hydrocodone Bitartrate &amp; Acetaminophen</strong></td>
<td>Box 10 x 10</td>
<td>100</td>
<td>51079-0420-20</td>
<td>UDL Laboratories Inc</td>
</tr>
<tr>
<td><strong>Hydrocodone Bitartrate &amp; Acetaminophen</strong></td>
<td>Box 5 x 20</td>
<td>100</td>
<td>51079-0420-21</td>
<td>UDL Laboratories Inc</td>
</tr>
<tr>
<td><strong>Hydrocodone Bitartrate &amp; Acetaminophen</strong></td>
<td>Box 6</td>
<td></td>
<td>51079-0420-96</td>
<td>UDL Laboratories Inc</td>
</tr>
</tbody>
</table>

...and the right route. To record the medication event, patient-care activities also must be accompanied by the use of an electronic medication administration record system. These systems are linked to other patient care information systems, including CPOE and the electronic medical record, all of which contribute to safe patient care as well as providing financial benefits to the hospital.8

To reduce errors in medication administration, healthcare providers must improve their processes. This includes consideration of transcription of pharmaceutical orders, accurate dispensing by the pharmacy, and accurate administration by the caregivers. The use of ABMA capabilities can build on or be expanded to other systems within the hospital or provider domain.

Because healthcare activities involve the use of diverse equipment and supplies as well as medications, it is logical to build on the use of ABMA to enable the capture of related data, including patient identification, supply tracking and consumption, and laboratory specimen tracking capabilities. Of course each of the respective systems should be integrated or interfaced appropriately using HL7 standards9 to ensure accurate transfer of data between systems in the most efficient manner.

Information systems using ABMA capabilities to provide auto-ID bar code data capture at the bedside should be used to enhance patient medication safety. The systems can be linked to other hospital systems, including the electronic health record and pharmaceutical and supply management systems, to provide financial information and related information system capabilities that can drill down to the patient level to report on the cost of providing care.

Thus, integrated healthcare information systems can provide access to both real-time and historical information for conducting queries on patient-care activities, pharmaceutical and supply usage trends, and internal performance benchmarks on quality of care and various types of supply efficiencies. Integrated systems can contribute to the development of standardized care paths by tracking and reporting on pharmaceutical and supply usage for various patient groups.
System Design and Implementation

There are numerous issues to consider when selecting an Auto-ID Barcode Medication Administration system. When adequately designed and implemented, the ABMA system should be fully integrated to other information systems and will enrich information available for quality performance and clinical and financial management at virtually all levels of hospital operations. The use of ABMA as a point-of-care system to track medication administration makes it a foundation for clinical information systems designed to work with other information systems and resources within the provider’s network.

When hospital staff use an ABMA each time a medication is administered, information is tracked and recorded in the patient’s medication administration record. The use of the drug is automatically sent to the hospital’s billing system with the essential details, facilitating audits, and quality control reviews.

“Using bar codes for automated data capture of the patient, medication, and nurse identities has been shown to radically reduce medication administration errors.”

Using ABMA at the point of care coupled with the electronic health record and related pharmacy information management systems increases users’ ability to monitor medication use at the patient, physician, and clinical unit level. The diversity of medications used daily in hospitals contributes to the complexity of patient-care processes, thus mandating automated systems to control use, prevent medication errors, and assure quality patient care.

Budgets for medications have risen steadily in the past several years, and this trend is expected to continue. As a result, hospitals have a critical need to understand pharmaceutical usage patterns as well as the efficacy of different treatment regimens on different diseases. ABMA systems coupled with a pharmacy information management system enable providers to track actual medication usage linked to patient and provider information. A pharmacy standards and therapeutics committee and individual physicians then can use this data to facilitate review and evaluate outcomes achieved. Accurate medication information is a strategic component of achieving quality patient care and influencing prescribing patterns of physicians.

According to HIMSS, the projected cost for a hospital to implement ABMA systems to read and capture bar code data at the bedside is slightly less than $2,000 per bed, with operating expenses estimated at more than $1,000 per year. Thus, for a 200-bed hospital, the costs to acquire and implement an ABMA will be in excess of $500,000. Start-up costs for ABMA systems include system hardware, software and data management systems, service costs, and user training. The decision to lease or buy an ABMA system must undergo the same strategic scrutiny that any enterprise IT system would require.

The key to understanding the costs of these systems is to have a solid understanding of system lifecycle costs, including increased patient stays or death, insurance, litigation, labor, and drug costs for each clinical area to be enhanced with an ABMA system. Obviously, the preceding estimates depend on numerous factors, including the existing provider infrastructure and systems capabilities.

The FDA’s review of potential benefits indicated that the introduction of the new technologies associated with the ABMA systems actually resulted in decreased productivity when the systems were first installed. “It is significant that in a time of nurse shortages, the FDA concluded there is a three percent degradation in patient unit productivity when BMAR systems are installed.” Thus, hospitals need to plan carefully when implementing these systems to ensure that patient care activities are not adversely affected, especially in units where there are staff shortages and critically ill patients. In the long run, many hospitals that have implemented ABMA report overall nursing productivity increases as a result of collateral efficiencies.

According to studies and reports from the FDA and others, the use of ABMA capabilities to prevent adverse drug or medication events (ADEs) is dramatic. Use of automated systems at the point of care by properly trained staff can significantly reduce the number of medication errors. As a result, healthcare providers can increase the quality of care and reduce hospital stays, and litigation, as well as achieve enhanced productivity from scarce healthcare resources.

Robert Krawisz, executive director of the National Patient Safety Foundation, contends that the benefits of automating medication administration using bar codes are significant, saying, “The technology’s impact at VA hospitals so far has been amazing.” In an article entitled “Strategies to Reduce Medication Errors” published by the FDA Consumer Magazine, it was noted that the Department of Veterans Affairs has substantially reduced medication administration errors by using bar codes as part of its medication administration processes in VA hospitals nationwide. “For example, the VA Medical Center in Topeka, KS, has reported that bar coding reduced its medication error rate by 86 percent over a nine-year period.”

To achieve error reductions, providers must link systems involved with initial physician orders (CPOE), transcription of orders, medication dispensing, and administration. In linking the ABMA system with other IS applications, the use of bar codes (and RFID tags in the future) provides both validation of the five rights and creates an audit trail for subsequent analysis of patient-care activities.
As providers plan for using ABMA system capabilities, providers should consider several different factors as part of their strategic planning. These include:

- The percentage of pharmaceutical products in the hospital formulary that can be acquired pre-labeled with bar codes.
- The existing capabilities in the pharmacy to support repackaging of medication, if needed, to support the ABMA system.
- Opportunities to use standard bar code readers for patient identification, other medical surgical supplies, biomedical equipment, and other uses.

After completing the initial evaluation of requirements and existing bar code capabilities, a plan can be developed to guide the subsequent acquisition of technologies, both software and hardware, necessary to achieve success with the ABMA initiative. Of course, this acquisition of technologies should consider the costs and benefits for integrating these capabilities or updating legacy systems as part of the overall strategic plans for the IS, nursing, and pharmacy departments.

With ABMA systems, as with any automated systems, there can be breakdowns or system failures. System up-time and service responsiveness must be defined and determined, using either trained hospital staff or the vendor service support technicians. Also, manual processes must be established so medications are always available whether or not the system is operational. Proper recording of all medication activities and immediate reconciliation of administration records after a system is returned to service, are important considerations after a service outage.

Balancing Needs in Trying Times

The integration of bar codes and radio frequency identification tags is critical for enhancing systems and support necessary for achieving effective and safe patient care. However, these systems are complex, and all parts need to be aligned; the systems must work together to produce the desired outcomes.

As hospitals and other healthcare providers evaluate their strategic needs for the future, the use of ABMA systems and related capabilities—while requiring upfront investment in IS capabilities—promises to deliver significant benefits to the quality of patient care. As such, these capabilities should be carefully considered and given priority as part of an organization's efforts to develop integrated capabilities for safe, efficient, and effective patient care. These systems also will have a positive impact on the financial performance of the provider organization as a result of avoiding costs by reducing lengths of stay associated with adverse medication events and cutting insurance costs for the institution in the long run.

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Adding User-Friendliness and Ease of Implementation to Continuous Speech Recognition Technology with Speech Macros: Case Studies

Harrison D. Green, PhD

Abstract

Continuous Speech Recognition Technology implementation is expensive, and the failure of leading companies in this niche can hamper usefulness. C-SRT, if deployed and used with speech macros, experiences vastly improved implementations and drastically reduces medical transcription costs. A speech macro is a short phrase that is automatically translated into a block of text or a graphic display. A more powerful form of speech macro can bring up predefined templates and insert spoken text into the proper position automatically, based on its interpretation. Cases from the author’s consulting experiences and from medical journals emphasize the need for speech macros from a cost-benefit standpoint. A prototype program is introduced that facilitates the process of creating macros. The need for macro management software is reconciled with current research on speech recognition and technology adoption. A planned experiment is discussed.

Keywords

- Continuous speech recognition
- Technology acceptance model
- Healthcare applications
- Speech macros
- Healthcare technology

Introduction

Continuous speech recognition entails the entry of full documents in a professional business setting. In contrast, discrete SRT is the entry of short voice commands to trigger an immediate response from the computer. Discrete SRT is more characteristic of telephone responses and older speech recognition applications. Discrete SRT has become more successful because it is easier to implement than continuous SRT. Throughout the remainder of this paper, the abbreviation “SRT” will refer to continuous SRT.

The success of speech recognition technology may depend on many interrelated factors, including the degree of computer expertise, the quality of computer software and hardware, the physical environment, and the degree of integration with the current application. Because of the high costs of transcription and the need for specialized vocabularies, the primary application of SRT (and the focus of this paper) has been to healthcare. There are, however, many potential applications to other fields as well.
need for software improvement. Subsequently, cases are presented, both successful and unsuccessful, that relate to the adoption of SRT. Success patterns in the cases then are reconciled with current research on SRT and technology acceptance. Prototype software is introduced that may address some SRT adoption issues. Finally, a research study is outlined that will test the effect of this software on variables from the Technology Acceptance Model (TAM) that may influence adoption of the technology. The TAM methodology has been widely accepted by MIS researchers; it relates certain intangible factors, such as perceived usefulness and perceived ease-of-use, to actual usage of a new technology solution.

Speech recognition technology promises large potential gains but also requires a significant investment of money and time. It is easy for the professional to be misled into thinking that SRT automatically increases the efficiency of document entry and processing. The latter can be evidenced by the recent failures of producers of SRT software. The remainder of this section treats each of these points in more detail.

**Large Potential Benefits, Costs**

Cost feasibility of any new technology is important to almost every business. One study examines the feasibility of converting document processing in large-volume healthcare institutions to voice automation. They estimate that such institutions can expect startup costs in the neighborhood of $250,000. For smaller installations, total costs can be more than $15,000 per physician.

Both hardware and software costs obviously can be significant. Usually, to provide the required computing power, new computers or major upgrades to existing computers are necessary. The cost of SRT software alone may vary from hundreds to thousands of dollars, depending on the program's built-in features. SRT software with enriched vocabulary in specialized fields such as radiology or cardiology can cost more than generic software. The startup costs also may include any macro or template management program. The most important component of the startup costs is the personnel time required for training, macro development, and the learning curve.

If properly implemented, the potential benefits of SRT can be significant. Henricks cites a case where a large hospital achieved a return on its initial investment in just two years. Similarly, Sistrom reports net savings of $150,000 in three years resulting from reduced transcription costs.

However, many articles written about SRT could be misleading to the inexperienced user. Reports based on an initial impression of the technology or testing under optimum conditions could be mistaken as proven guidelines. Software vendors may have written some of the articles; others may be based on research using a very small sample.

An article by Lucas compares several SRT software products. The specific application is internal medicine. He concludes that Provox is superior in the areas of accuracy and the ease of editing. The author's findings, however, cannot be considered unbiased because he is the president of Provox.

Zick and Olsen completed a study about the potential application of SRT to entering charts in the emergency room. They concluded that turnaround times could be increased tenfold and that the annual savings to the hospital in transcription fees would be approximately $334,000. These were very rough projections, considering that their data was obtained from their experience in creating only 47 charts with two users.

In an article geared toward orthodontists and oral surgeons, Powers emphasizes the need for selection of the right hardware and software to have a successful SRT implementation. There was little attention given to practical implementation issues that have proven to be major deterrents to success, such as unacceptably high error rates and inability to perform productively in a high-pressure work environment.

**Speech recognition technology promises large potential gains but also requires a significant investment of money and time.**

**Failures of SRT Companies**

The failures of companies that produce SRT also justify the need for more applied research in this area. Vendors of several leading SRT software products have gone bankrupt and sold their interest in their product to more diversified companies. For example, Dragon sold out to L & H Distributing, which then went bankrupt after a few years and sold their interest in Dragon to Scansoft. In the radiology area, TalkStation Radiology, originally developed by Talk Technology, has been acquired by Lanier Health Care. IBM has discontinued their Medspeak radiology software.

In an attempt to isolate underlying success factors, the following two sections present recent case studies in the implementation of SRT. One important source of material on SRT is the author's consulting experiences. Although very limited in scope, the major advantage of personal observation through consulting is that many of the details about the technology and the attitudes and the adoption process can be observed that otherwise might have been omitted in journal articles or even in surveys. Several of the...
professionals cited in this article have consented to be contacted as a reference regarding these experiences.

**Some Successful Cases**

A psychologist wanted to use SRT to enter transcripts of his patient sessions. The psychologist was a novice computer user, and this case occurred when practical speech recognition programs first became widely available. He experienced frustrations not only because of his lack of computer literacy, but also because his hardware and software were inadequate to support SRT. He exhibited a great deal of endurance during this process. After major hardware and software upgrades and more than 50 hours invested in training and testing, he was able to use the technology to enter transcripts of patients' sessions.

Before using SRT, he used a telephone transcription service company at a cost of $85 per recorded hour. He estimated that he was spending approximately 10 hours per week with the telephone service, mostly in the evenings. In addition to the cost savings, SRT added flexibility and convenience because the telephone service was only available for certain blocks of time. With current improvements in hardware and software, there is much less chance that new adopters of SRT will experience similar compatibility problems.

A general practice physician now uses a comprehensive set of speech macros for entering physical exam results. The physician compiled the list of macros, and the author programmed them into the software. An example of one of his macros are the words, “Lung exam OK,” which expand into “Were clear to auscultation and percussion. Good air exchange was noted. No use of accessory muscles of respiration.”

An osteopathic surgeon, with the aid of his wife, who is a programmer, has set up his office to be almost 100 percent voice-controlled. For example, to enter a patient’s charges, he issues a command such as, “Bring up billing template.” Because proper names are not reliably recognized, he would need to locate the patient through one or more menus. Assume that the name is Pietkewitz, Nikita. To narrow the list down to those names beginning with the letter P, he says, “Show P list.” The program would automatically number the patients with last names of P, and he would only need to speak the number.

**Less Successful Cases**

Another general practitioner purchased SRT software with medical vocabulary included. To date, he uses it only occasionally. He did not have much computer experience and did not invest the time to acquire the training needed to use SRT effectively.

A neurologist, who makes referrals to other specialists, purchased the software and uses it infrequently. The main problem he has encountered is that the software has difficulty recognizing proper names. He did not have sufficient local technical support to solve this problem.

A veterinarian owns two clinics, and each employs about five physicians. He purchased the network version of the software, hoping that all of his physicians would use the software at the various workstations in the clinic. The owner uses it frequently, but the other physicians have only experimented with it. The staff physicians have a heavier workload than the owner and did not have enough time to learn to use it. One of the major limitations they faced was that many of the features of Dragon’s Naturally Speaking, including the commands to select or correct a phrase, would not work from within their veterinary software. The compatibility issue should be resolved as the software

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**Table 1: Summary of Consulting Cases**

<table>
<thead>
<tr>
<th>Medical Professional</th>
<th>Dollar Investment Level</th>
<th>Time Investment</th>
<th>Degree of Success</th>
<th>Major Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychologist</td>
<td>High</td>
<td>High</td>
<td>Moderately successful</td>
<td>Early adopter, motivated by high potential cost savings</td>
</tr>
<tr>
<td>General Practitioner (1)</td>
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<tr>
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<td>Above average</td>
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<td>Proper names: lack of a creative solution</td>
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<td>Limited success</td>
<td>Weak computer skills, accent</td>
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<td>Average</td>
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<td>Good computer skills, high need for technology</td>
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becomes more sophisticated.

Recently, a general practitioner and a cardiologist purchased SRT software. They both have powerful computers that run at 2.4 gigahertz and have 512 megabytes of RAM memory. These physicians have both received support from a computer science student who, although highly computer literate, did not have specific expertise in SRT. The general practitioner has had more success than the cardiologist. The general practitioner quickly began adapting the system to his specific needs and creating speech macros. The cardiologist required more technical assistance and, at this point, uses SRT only occasionally. The general practitioner was more familiar with technology and was able to identify more repetitive phrases and tasks that could be handled by speech macros. The cardiologist also speaks with a stronger accent than the general practitioner.

**General Trends from Consulting Cases**

Table 1 summarizes the dollar investment level, degree of success, and major factors affecting the consulting cases. All medical professionals except the veterinarian purchased the medical version of Dragon's Naturally Speaking. The veterinarian purchased Dragon's Naturally Speaking Professional Version and loaded a veterinary-specific vocabulary.

The major differentiating factor for costs was computer hardware. Time investment was more of a determinant of success than expenditure. Limited computer skills, strong accent, and need to use proper names were stumbling blocks.

**Cases from the Medical Literature**

The most successful applications of SRT have required a considerable amount of planning and effort on the part of both the implementation team and the users. Usually, there are certain trade-offs or compromises. For example, there can be a learning period ranging from weeks to months before users feel comfortable with SRT.

An extensive amount of macro programming may be required on the part of the developers, and or users before the technology becomes productive. Programming may be accomplished with a language such as Visual Basic or a built-in macro creation facility within the SRT program.

Physicians that adopt speech recognition technology may feel that their workload has increased. They are forced to do their own editing and correction instead of relying on a transcriptionist.

A dermatologist who adopted SRT relatively early in its evolutionary process. During a period of six years, he programmed more than 9,000 phrases. He saved more than $100,000 in salary costs from 1993 to 1998. Many of the features that he was required to program now are standard components of SRT software. He found it very efficient to use overlapping phrases, such as “the left upper chest” and “the left upper abdomen,” so he did not have to remember too many commands. His initial investment was about $10,000.

In one case, speech recognition technology was implemented in the radiology departments of three Air Force medical centers. Programs for macros and workflow integration were self-developed in Visual Basic. Their self-developed Voicepatch program provided the interface between the radiology software and Dragon's Naturally Speaking. One distinctive feature of Voicepatch was that it would read back the radiologist's dictation during the review process, removing any need to focus on the computer screen. There was, however, some staff resistance to the extra work required to implement the system. The project cost about $3,000 per computer. In the short run, a savings of $55,000 and a reduction in turnaround time for dictated reports was achieved. There is no data available regarding continuing cost savings.

An implementation study at the University of Florida hospital covers a longer time period. In this setting, users were required to develop an extensive set of personal macros. Macros and templates were stored in a central database that enabled easy access from any workstation. Radiologists also could import macros from other users. Some macros could be triggered through bar code, thus enabling an alternate form of data entry. In the long run, there was a high degree of user satisfaction and a savings of $150,000 over three years because of the elimination of five positions.

The surgical pathology unit of the Cleveland Clinic purchased SRT software designed specifically for pathology. With accuracy averaging only about 85 percent, they would not have been successful without the use of templates. Their “templates consist of a skeleton of fixed text (black text) with prompts (blue text) to speak trigger words and phrases and prompts to insert numerical measurements (blue brackets).” To operate the system, they needed only to remember a few trigger words and phrases. About 160 hours were required to develop and test the templates. With a transcription cost savings of $2,625 per month, the estimated payback period was two years.

**Less Successful Cases**

In situations where there has not been as much effort in the development of macros, implementers often have complained about the need for more built-in integration with their existing software. At Elmhurst Hospital Center in New York City, Hayt describes the need for more connectivity between SRT software and their existing radiology and document management systems. In contrast to the Air Force medical centers, there was no software to directly link their voice recognition system to their radiology software, although they planned to link it in the future. There were...
occurring incidents where workstations froze, and in some cases, inadequately trained users caused errors.

A physical therapy clinic purchased a turnkey SRT system that included both software and compatible hardware. The cost was approximately $15,000 per physician. Because additional time and effort were required to create about 70 macros tailored to their specific practice, the system was not “turnkey” in the strictest sense. These macros, which minimized the use of repeated phrases, were necessary to achieve a 50 percent reduction in dictation time. With a transcription cost savings of approximately $2,500 per month, five years was the projected payback period. The five-year payback is approximately twice that reported for some of the most successful implementations.

General Trends from Medical Literature

These case studies illustrate that SRT does not automatically improve document production efficiency. Each business setting has its own unique customization requirements. Despite increasingly sophisticated technology, a significant amount of effort is still required to make SRT successful. In addition to programming and adapting the software, new users must learn and adjust to the technology. In several studies, physicians experienced frustration from having to correct their own reports, a task that was formerly delegated to transcriptionists.

Table 2 summarizes the cost savings, time period, time required, degree of success, and major factors for each institution. The savings cited are gross transcription cost savings and do not directly reflect the increase in efficiency and quality of care resulting from dramatically reduced report turnaround times.

With the exception of the dermatology office and the physical therapy clinic, startup costs per workstation should be comparable. All of the larger institutions purchased comparably priced high-end SRT software that has multi-user speech recognition and workflow integration capabilities that are not available with off-the-shelf products. The physical therapy clinic also purchased high-end software but paid extra for pre-programmed macros, which they found to be inadequate. The dermatologist purchased an inexpensive off-the-shelf product.

The Air Force Medical Center, University of Florida, and Cleveland Clinic all expected payback periods of less than three years with continued cost savings. However, the fact that many of the vendors of the high-end SRT software have either discontinued their product or sold it to other companies may mean ongoing support costs will rise. These hospitals may find it necessary to rely on more expensive private consultants in lieu of the original software vendor.

The most successful hospital, the University of Florida, had very personalized macros. Personalized macros are speech commands developed by the users themselves rather than the programmers or system developers. Elmhurst Hospital made the mistake of not integrating the SRT software with their Picture Archiving and Communications System software at the outset. It could be inferred that the Air Force Medical Center and the Cleveland Clinic could have been even more successful if more emphasis had been placed on personalized macros.

Current Research

There is a need to determine if observations and patterns in the case studies can be explained, or at least framed, by current related research.
Al-Aynati and Chorneyko\textsuperscript{14} compared SRT with traditional transcription for generating pathology reports. The mean accuracy rate was 93.6 percent for SRT and 99.6 percent for transcription. Because of additional editing, twice as much time was required on the part of the pathologist. They concluded that the extra burden on the physician would limit the widespread use of SRT. It should be noted, though, that a transcriptionist was not required with SRT.

In a similar study by Mohr\textsuperscript{15} secretaries were only 88.8 percent as productive using SRT. The only group that showed improvement with SRT was the poorer typists. Rebman\textsuperscript{16} using students as subjects, found accuracy for SRT to be significantly less than typing accuracy. SRT was faster only when students were not focusing on accuracy.

It is evident that, without introducing context-related measures to enhance productivity, the benefits of SRT compared to typing will be marginal, if there are any benefits at all.

**Technology Acceptance Model Framework**

To identify variables that these laboratory studies may have overlooked, it is necessary to apply a comprehensive framework for technology adoption. There is research evidence to suggest that TAM2 (Technology Acceptance Model 2) is most appropriate for experiments involving healthcare professionals.\textsuperscript{17} TAM originally was developed by Davis.\textsuperscript{18} It incorporated relationships among perceived usefulness, perceived ease of use, intention to use, and usage behavior (see Figure 1).

In TAM2, Venkatesh and Davis\textsuperscript{19} enhanced TAM by introducing more specific variables that would be predictors of perceived usefulness and intention to use. Independent variables in TAM2 consist of three social influence processes (subjective norm, voluntariness, and image), four cognitive instrumental processes (job relevance, output quality, result demonstrability, and perceived ease of use), and experience.

In this model, all independent variables except voluntariness affect perceived usefulness (see Figure 1). Subjective norm and perceived ease of use affect intention to use. Image and voluntariness moderate the relationship between subjective norm and intention to use. Image also moderates the relationship between subjective norm and perceived usefulness. Venkatesh and Davis\textsuperscript{19} found all relationships in TAM2 to be significant. Their experimental subjects were from a broad range of industries.

The most closely related application of TAM2 is a study by Chismar\textsuperscript{20} concerning adoption of Internet-based health applications by physicians. They measured subjective norm, image, job relevance, result demonstrability, output quality, and perceived ease of use. Other TAM2 variables were not relevant to their experiment. The only significant correlation was between job relevance and perceived usefulness. Output quality was a weak predictor of perceived usefulness but not significant.

Previously mentioned studies,\textsuperscript{14,15,16} which focused on productivity measures, were mainly concerned with output quality and result demonstrability. These may not have placed sufficient emphasis on factors that are related to job relevance. One such factor is software enhancements that directly support the task at hand.

**The Need for Software Support**

One common feature of successful SRT installations was the incorporation of an extensive set of personalized speech macros.\textsuperscript{5,6,11} According to a survey conducted by \textit{HHN Most Wired Magazine},\textsuperscript{21} fewer than 50 percent of all hospitals have voice-recognition capabilities. It is likely that many who have the capabilities do not use them extensively. It would appear that the creation of speech macros, because of the time and effort involved, can be a major stumbling block. In the consulting case studies, those with less technical expertise had more difficulty developing creative applications. There is a need to enable the non-technical professional user to develop speech macros with less investment of time and money.

A speech macro is a short phrase that is automatically translated into a block of text or graphic display. A more powerful form of speech macro can bring up predefined templates and insert spoken text into the proper position automatically based on its interpretation. In a closely monitored test in the radiology unit of a large hospital, Langer\textsuperscript{2} found that speech macros increased productivity. In an informal survey of physicians and consultants,\textsuperscript{22} more powerful macros were listed as an important factor to the success of SRT. The ability to create speech macros may increase the job relevance of SRT. The next section introduces a prototype program to facilitate the process of creating macros.

**A Macro Management Program**

Not every application is appropriate for speech recognition. One reason is that not all software is compatible.
with speech recognition programs. Although it is possible to enter text into most software that works with Microsoft Windows, the function keys and navigation keys may not work through voice activation.

Software extensions have been written for an increasing number of business applications to make them more compatible with speech recognition software. However, speech macros have become so powerful that they can completely replace certain application software. The speech macros can be less expensive than the application software and have a guarantee of 100 percent speech compatibility.

The latest version of Dragon’s Naturally Speaking, as well as similar continuous speech recognition software, has built-in macro creation and maintenance features. The macro features in these programs can be difficult for an inexperienced user to master, especially in the area of reviewing and updating macros. Students at our university have developed a prototype program for macro creation and maintenance. It is written in Visual Basic and interfaces with a Microsoft Access database. Macros, when created (see Figure 2), are automatically dated and labeled, and the author is designated.

The example shows the expansion of “Lung Exam OK,” an actual macro from a physical exam. The speech macro consists of the name assigned to the macro, the voice command to trigger the macro, and the actual text that is typed on the screen. An identifying number, the name of the owner, and creation date also are automatically stored with each macro.

Much longer macros are possible. If deviations from the standard expansion text are necessary, it is often easier to apply the macro and then make minor corrections. Although this program still is being refined and improved, it has received positive feedback from local physicians who have tested it.

Although the program was initially designed for physicians, other professionals should find it useful. The program enables the user to add, modify, delete, sort, and search for speech macros with a user-friendly interface. When the program closes, all of the macros are automatically transferred to a file that easily can be imported to Naturally Speaking. The program is 100 percent speech compatible, meaning that all command buttons can be activated by voice. All data can be entered and easily corrected through a speech interface.

The macro management program, with some improvements, has the potential to greatly increase the productivity and usefulness of SRT software. Planned improvements include the following:

- Enabling users to enter parameters within the voice command. For example: “Call back 6 days” would translate to “I will call you back in six days. Please have a decision regarding our business transaction at that time.” Any number of days could be entered.
- Implementing prompts for the user if some parameters required within the voice command are omitted.
- Enabling users to press a hot key, speak in a topic, and have a popup menu appear containing related voice commands.

For maximum success, voice commands need to be as distinctive as possible. Users should select easy and unique voice command for macros. This uniqueness of the voice command not only enables the search engine to locate the correct macro but also helps the user to remember the correct key words. As with all voice-activated software,
it is important to speak as distinctly as possible. A minimal amount of training is required to effectively use these programs. Users with basic computer literacy should need only about 30 minutes of formal training. The SRT software, because it has more commands and options than the macro management software, will normally take longer to master. Other researchers interested in pursuing this topic may contact the author for a copy of the software with instructions.

Outline of the Research Study
An empirical test is planned to determine the impact of the macro management software. A survey will be administered over the Internet. An existing speech recognition Web site will be promoted and set up for user interaction according to Birnbaum's guidelines. The site already receives a significant number of daily visitors. Respondents will be limited to medical professionals. The incentive to participate will be a free downloaded copy of the macro management software. Each subject will complete a survey, view a six-minute demo of the software, and then complete a second survey that measures the impact of the online demo.

"One common feature of successful SRT installations was the incorporation of an extensive set of personalized speech macros."

Because this is an applied experiment, independent or predictor variables from TAM2 now are treated as dependant variables. The independent variable is the awareness of the capabilities of macro management software. A diagram of the experimental model is shown in Figure 3. The four cognitive influence processes from TAM2 will be measured, while the three cognitive instrumental forces will be excluded. Image and subjective norms may be too subjective to test in this format. Voluntariness would not be meaningful because participation is not mandatory. Experience is excluded because it is a moderating variable on subjective norm. Technical expertise is added as a moderating variable. It is suspected that users with higher self-assessed technical expertise will be more likely to perceive the benefits of the software.

Surveys from the original TAM2 study will be reworded to be specific for SRT and the macro management program. The surveys will be pre-tested for validity with a group of local medical professionals.

The following four hypotheses will test for a significant impact of the macro management software on each of the four cognitive influence processes moderated by technical expertise:

- Awareness of the software capabilities will have a positive effect on job relevance for users with higher self-assessed technical expertise.
- Awareness of the software capabilities will have a positive effect on perceived output quality for users with higher self-assessed technical expertise.
- Awareness of the software capabilities will have a positive effect on result demonstrability for users with higher self-assessed technical expertise.
- Awareness of the software capabilities will have a positive effect on perceived ease of use for users with higher self-assessed technical expertise.

Because the subjects will have very limited exposure to the treatment variable, perceived usefulness and intention to use will be impractical to measure. The results, however, will be somewhat meaningful if H1 and H2 are significant. Job relevance and output quality were found to be predictors of perceived usefulness in a previous technology adoption study of medical professionals. Repeated studies have found a high correlation between perceived usefulness and intention to use. If H3 and H4 are significant, subsequent research will be necessary to determine whether perceived ease of use and result demonstrability influence intention to use in this setting.

Limitations and Conclusions
This experiment is exploratory research. There are many uncontrollable factors including area of specialization, job content, and amount of attention devoted to the software demonstration. However, a large sample size should compensate for some of the subject-related variations. The survey will be measuring initial reactions to software that has not been professionally developed.

Despite the limitations, this experiment should increase the awareness among researchers of the need to apply TAM to SRT as well as to other new technologies.

More practical research, with larger sample sizes and spanning longer time periods, will be necessary. Longitudinal studies are needed to precisely measure usage rates, errors encountered, hidden costs, and productivity gains in larger institutions that have adopted SRT. To measure the impact of SRT on smaller clinics or businesses, it will be necessary to gather a complete sample of feedback from users across different fields, analyze the data and look for common trends. The experimental model can be refined as more confirmatory research is completed with TAM; that is, more precise correlations between independent and dependent variables.

Although not yet supported by experimental evidence, it has been the author's observation that first-stage adopters tend to be those with handicaps or very poor typing ability.
Second-stage adopters are usually professional people who need to economize on time or have very specialized vocabularies. Third-stage adopters are likely to be operational-level workers who use complex programs and can benefit from the power of speech macros specifically tailored to their software. To test this theory, it will be necessary to introduce more precise variables related to job content and experience with technology. The ultimate goal of continuing research will be to provide better software support for SRT and similar technologies.

About the Author
Harrison D. Green, PhD, is an assistant professor of computer information systems at Eastern Illinois University. He has written several journal articles and conference papers on speech recognition technology.

References
The Application of Volume-Outcome Contouring in Data Warehousing

James Studnicki, ScD, Donald J. Berndt, PhD, Stephen L. Luther, PhD, and John W. Fisher, PhD

ABSTRACT

Despite a compelling body of published research on the nature of provider volume and clinical outcomes, healthcare executives and policymakers have not managed to develop and implement systems that are useful in directing patients to higher volume providers via selective referral or avoidance. A specialized data warehouse application, utilizing hospital discharge data linked to physician biographical information, allows detailed analysis of physician and hospital volume and the resulting pattern (contour) of related outcomes such as mortality, complications, and medical errors. The approach utilizes a historical repository of hospital discharge data in which the outcomes of interest, important patient characteristics and risk factors used in severity-adjusting of the outcomes are derived from the coding structure of the data.

KEYWORDS

- Data warehousing
- Surgical volume
- Health outcomes

Introduction

Information technology can be an important means of applying knowledge derived from health services and clinical outcomes research, with the goal of improving healthcare delivery and the quality of provider and consumer decision-making. This paper describes how data warehousing technology can be applied by various groups of users such as hospitals, insurance companies, and consumers, to utilize the knowledge accumulated over three decades regarding the relationship between the volume of service provided by physicians and hospitals and the likelihood of favorable outcomes.

Background

A compelling body of published research, gathered over nearly three decades, suggests that patients treated at higher-volume hospitals or by higher-volume physicians experience on average lower in-hospital mortality rates and other adverse consequences of care than those treated by lower-volume hospitals and physicians.1

In the time since the earliest studies,2,3 most of the research has focused on surgical procedures such as coronary artery bypass grafting,4,5 carotid endarterectomy,6 abdominal aortic aneurysm,7,8 and surgery for various sites and types of cancer.9,10,11,12,13

An important meta-analysis conducted by Dudley and colleagues identified 10 surgical procedures in which the evidence was most persuasive regarding the volume-outcome relationship. These procedures represent high-risk events that are performed exclusively during inpatient episodes of care.9 While there continues to be questions concerning the various explanations for the volume-
outcome relationship (such as patient selection, physician skill, practice, and other possibilities) and while it is acknowledged that volume may be a proxy measure for other factors that affect care, there is no doubt that volume has been shown to be a valid indicator of quality. Of the studies that are of the highest quality, all found statistically significant associations between higher volume and favorable outcomes. No single study has found a significant relationship in the opposite direction.\(^{16}\)

Despite the strong evidence linking hospital and surgeon case volumes to outcomes, clinicians and policymakers have not managed to develop and broadly implement systems that use this information to increase the likelihood that the typical patient will be able to avoid the increased risk associated with a low volume provider.

In an important editorial in the April 2002 *New England Journal of Medicine*, Arnold Epstein from the Harvard School of Public Health stated that “few doctors would routinely send their own family members to undergo a high-risk, elective operation at a hospital where such operations were rarely performed (or to a physician who rarely performed them) if good alternatives were nearby.”\(^{17}\)

Concluding that “after decades of research, it is time to move ahead,” he suggests a series of initial actions, including educational programs for physicians and patients, pilot programs intended to shift patients from higher- to lower-risk providers via selective avoidance, and demonstrations and evaluations of programs developed to effect these shifts.

The unavailability of volume-related information continues to be a major barrier to the widespread application of volume/outcome studies to patient or physician decision-making or selective referral. About half the states maintain hospital discharge databases, which contain basic information on the diagnostic and procedural codes that characterize the major reason for hospitalization, co-morbidities, and the surgical procedures performed, if any. These databases serve primarily administrative purposes (such as billing) and typically provide limited clinical information.

However, some of these available data elements such as sociodemographic factors, age, gender, and payment source, can be combined with actual diagnosis codes, describing co-morbid conditions, to case mix or severity adjust the aggregated patient groups. Many hospital discharge databases also identify both the attending (or admitting) physician and the operating surgeon, if they are different. Physician volume studies have occurred less frequently than hospital volume studies because the physician identifier is less often available than the hospital identifier. When both the physician and hospital can be identified for every surgical procedure, specific volume-outcome relationships can be drawn from the database, and when this information is available to trend values for multiple years, an effective volume/outcome provider profile system can be developed.

**Design Objectives and Applications**

The purpose of the volume-outcome contour (VOC) is to identify, for any specifically defined surgical procedure and any specifically defined population of individual surgeons and hospitals performing that procedure, the overall pattern of procedure volume and its relationship to defined outcomes such as in-hospital mortality and complication rates. The system focus and its objectives can be adapted for various types of users. Policy analysts and researchers are most likely interested in the highest levels of data aggregation to understand the volume-outcome relationship involving larger numbers of physicians and hospitals.

For example, certificate-of-need (CON) issues within a state may prompt a comprehensive assessment of hospital volume “thresholds” or “breakpoints” at which there is a measurable reduction in mortality rates. CON guidelines typically involve the establishment of hospital volume minimums, such as 200 procedures annually, based on the assumption that certain defined outcomes are positively maximized at that point; for example, that inpatient mortality rates or complication rates are minimized.

The VOC system provides the basis for an empirical validation of those hospital standards while extending the analytical capability to include the synergistic effects of physician and hospital volume on outcomes. Research on coronary artery bypass graft (CABG) mortality in New York, for example, found a considerable protective effect for the low volume surgeon operating in a high volume hospital.\(^{18}\)

Health insurance companies and managed care plans may be interested in volume profiles for physicians and hospitals to identify providers to be included within or excluded from regional networks. Under one such scenario, all physicians and hospitals performing a list of procedures on a geographically defined population would represent the universe from which the subset of network providers would be selected based upon volume/outcome considerations. In another potential managed care application, health plan primary care “gatekeeper” physicians could use the VOC system to identify and evaluate the surgical specialists to whom they would make referrals.

Hospitals and hospital systems also will find multiple applications for VOC data. Minimum procedure thresholds can be integrated into the process of granting and specifying hospital privileges for surgeons. Hospitals and hospital systems also may profile all those combinations of physician/hospital/procedure, where the data suggests an increased likelihood of some adverse event. These profiles can serve to focus quality assurance and risk management activities on cases with higher risk exposure. In systems with multiple facilities, a decision can be made to concentrate identified low-volume procedures in a single hospital.
as a means to maximize volume.

The VOC system also can be used to identify patient populations for comparisons between high and low volume in terms of the underlying processes of care, such as the use of appropriate medications and surgical techniques.

Perhaps the most controversial use of the VOC system is to communicate directly to consumers more broadly through public Web sites, via advocacy groups, or widely distributed quality report cards. It is possible, for example, to provide comparative information on volume and outcomes after a specific hospital, surgeon, and procedure are determined. Consumers with access to the VOC system would be able to view hospital and physician specific volume distributions for their pending surgical procedure.

For coronary artery bypass graft surgery in Florida (1998), for example, they would be able to see that there were 25,124 procedures done by 384 physicians, but that the bottom half of surgeons by volume completed fewer than 2 percent of all procedures. Inpatient mortality for these low-volume physicians was 5.1 percent, compared with a rate of 3 percent for the top half of all surgeons, and 2.5 percent for the top 10 percent of surgeons. More importantly, the actual outcome experience of any combination of hospital and physician can be easily identified.

**System Description**

Faculty investigators from the University of South Florida, Colleges of Public Health and Business Administration, with grant support from the U.S. Department of Commerce, have designed and now operate a comprehensive data warehouse that contains healthcare data from a variety of sources throughout Florida.

The original application was to support comprehensive community health status assessments, following a methodology that had been evolving for more than a decade.19 However, the healthcare applications of the data warehouse have expanded to include other areas of decision support, such as bioterrorism pattern recognition and alert algorithm development and the tracking of environmental hazards and their association with variation in health status. More recently, as described in this paper, the data warehouse is being used in clinical applications, such as for exploring the relationships between surgical volume and outcomes; one example being mortality and complications.

The warehouse contains large-scale secondary databases that are available in Florida including hospital discharge data, ambulatory surgical data, cancer registry information, and vital statistics (birth and death registration). In addition, the warehouse contains a number of both public and commercial databases (e.g. census), which are used to compose population unit denominators and provide some national comparison information.

The healthcare data warehouse includes fine-grained data such as hospital discharges, births, deaths, and specific disease registries. In addition, demographic, economic, and marketing data are used in conjunction with the healthcare data to derive several hundred health status indicators.

The warehouse performs several missions, including support of decision-making activities and the creation of an infrastructure for ad-hoc exploration of very large data collections. Decision makers and research analysts should be able to pursue many of their investigations using browsing tools without relying on database programmers to construct complex queries. The emphasis on end-user data access places a premium on an understandable database design that provides an intuitive basis for navigating through the data. It should be noted that this system is completely transferable to any state in which physician-identified hospital discharge data is available.

The dimensional model, or star schema, has been recognized as an effective structure for organizing many data warehouse components.20 The star schema is characterized by a center fact table, which usually contains numeric information that can be used in summary reports. Radiating from the fact table are dimension tables that provide a rich query environment. This structure provides a logical data cube, with dimensions such as time and location identifying a set of numeric measurements within the cube.

Figure 1 shows a hospital discharge star (not all dimensions are shown), which is one component from the interconnected constellation of data elements included in the data warehouse. The dimensions define the query environment; the richer the set of dimensions, the more ways data can be accessed via queries. The dimension hierarchies enable roll-up and drill-down operations that control the level of detail in the queries. These formally defined hierarchies also provide the framework for navigating or data browsing.

An illustration of this dimensional model can be derived by focusing on two of the dimensions inherent in the hospital discharge star schema. The International Classification of Disease Clinical Modification Version 9 (ICD-9-CM) provides a hierarchical coding structure with which to specify—for every hospital discharge—the diagnoses and surgical procedures that may have been performed during the period of hospitalization. These two dimensions provide tremendous analytical power in...
characterizing various attributes of the hospital discharge, such as the severity of illness and complexity of treatment.

For example, the Agency for Healthcare Research and Quality (AHRQ) has developed a series of quality indicators, including patient safety indicators (PSIs) intended to be calculated from information available from most state-level hospital administrative data sets.\textsuperscript{21} Data elements in these sets include the ICD-9-CM discharge diagnosis and procedure codes; dates of admission; age; gender; diagnosis-related group (DRG); and other important items. The PSIs are adverse events that have at least a reasonable possibility of being iatrogenic (i.e. care-system caused).

For example, one of the PSIs is postoperative pulmonary embolism or deep vein thrombosis. To calculate the rate of this indicator, the numerator is equal to all discharges with ICD-9-CM codes for deep vein thrombosis (41511, 41519, 45111, 45119, 4512, 45181, 4519, 4538 and 4539) or pulmonary embolism (41511 and 41519) in any secondary diagnosis field per

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### Figure 1: A Partial Hospital Discharge Star Schema

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1,000 discharges. The denominator would be all the hospital discharges with codes that characterize the surgical procedures of interest.

Twenty PSIs have been validated for use and are available for applications that can be used to monitor or analyze the relationship between hospital volume and these adverse events.

The Volume-Outcome Contour

One of the more powerful analytical tools for identifying patterns in large volumes of data is to visualize the domain distribution. The volume-outcome contour plot uses this technique to graphically display the relationship between the numbers of procedures performed by individual physicians and hospitals and the quality of outcomes experienced by patients.

For each selected procedure, hospitals are first rank-ordered from the highest to the fewest number of procedures performed over some time period. Next, all of the hospitals performing the selected procedure are divided into deciles by procedure volume. Calculations then provide the average, maximum, and minimum volumes for hospitals in each decile and identify the number of inpatient deaths and mortality rates. Additionally, relevant patient safety indicator values are calculated for the specific procedure selected. This presentation enables the user to place any hospital into a decile and thereby have some sense of the additional risk associated with the subject hospital compared with others.

The same analytic approach then is performed for physicians, by calculating physician deciles determined by procedure volume. By plotting the relative position (decile) of the hospital volume for a selected procedure on one axis of an x-y plot and relative position of physician volumes on the other (again, the physician decile), a contour map may be displayed inside a 10-by-10 matrix composed of surgeon and hospital volume deciles. The z-axis then is used to plot either an independent variable, such as average volume, or a dependent variable, such as mortality rates or PSI values.

Figure 2 represents the distribution of surgeon and hospital volumes for two surgical procedures: CABG and oophorectomy. Note that the distributions of case volume by hospital and surgeon are very similar for both surgical procedures, with the overwhelming number of cases being performed by the highest volume physicians practicing in the highest volume hospitals. This highly skewed distribution is characteristic of all surgical procedures, with the top 10 percent of surgeons by case volume accounting for between 25 percent to 50 percent of all procedures. This pattern holds true even though the total number of procedures performed varies widely.

These volume contours represent five years (1998-2002) of Florida data, and during that period, there were approximately 125,000 CABG procedures and 25,000 oophorectomies. The CABG procedures are slightly more clustered or concentrated in the highest volume providers, and this is characteristic of the other heart procedures usually performed by cardio-thoracic surgeons (for example, other open heart surgeries or removal of coronary artery obstruction).

Figure 3 represents the same surgeon and hospital volume decile matrix but presents calculated mortality rates and displays them on the z-axis for every surgeon/hospital decile combination. For CABG procedures, the concentration of highest mortality in the lowest volume surgeons and lowest volume hospitals is evident, although mortality spikes representing low volume surgeons operating in high volume hospitals also are apparent.

“...a health plan may want to analyze their own hospital and physician network or assess the impact of including or excluding surgeons and hospitals.”
The oophorectomy volume-related mortality rate contour also indicates that surgeons in the five lowest volume deciles are much more likely to experience a post-operative mortality, but a visible mortality “stack” is evident where surgeons in the sixth to eighth deciles practice in hospitals in the fifth to seventh deciles. Similar to the CABG patterns, low-volume surgeons also continue to have difficulty, even in some high-volume hospitals.

These contours enable a comprehensive view of the surgeon, hospital, and specified outcomes relationship for any defined study population of providers. In Figures 2 and 3, for example, every physician and hospital in Florida over a five-year period is included. Depending on the application, however, the study population can be defined in numerous ways.

For example, a health plan may want to analyze their own hospital and physician network or assess the impact of including or excluding surgeons and hospitals. Comparison provider values can be derived from any aggregate in the data warehouse, such as all hospitals within some defined geographical area (such as a county or region) or bed size category (for example, 250 to 499 beds). Similarly, the physician analysis may focus on specialty, board certification, or physician age group comparisons. Values derived from national databases, such as the AHRQ Healthcare Cost and Utilization Project, National Inpatient Sample, or State Inpatient Data, can be utilized to develop various useful comparative values.

All of these comparisons require very careful attention to the appropriate use of some case-mix and severity adjustment to assure the validity of any analysis involving groups of patients, physicians, or hospitals.

Case Mix and Severity Adjustment

The VOC system attempts to identify the association of physician and hospital case volumes with defined outcomes, such as inpatient mortality, complications, and other adverse events. To isolate the influence of volume on these outcomes, it is statistically necessary to account for (or control) other factors that may affect the outcome in some systematic manner.

Health services researchers have developed many approaches of risk adjustment that permit the comparison of outcomes across different patients, treatments, providers, health plans, or populations. Various methodologies, both public and proprietary, are available. These methods typically identify patient characteristics (such as age, gender, race, or admission priority), preoperative clinical risk factors (for example, chronic diseases such as hypertension, diabetes, or chronic obstructive pulmonary disease), and previous healthcare (such as cardiac catheterization or prior heart surgery) that have been associated with specified outcomes. Those factors, their prevalence, and their relationship to specified outcomes (e.g., mortality or complications) are used to “risk adjust” the outcomes.

The data warehouse considerably expedites the use of these methods because the various risk factors are embedded into the ICD-9-CM coding structure used in the hospital discharge data. Methodologies for these purposes now are applied routinely.

Conclusion

Data warehouses provide a powerful infrastructure for decision support systems, such as the volume outcome contour discussed in this paper. To present helpful summary information at the appropriate level of detail, a substantial amount of computing must be accomplished. For instance, many millions of hospital discharge records must be organized by physician, hospital, and time. In addition, data quality procedures and issues, case-mix and risk adjustments, as well as patient safety indicators all must be handled.

Much of this work can be performed beforehand and then deployed to presentation servers for Web-based access if applicable. In particular, pre-computed aggregate structures can be built for important units of analysis, such as physicians or hospitals, so that common queries can run much more quickly. Query speed, aesthetics, ease-of-use, and many other factors contribute to the overall usability and ultimate satisfaction of these Web-enabled systems.
FOCUS: New Technology Trends

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References
Electronic Implementation of National Nursing Standards—NANDA, NOC and NIC as an Effective Teaching Tool

Sharon K. Allred, Kevin F. Smith, MD, MPH, and Laura Flowers, MPH

ABSTRACT

With the increased interest in evidence-based medicine, Internet access and the growing emphasis on national standards, there is an increased challenge for teaching institutions and nursing services to teach and implement standards. At the same time, electronic clinical documentation tools have started to become a common format for recording nursing notes. The major aim of this paper is to ascertain and assess the availability of clinical nursing tools based on the NANDA, NOC and NIC standards.

Faculty at 20 large nursing schools and directors of nursing at 20 hospitals were interviewed regarding the use of nursing standards in clinical documentation packages, not only for teaching purposes but also for use in hospital-based systems to ensure patient safety. A survey tool was utilized that covered questions regarding what nursing standards are being taught in the nursing schools, what standards are encouraged by the hospitals, and teaching initiatives that include clinical documentation tools.

Information was collected on how utilizing these standards in a clinical or hospital setting can improve the overall quality of care. Analysis included univariate and bivariate analysis.

The consensus between both groups was that the NANDA, NOC and NIC national standards are the most widely taught and utilized. In addition, a training initiative was identified within a large university where a clinical documentation system based on these standards was developed utilizing handheld devices.

KEYWORDS

- North American Nursing Diagnosis Association (NANDA)
- Nursing Outcomes Classifications (NOC)
- Nursing Interventions Classifications (NIC)
- Standardized Nursing Languages (SNLs)
- Clinical documentation tools
- Evidence-based medicine

Introduction

The nursing industry’s reliance on evidenced-based medicine, a lack of adoption of national standards and the widespread use of the Internet as a source of medical information has created the need for using Standardized Nursing Languages (SNLs). In many states, NIC, NOC and NANDA have been endorsed as parts of the single unified nursing language system that should be supported for describing and documenting nursing care.

Electronic clinical information systems are becoming more prevalent in the clinical setting, necessitating a paradigm shift by the nursing staff. This shift encompasses changes in documentation formats (paper vs. electronic), changes in where documentation is completed (bedside vs. nursing station), and changes in the decision-making processes (immediate vs. gradual). The challenge for nursing schools is to embrace this shift by teaching and implementing these standards and for hospitals to focus on these standards by applying them daily in the clinical setting.
Change is not typically welcome and often comes with some resistance. Generally, it is easier to identify the barriers to change than to focus on the positive attributes associated with the change. This is true in the case of electronic implementation of national nursing standards. The purpose of this paper is to identify and present a study on the teaching and application of SNLs in nursing schools and hospital settings, to ascertain and assess clinical nursing tools based on these standards, and to identify positive and negative factors influencing training, implementation and use of SNLs in these settings.

**Standardized Nursing Languages**

The nursing process is complex and consists of three principle components: assessment, problem identification, and problem management. Since the early 1990s, there has been an ongoing effort to develop and promote a standardized nursing language.

Until recently, good information from nursing documentation has been difficult to utilize in decision-making processes in areas such as the cost and quality of nursing care, resource allocation, effective research, and level of staffing. The documentation was inconsistent and non-standardized, and it provided a poor assessment of the knowledge and skill that nursing brings to healthcare.

One basic component of any data collection process is a standardized language. Standardized language involves defining a series of terms or phrases that can be applied where there are many ways of saying the same thing. In the case of nursing, there was a need for a common language that addressed and linked the three components of nursing care data elements—diagnoses, interventions, and outcomes. In the case of the SNLs, three different sets of nomenclatures are needed.

**The North American Nursing Diagnosis Association (NANDA)** was initially developed in 1973 as a nomenclature to document nursing diagnoses that are not focused on the disease process, but address human response to health conditions. It represents clinical nursing judgment about disease processes. The taxonomy includes 13 health pattern domains with 46 classes.

Using NANDA, pain would be defined as “an unpleasant sensory and emotional experience arising from actual or potential tissue damage or described in term of such damage; a sudden or slow onset of any intensity from mild to severe with an anticipated or predictable end and a duration of less than six months.” When formulating a nursing diagnosis, nurses can use a PES system (problem, etiology, and signs and symptoms). For example, in the case of dizziness, the problem is dizziness; the etiology is inadequate water intake and increased activity; and the signs and symptoms are patient states “feels-light headed” and has dry mouth and decreased urine flow.

**The Nursing Intervention Classification (NIC)** is nomenclature for interventions performed by nurses in healthcare settings. Work on this SNL began in 1987. It is a three-level system with seven domains, 30 classes, and 486 interventions. In all, it includes more than 12,000 activities with individually assigned code numbers. Each intervention includes a set of defined activities, which are steps to completing the intervention. An example of NIC for dizziness could be “fluid monitoring,” defined as the collection and analysis of patient data to regulate fluid balance. Some of the associated intervention activities include monitor weight, monitor serum and urine electrolytes, keep accurate record of intake and output, and monitor blood pressure and heart rate.

>“This process of self-assessment has revealed a basic need, common to all groups, for a standardized language, specifically in nursing care…”

**The Nursing Outcome Classification (NOC)** consists of more than 190 patient outcomes used by nurses. The outcomes use a three-layer system of seven domains, 29 outcome classes, and 260 outcomes. The outcomes are focused on individuals, family, and community clients, and each outcome has been assigned a code. An example of NOC for dizziness could be “fluid balance”—the balance of water in the intracellular and extracellular compartments of the body. Some of the associated outcome indicators include stable body weight, absence of sunken eyes, abnormal thirst not present, and urine-specific gravity within normal limits.

These SNLs have linkages that enable them to be complementary to each other. They can be utilized together to provide an integrated care plan that can be followed in many different care settings. These SNLs, when combined with a coding system, enable data collection and data analysis.

**Factors Driving Implementation**

Healthcare has been experiencing a technology revolution. Initially, the revolution involved hospital services not directly related to patient care, including billing and collections, supply ordering, inventory, and scheduling. These technological changes, while important and extensive, did not directly affect the evaluation, treatment, and quality of care surrounding direct patient care.

Progress in evidence-based medicine has set into motion a process in which different groups that interact with patient care have to complete a self-assessment of their contributions. This process requires an evaluation of their
contribution to the patient’s care and the outcome of that contribution or intervention. This process of self-assessment has revealed a basic need, common to all groups, for a standardized language, specifically in nursing care, because of issues encompassing resource allocation, efficacious interventions, consistency of outcomes, and clinical decision-making.1,3

A greater understanding and knowledge of SNLs will facilitate consistency in coding and improve data collection and analysis. From a practical standpoint, when a nurse is documenting more effectively, the data has more applications for use. In evidence-based medicine, the ability to collect “good” data enables better documentation of nursing contributions to patient care. When this data is collected electronically, nursing contributions can be assessed in multiple settings throughout the spectrum of patient care.

With Internet access so readily available to healthcare providers in many different healthcare settings, providers of data management tools now are able to offer software in a wider variety of settings and often at less cost. Healthcare institutions (hospitals, clinics, and nursing homes) that have not already implemented some form of electronic clinical information system are most likely headed in that direction.1

Nurses increasingly see that they are now part of the technology revolution, and they will have to embrace the application of new technology in the workplace. This may necessitate a particular level of proficiency in information technology—both software and hardware, including handheld technology—for a nurse to remain competitive in the workplace.

Nursing students are having technology added to more courses, and student reviews have been positive. Currently, there is a push to add handheld technology (such as personal digital assistants, or PDAs) to course material requirements. The PDA enables quick access to reference material, personal organization applications, and e-mail communication. The student and the teaching staff now have a means of direct communication that enables offsite documentation and evaluation of student activities, skill-set development, and student performance of clinical skills when out in the field.

Changes in nursing services, when combined with evidence-based medicine and the Internet, make it apparent that a standardized nursing language is necessary to identify and define the nursing component of patient care. As evidence-based medicine and the Internet play a prevalent role in healthcare documentation, nursing services will become increasingly dependent on standardized nursing languages to adequately identify and define the nursing components of patient care.

By using SNLs in an electronic clinical information system, the data becomes uniform, and data analysis can be conducted—leading to immediate nursing decision-making.4 On a larger scale, benchmarking and healthcare outcome improvements can also be identified.1

Clinical Nursing Tools

The reasons behind developing electronic clinical information systems that utilize SNLs vary depending on the point of view.

From the viewpoint of nursing schools, development is needed for the nurse to remain competitive and proficient11 and to fully develop the nursing student’s learning.12 In the case of the nursing school’s faculty, it enables easy evaluation of nursing assignments, development of curriculum, and facilitated research.11

If a nursing student can practically apply the SNLs through the use of a documentation tool that can be utilized at the bedside, nursing schools can better ensure the quality of care of every patient under direct student care. In the healthcare setting, factors such as nursing shortages, improved patient safety, quality of care, benchmarking,5 and the Joint Commission on Accreditation of Health Care Organizations (JCAHO) dictate a standard for assurance of quality care.

Methods of Research

Phone interviews were conducted at 20 nursing schools and 20 hospitals in the United States. Interviews focused on the use of standardized nursing languages in electronic clinical information systems, not only for teaching purposes but also for use in the clinical setting to ensure patient safety.

A survey tool was developed by the authors and was used to address questions regarding nursing standards that were being taught in nursing schools—standards encouraged by hospitals and teaching initiatives that included documentation tools. Information also was collected on how use of these nursing standards in the clinical or hospital setting can improve the overall quality of care. Both univariate and bivariate analyses were performed.

The survey was intended to identify the teaching and application of SNLs in nursing school programs and in hospital settings; to ascertain and assess clinical nursing tools based on the NIC, NOC and NANDA standards; and to identify factors having either a positive or a negative influence on the training, implementation, and use of SNLs in school of nursing programs and in hospital settings.

Results

The telephone survey was conducted in January 2004 to ascertain the use of standardized terminologies: NIC, NOC and NANDA at 20 nursing schools and 20 hospitals. The purpose of the survey was to evaluate the impact of the languages in teaching and the continued use of the

Original Contributions
standards in the clinical setting. In many states, the standardized nursing languages have been endorsed as the single unified nursing language system that should be supported for describing and documenting nursing care. The terminologies contain terms and measures that represent nursing diagnoses, outcomes, and interventions.

Faculty members who knew the school’s nursing curriculum were interviewed from each of 20 nursing schools. Directors of nursing were interviewed in each of the 20 participating hospitals to ascertain the uses of the terminologies.

Most of the respondents from both the nursing schools and hospitals were trained as nurses. The average length of time as a nurse was 10.3 years, with a range of 3 to 19 years. The nursing school respondents represented nine states, with the majority of the respondents in New York and Pennsylvania. The hospital respondents also were from nine states, with the majority of the respondents in Pennsylvania.

Only 60 percent of the nursing school respondents indicated that SNLs were currently being taught in their schools. However, all respondents indicated that NANDA was the SNL being taught. Among hospital respondents, only 40 percent confirmed the use of SNLs in the clinical setting, primarily in the form of clinical documentation tools. The hospital respondents most often cited the use of NANDA (75 percent).

Also, 61 percent of the nursing schools used clinical documentation tools as part of their teaching methods, while a greater percentage of hospitals (70 percent) confirmed they were currently using some type of clinical documentation tool. Of the nursing school respondents, 73 percent said they believed it would be beneficial if the clinical documentation tool provided a detailed task list at sign-on. By comparison, almost all hospital respondents (90 percent) indicated that a task list would be valuable.

The nursing schools that indicated they were teaching the standardized languages felt the knowledge and practical use of the SNLs would dramatically increase the effectiveness of nursing students after graduation. In addition, the hospitals utilizing the standards felt the new technological advances surrounding clinical documentation enabled information to be captured in a meaningful and standard format and lent credibility to the overall clinical process (see Table 1).

When asked if the current nursing shortage is affecting their hospital, 90 percent of respondents indicated they were experiencing a shortage. Of the respondents from the nursing schools, 77 percent said they believed that clinical documentation tools based on language standards would enable hospitals to staff with higher percentages of new nursing school graduates, and 78 percent of the hospital respondents agreed when asked the same question.

When the participants were asked what could be done in nursing to improve the overall quality of care, there were several different responses. The nursing school respondents said they believed it was critical to give more hands-on clinical time to nursing students, while hospital respondents felt it was important to increase staff and lighten patient loads. Only 20 percent of hospital respondents indicated that they were aware of clinical documentation tools that included the language standards.

“…nursing schools that indicated they were teaching the standardized languages felt the knowledge and practical use of the SNLs would dramatically increase the effectiveness of nursing students after graduation.”

Secondary to teaching the standards is the practical application of the standards during teaching and the continued use following graduation in the clinical setting. Only 40 percent of the hospital respondents and 28 percent of the nursing school respondents were actually using any type of handheld devices, and most of the time it was for personal use, not for use as a clinical documentation tool. When asked if they believed that handheld devices are effective as clinical documentation tools, 63 percent of the nursing school respondents answered yes, and 79 percent of the hospital respondents agreed.

One participating nursing school is in the beginning stages of a pilot project that will enhance the nursing students’ learning experience. The project is based on teaching the language standards in a clinical setting while also enabling the students to develop their clinical documentation skills. At the same time, they will apply the standards to the levels of care their patients are receiving.

During their practicum, nursing students will use a handheld device pre-loaded with clinical documentation software that includes the NIC, NOC, and NANDA standards. The handheld devices give the students the
freedom to document care at the bedside. In addition, the university can use the information obtained from the documentation to evaluate and further develop the clinical skills of nursing students.

According to the respondent, “The pilot project will not only solidify the teaching of the NIC, NOC, and NANDA standards in a clinical setting but also will allow the students to develop their skills with more assurance that the level of care given will be standardized and quality-based.”

**Conclusion**

The survey results suggest that the teaching of NIC, NOC, and NANDA is increasing in nursing schools and is being endorsed as the single unified nursing language system that should be supported for describing and documenting nursing care. In addition, hospitals feel the teaching and adoption of these standards in clinical documentation tools enhance clinical communication and the overall quality of nursing care, thus improving the margin of error and improving patient safety.

The usage of NIC, NOC, and NANDA has dramatically increased in nursing schools and is continuing to be utilized through clinical documentation systems in many hospitals, as the awareness of patient safety and quality of patient care become the forefront of many healthcare discussions and legislative initiatives.

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The Case for Regulatory Compliance of Electronic Medical Records About Human Tissue Intended for Transplantation

Robert Carrier

ABSTRACT

It is vital that patients receiving human tissue by transplantation be able to trust in the suitability of the product. In short, patient safety must be ensured to the highest degree possible. To this end, firms operating tissue banks and those providing tissue donor coordination services are inspected by the U.S. Food and Drug Administration (FDA). The suitability of tissue for transplantation is objectively documented at all phases, beginning with donor screening. This process often involves the use of custom software applications that produce electronic medical records (EMRs) and databases that store the results. When a firm elects to keep the medical records relevant to human tissue products in electronic form, the record system must comply with applicable codified regulations. Unfortunately for the patient, many firms have yet to achieve regulatory compliance, and FDA enforcement is only beginning to approach the intensity appropriate to regulate this fast-growing industry. This article discusses current FDA trends in enforcement and rule-making related to human tissue intended for transplantation, as well as expectations the FDA has during an inspection.

KEYWORDS

- Electronic medical record (EMR)
- Good tissue practice
- Human tissue products
- U.S. Food and Drug Administration (FDA)

Introduction

It is vital that patients receiving human tissue by transplantation be able to trust the suitability of the product. It is equally important to donors and recipients that medical records remain confidential and accurate. Additionally, the person who declines tissue donation in advance must be assured this directive will be acted on reliably.

Ensuring patient safety is the job of the U.S. Food and Drug Administration (FDA). Human tissue can transmit disease, and it is possible for one donor to infect multiple recipients. The FDA enforces codified regulations by conducting establishment inspections of tissue banks, processors and donor coordination services. The regulations require that tissue establishments maintain records that are accurate, indelible and legible¹ and that they implement written procedures for all significant steps that they conduct.²

It is important that tissue establishments comply with existing regulations, thereby operating in support of the public interest. For example, maintaining accurate records of donor screening and testing and determining suitability contributes to recovering only safe tissue from eligible
donors. Following written procedures for donor screening, donor infectious disease testing and donor eligibility determination by a responsible person ensures tissue is free from the presence of communicable diseases. Unfortunately for the patient, many firms have yet to achieve regulatory compliance, and FDA enforcement is only beginning to approach the intensity appropriate to regulate this fast-growing industry.3

Background

Tissue and organ donation differ in both their clinical applications and applicable regulations. Tissue products can be recovered, processed, and stored for later use, while organs are viable for only a short time once they are recovered. Tissue transplants are typically life-enhancing, while organ transplants are considered life-saving measures. However, the general public equates tissue and organ donation to such an extent that any adverse event related to a tissue product can have a detrimental impact on organ donation.

The human tissue products industry is a burgeoning for-profit enterprise. It is estimated that industry revenue totaled $1 billion annually in 2003, up from $20 million a decade ago.4 Tissue refers to skin, heart valves, and musculoskeletal tissue such as bone, cartilage, ligaments, and tendons. Tissue products are used in hundreds of surgical procedures such as heart valve replacement, ligament replacement, reconstructive surgery, and burn treatment. The industry growth is driven by the fact that "scientists have developed new techniques, many derived from biotechnology, that enhance and expand the use of human cells and tissues as therapeutic products."5

The process of making available a human tissue-based product begins with the generosity of individuals and families who consent to donation. Donor coordinators who work at tissue banks and at communications centers conduct medical screening interviews with hospital staff and families to determine the patient's eligibility for donation. The process continues with recovery of acceptable tissue that is processed, tested for infectious disease, packaged, labeled, stored, and distributed for use. At each step of the way, records are produced to document what was done, by whom, when, and to what outcome. It is this documentation that represents the purported quality and identity attributes attesting to the suitability of the tissue for transplantation.

Record Keeping Practices for Donors

Record keeping at tissue establishments often relies on networked computer systems running custom software applications that produce electronic medical records. Databases are used to store data obtained from medical screening interviews, diagnostic laboratory test results, visual observations, determinations of donor suitability, recovery, and subsequent processing. Report generation software draws from these databases to document the suitability of each final product.

Many establishments operate hybrid record-keeping systems in which traditional paper records and handwritten signatures co-exist with electronic records. For example, a record created using an information management system may be printed and approved by handwritten signatures. This is an acceptable practice as long as the content and meaning of those records are preserved. In other words, both the EMR and the hand-signed documents must be retained, linked (cross-referenced), and made available for inspection.

A computerized medical record-keeping system employed in the process of tissue donor screening works like this: After a hospital is contacted about a potential tissue donor, the donor coordinator conducts a verbal medical screening interview in accordance with questions presented on computer-automated interview screens.

While the information may reside in a hospital electronic records system, current practice relies on verbal communication of donor screening information between the two entities. Responses to the questions are documented in a database by populating fields with pull-down menu selections or with free-text entries. Specifically, the EMR documents a patient's disease history, medical treatment history, lifestyle, physical appearance, and lab test results that altogether serve as indicators of risk factors for communicable disease agents and diseases. Eligible donors must be free from these risks.

Donor-screening software maintains a set of criteria against which the data obtained in the medical screening is used to determine the appropriateness of the donor for each type of tissue donation. Donor eligibility determinations may be made automatic, but they can be overridden by the coordinator—allowing for human expert interpretation of available data. Different criteria can be applied based on requirements specified by the recovery and processing establishment.

In most cases, donor consent must be obtained to proceed with tissue recovery. One exception is the use of legislative consent for corneal tissue recovery. Consent information may be stored in external databases such as

“Many establishments operate hybrid record-keeping systems in which traditional paper records and handwritten signatures co-exist with electronic records.”
U.S. state motor vehicle departments or in donor alliance databases. Medical screening systems can read data from these external databases to quickly determine if the potential donor has pre-consented to donation. In this way, precious time is not lost in trying to determine consent status.

For recovered tissue, the medical-screening EMR serves as only the initial part of the larger historical record for a tissue product. The EMR for each donor must be available so it can be exported to the downstream processor, where it can accompany the final product as part of documentation supporting donor suitability.

While the use of EMRs is highly desirable in recovering suitable donors, failures in the EMR system potentially can result in adverse outcomes. For example, if data security controls fail and an EMR undergoes unauthorized modification, the resulting record could be used to make an incorrect decision as to donor eligibility. In another scenario, producing an incorrect determination of donor suitability through comparison of medical screening data against inappropriate acceptance criteria could result in recovery of unsafe tissue. Other types of failures that could produce similar results are incorrectly reporting data fields from a database to the individual case EMR or erroneously calculating a secondary medical value on which the suitability decision is made. Controlling risks related to EMR failure requires challenging and qualifying the system so that it is known to be working as intended.

FDA Rulemaking and Enforcement

These are times of constant change in FDA rule-making as the agency continues to reshape the regulatory landscape for tissue establishments. An ongoing rules discussion is continuing in the Federal Register between the agency and industry representatives.

In July 1997, regulations became effective for establishments engaged in recovery, screening, testing, processing, storage, or distribution of human tissue promulgated in 21 CFR 1270, Human Tissue Intended for Transplantation. That same year, the FDA published an initiative entitled “Proposed Approach to Regulation of Cellular and Tissue-Based Products,” which presented a more comprehensive approach to the regulation of human cellular and tissue-based products. The FDA published a “talk paper” in 2001 discussing proposed new rules known as “Current Good Tissue Practice” designed to implement the regulatory approach proposed in 1997.

Since then, the FDA has finalized two of three proposed rules that comprise 21 CFR Part 1271, “Human Cells, Tissues, Cellular and Tissue-Based Products.” When complete, the more comprehensive provisions of 21 CFR 1271 will replace 21 CFR 1270. To date, 21 CFR Part 1271 Subparts A and B are in effect, specifying general provisions and procedures for registration and listing a tissue product manufacturer. Most recently, the FDA finalized 21 CFR Part 1271 Subpart C, specifying requirements for determining donor eligibility. It will become effective in May 2005. The third proposed rule that will complete 21 CFR 1271 specifies current good tissue practice regulations. When completed, this rule will require tissue establishments to meet many of the regulatory controls under which pharmaceutical and biopharmaceutical companies now operate.

While the use of EMRs is highly desirable to gain speed in recovering suitable donors, failures in the EMR system potentially can result in adverse outcomes.

The FDA inspection program for human tissue-based products has been increasing in intensity as evidenced by the most recent semi-annual report of the Office of the Inspector General to Congress. The report reiterated recommendations from a 2001 OIG report that the FDA should determine the minimum cycle for tissue bank inspections.

Since June 2002, FDA inspections resulted in six warning letters to tissue establishments for failing to comply with regulations. For the most part, observational findings in these warning letters largely involve failures to prepare, validate, and follow written procedures. In some cases, compliance failures occurred in tissue processing, resulting in the transmission of communicable disease or an infectious agent to the recipient with adverse outcomes.

In March 2003, the FDA issued a proposed compliance program guide regarding the inspection of tissue establishments that change tissue function or characteristics through processing. “The objective (of this CPG) is to assure that (a) all human tissue subject to 21 CFR 1270 and subparts A and B of Part 1271 is recovered, processed, stored, and/or distributed under conditions designed to prevent transmission of communicable disease, and (b) each donor was adequately screened and tested.” While this inspection guide has not yet gone into effect, it provides valuable information about how the FDA plans to act on compliance and surveillance of human tissue product manufacturers.

While the use of EMRs is highly desirable to gain speed in recovering suitable donors, failures in the EMR system potentially can result in adverse outcomes.
Current Regulations Affecting EMRs

The FDA’s intent regarding records maintained in response to regulatory requirements is that they be trustworthy, reliable, and available for inspection. When a tissue establishment keeps medical records in electronic form, the computerized record-keeping system must comply with applicable regulations. The regulations do not require tissue establishments to use computer systems, but this decision is left to each individual firm.

Comments made by FDA-regulated firms regarding information systems have repeatedly raised the concern that regulations unnecessarily impede the implementation of new technology. The industry maintains that the cost and complexity of implementing new information systems that comply with regulations is too high and discourages modernization. The FDA has replied that regulations are intended to permit the widest possible use of electronic technology that is compatible with the agency’s responsibility to protect the public health. For the FDA to function in this role, EMRs must be available for inspection by the FDA, and they must be trustworthy.

Current requirements for record keeping and procedural controls related to tissue-based products are specified in 21 CFR 1270. This regulation defines “relevant medical records” to include donor medical-screening interviews, physical assessments, laboratory test results, and information obtained from any other source for use in determining donor suitability. Further, the regulation specifies that written procedures be implemented for the collection of this information and that records, including EMRs, be accurate, indelible, and legible.

During a tissue establishment inspection and at the discretion of the FDA, the regulations of 21 CFR 1270 may be supplemented by applicable predicate rules. Specifically, FDA enforces provisions of the Quality System Regulation16 and the Electronic Records; Electronic Signatures Rule.17 For example, a section in the Quality System Regulation18 specifies that an automated data processing system, such as an EMR system, must be validated for its intended use.

The Electronic Records and Signatures Rule specifies requirements for computer system security controls, audit-trail functions, and records availability for inspection that must be met if electronic records are to be considered generally equivalent to paper records.19 A major concern with electronic records is that they could be modified in an authorized yet undetected way to create a fraudulent result that compromises patient safety. This rule is designed to prevent unauthorized access to and changes to electronic records, and it creates an audit trail to record changes to protected records. The access control, authority checking, and device checking provisions of this rule include identification code and password controls or, alternatively, biometric means for identifying the user. The Electronic Records and Signatures Rule provides an excellent standard that a firm can use to assess the robustness of its EMR system and operating procedures.

Proposed Regulations With EMR Impact

The proposed third rule comprising 21 CFR 1271 specifies new requirements for record management systems20 and for tracking tissue products.21 Of particular concern to EMR system users are requirements that ensure availability for inspection of records maintained by another related establishment, such as a donor screening service provider or a donor testing laboratory; the assignment of a distinct identification code for tracking each product; and compliance of records maintained in data processing systems with the Electronic Records and Signatures Rule.

Under pending rules, tissue products made available for distribution and the accompanying documentation must be identified by a distinct identification code. This would protect the confidentiality of sensitive donor information such as name, Social Security number and medical record numbers. Protecting privacy and confidentiality of personal health information is a shared goal of 21 CFR 1271 and HIPAA. Because cadaveric tissue donation is not considered a healthcare activity, HIPAA facilitates donation by permitting a covered entity to disclose protected health information to other entities engaged in procuring tissue for transplantation without the individual’s written consent.22 To maintain an individual’s privacy rights, the pending tissue rules appear to come into play where HIPAA ends by concealing the donor’s identity in a code.

Tracking tissue products from donor to recipient or other disposition and managing the many records created during a product’s history is a challenge likely to be met in the future through Web-enabled software applications. The same software eventually will automate workflow for records review and approval by authorized persons. These applications will bind geographically distant establishments, enabling them to work together to make tissue available for distribution. In this scenario, compliance with requirements specified in the Electronic Records and Signatures Rule will be essential to protect record integrity and confidentiality. Yet, this rule’s final form is still emerging.

In February 2003, the FDA withdrew all guidance documents related to the Electronic Records and Signatures
Rule in response to industry pressure for clarification and a narrowing of the scope of application for this rule. In August 2003, the FDA issued a final guidance document regarding the scope and application of the rule. While it is clear that the FDA is rethinking, and probably will reissue, this rule, it remains in effect as written, and FDA inspectors will enforce it with discretion. The impact these rule changes will have on electronic medical record-keeping systems is unknown.

**FDA Expectations During Inspections**

The FDA has definite expectations when it inspects a tissue establishment. First and foremost, the agency expects that the organization's managers with executive responsibility have established policies and procedures for the quality system. Further, the FDA expects executive management to ensure that there is sufficient staff to implement the quality system, and it is well understood and implemented at all levels of the organization.

Quality systems must have these attributes:

- Standard operating procedures for all significant steps conducted by the firm.
- Second-person review of records by a responsible person who is qualified and authorized.
- A training program and documentation of training qualifications.
- A system for managing complaints and product deviations.
- A process for implementing corrective actions and preventive actions regarding product deviations.
- A system for management of current good tissue practice documents.
- A system for tracking the product from donor to recipient or other disposition.
- A process for controlling changes to any critical business process or system, such as the EMR system.

The FDA expects that computer systems employed in processing regulated electronic medical records be validated, which involves producing objective evidence that, to a high degree of assurance, proves the system is operating as intended. Validating an EMR system requires challenging the system under nominal and abnormal operating conditions through approved protocols that can later be reviewed by an inspector.

**Surviving an Inspection**

The best practices for avoiding adverse inspectional findings are advance preparation and efforts to make regulatory compliance integral to current good tissue practice business processes. A good way to get started is to conduct a regulatory risk assessment through which an establishment's compliance position is evaluated against current and proposed regulations. For ongoing surveillance, conducting an internal quality assurance audit tests the efficacy of the established quality system, the results from which can be used to make necessary adjustments.

Some key areas should undergo preparatory audits. These include:

- Donor screening criteria and records management.
- Donor testing laboratory services and test result records.
- Business process for records review, donor eligibility determination, and product release.
- Availability and appropriateness of written procedures.
- Validation of manufacturing processes and procedures.
- Product deviation reports, and corrective and preventive action records.
- Complaint records and adverse reaction reports.
- Records of notifications received from other establishments and issued by yours.
- Retention and accessibility of records for inspection.
- EMR computer system validation.
- Control record changes.
- Staff training records.

**Risks of Noncompliance**

If the FDA inspects an unprepared establishment, it likely will result in adverse observations that inspectors will document on Form FDA-483. Continued failure to comply can lead to escalating FDA enforcement actions, such as a warning letter, product seizure, and consent decree, the details of which are readily available to the public. In the event of such enforcement activity, tissue establishments face disruption to business operations, fines, and bad publicity.

So far, there have been no fines levied against a tissue establishment for noncompliance. However, as an example of what might happen to a tissue establishment, the FDA does have a consent decree agreement with the American Red Cross related to compliance failures in blood banking. A recent revision to this consent decree specifies a schedule of monetary penalties, some as high as $500,000 per event, for each type of future infraction.

As a second example, Schering-Plough agreed to pay a record $500 million fine related to violations in facilities, manufacturing, quality assurance, equipment, laboratories, and packaging and labeling. While Schering-Plough is a pharmaceutical company and the fine was of exceptional magnitude, this is a harbinger in the tissue industry.

**Conclusion**

Tissue transplant recipients must be able to trust the suitability of the product they receive. Tissue donor suitability and product information are documented by the
collective record, which is created during the process of donation, recovery, processing, packaging, labeling, and distribution. Hybrid record-keeping systems are now common, with only some records and signatures entirely maintained electronically. The future lies in fully computerized systems being able to track tissue products from donor to final disposition, organize all relevant EMR components, and automate workflow for records review related to determination of donor eligibility. Because these records in any form represent purported quality attributes and are relied upon to trace products through the process of being made available for distribution, it is in the interest of patient safety that tissue establishments comply with all applicable regulations.

Aside from patient safety, donor and recipient patients alike need to be assured that their highly confidential information remains protected from unauthorized use or distribution. The validation of data system security controls and the establishment of effective written procedures go a long way towards meeting this requirement.

Loss of trust by tissue donors and recipients can result from inappropriate management of EMRs or a poorly functioning quality system. Such a loss of trust will cast aspersions on the integrity of this rapidly advancing therapeutic industry. Demand for tissue products will increase as the aging Baby Boomer generation continually seeks to improve their existence. Compliance with all provisions of Good Tissue Practice regulations will help ensure that future patients receive only safe, high-quality tissue products that produce successful outcomes.

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Patient Education And Recovery Learning System (PEARLS) Pathway: A Tool to Drive Patient Centered Evidence-based Practice

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ABSTRACT

Myocardial infarction is a significant problem for Americans and individuals in developed countries. According to the American Heart Association, coronary heart disease is the single largest killer of Americans. Variation in practice is recognized as a key barrier to promoting positive outcomes in patients with cardiac illness. Implementation of clinical practice guidelines has been identified as one way to promote evidence-based practice, reduce practice variation, and ultimately improve the quality of care and outcomes of cardiac patients. Improving patient knowledge and understanding of guideline recommendations and the ways in which evidence-based recommendations are linked to recovery is recognized as one means of facilitating guideline adherence. Automated patient pathways are proposed as a means to improve patient access to guideline-based information at the point of care. Within this context, the prototype development of a Patient Education And Recovery Learning System, or PEARLS, is discussed along with the potential benefits of the use of automated patient pathways as one means for overcoming challenges associated with acute care patient education and facilitating patient adherence to clinical practice guideline recommendations.

KEYWORDS

- Practice guidelines
- Clinical pathways
- Patient pathways
- Informatics
- Evidence-based practice
- Self-management
- Chronic illness
- Myocardial infarction
- Patient education
- Web-TV

Introduction

Myocardial infarction is a significant problem for Americans and individuals in other developed countries. According to the American Heart Association, coronary heart disease (including myocardial infarction and angina pectoris) is the single largest killer of Americans. The incidence of myocardial infarction is 1.1 million new and recurring cases per year, with more than 40 percent resulting in death. There were 529,659 deaths in the United States resulting from coronary heart disease, or CHD, in 1999. In the period from 1989 to 1999, the age-adjusted death rate from CHD and heart attack declined 24 percent, but the actual number of deaths declined only 6.8 percent.1

Despite these grim facts, there is mounting evidence that evidence-based care, including lifestyle modification and medication management, can reduce vulnerability to recurrent myocardial infarction and associated morbidity and greatly improve both quality of life and life expectancy. Variation in practice is recognized as a key barrier to promoting positive outcomes in patients with cardiac illness. A tool to overcome this variation is the use of automated patient pathways, which can improve patient access to guideline-based information at the point of care.
illness. Implementation of clinical practice guidelines has been identified as one way of promoting evidence-based practice, reducing practice variation, and ultimately improving the quality of care and outcomes of cardiac patients. Clinical practice guidelines have been defined by the Institute of Medicine as “statements to assist practitioner and patient decisions about healthcare for specific circumstances.” Many professional groups, organizations, and government agencies have developed and disseminated clinical practice guidelines for managing patients with cardiac illness.

Despite widespread availability of clinical practice guidelines, clinician adherence to these recommendations remains an elusive goal. Furthermore, while the Institute of Medicine definition explicitly states that clinical practice guidelines are tools intended to inform both practitioner and patient decision-making, these guidelines often are not disseminated to patients. Recent IOM reports link information accessibility by patients with safer and more effective care.

Therefore, a mechanism is needed to disseminate clinical recommendations to patients at the point of care and in a format that is understandable by healthcare consumers and clearly defines the ways in which evidence-based recommendations are related to recovery. Only then will it be possible for patients to use clinical practice guidelines for informed decision-making.

This article provides an overview of the challenges associated with providing guideline-based education to patients with chronic illness (such as heart disease) in a fast-paced acute care environment. Then, the prototype development of the Patient Education And Recovery Learning System, or PEARLS, is discussed along with the potential benefits of using automated patient pathways as one means for overcoming these challenges. PEARLS is an automated patient pathway and educational tool. It was designed to reduce barriers to the use of clinical practice guidelines from a patient perspective in acute-care settings and to drive patient-centered informatics processes for evidence-based practice.

Barriers to the Use of Practice Guidelines

Several factors within the healthcare environment have been identified as barriers to clinical guideline adherence. Barriers fall into three general categories:

The inconsistent and dynamic nature of scientific literature. The compilation of available guidelines and skepticism regarding the sources of evidence within practice guidelines have been identified as barriers to guideline adherence. The dynamic nature of scientific evidence and the pace at which new evidence is available also have been described as barriers.

The healthcare environment. The turbulent nature of the healthcare environment, including organizational systems and local practice patterns, have been recognized as significant barriers. In addition, the fear of loss of professional autonomy and the belief that adherence with guidelines may increase exposure to litigation are also perceived as barriers.

Workflow issues. Workflow issues, including the feasibility and efficiency of guidelines with regard to accessing clinically relevant evidence for individual patients at the point of care, are also seen as barriers.

Although the number of clinical practice guidelines and the inconsistent nature of guidelines have been identified as barriers to adherence, the level of sound scientific evidence that has accumulated over the past decade for the prevention and management of acute myocardial infarction makes these issues intuitively less noteworthy. While many professional groups have developed guidelines for acute myocardial infarction, recommendations across guidelines are generally consistent. Differences that exist are related to publication dates rather than conflicting evidence. Barriers related to the healthcare environment and workflow issues appear to be more significant.

Many organizational, workflow, and patient-related barriers to guideline adherence have been identified. Traditionally, research on practice guidelines and clinical decision-making, user interaction, and disease management have demonstrated that organizational and workflow barriers are sensitive to informatics solutions. Information technology has improved clinician access to guidelines and other evidence at the point of care and improved adherence with recommendations. However, the challenge remains to identify solutions that consider patients and healthcare consumers as equally important recipients of evidence for health-related decision-making.

To play a collaborative role in treatment, patients require access to evidence and assistance in understanding how this information relates to their concerns, management of their condition, and the decision-making process. Lack of patient access to evidence or incomplete understanding of evidence may be key barriers to adherence to clinical practice guidelines. Therefore, developing strategies for translating guidelines and other sources of evidence into formats accessible and useful to healthcare consumers has been identified as a worthy goal.

One increasingly common source and route of dissemination of healthcare information is the Internet. Growing consumer interest in the Internet as a health information resource further suggests that Internet applications show promise as one means of improving access to evidence-based healthcare information. However, much of the information available on the Internet is not held to standards of efficacy; information on the Web may not be valid, and information that is valid may be difficult for the layperson to understand.
Providing patients with access to valid information from evaluated Internet sources, such as MedlinePlus (National Library of Medicine: http://medlineplus.gov/), in settings where they may ask questions and collaborate with healthcare professionals may be an important first step towards promoting patient access to evidence at the point-of-care. However, in this context, access to information alone may not be sufficient to facilitate patient decision-making. Tools are needed that tailor information so it is relevant to individual patient characteristics and presented within the context of specific health conditions or problems.

Automated patient pathways made available through a bedside Web-TV application in acute-care hospitals could provide patients with access to information within an appropriate context and in a setting where healthcare professionals are available for consultation and clarification. Improved access to information and understanding of the ways in which evidence-based recommendations are linked to recovery may facilitate clinician and patient adherence to clinical guidelines.6,27,35

Clinical Pathways: An Overview

Clinical pathways have been defined as the sequence or timing of key interventions designed to promote desired patient outcomes.38 The integration of clinical practice guidelines recommendations into clinical pathways appears to address multiple issues. Clinical pathways can be easily tailored to address local interdisciplinary practice patterns and provide an additional source of data for implementing and tracking workflow modifications. Practice guidelines embrace external best-practice and gold-standard evidence. Integration of practice guideline recommendations into a clinical pathway framework provides a means of making guideline evidence available at the point of care.

Not unlike interdisciplinary clinical pathways, patient pathways delineate key interventions designed to drive desired patient outcomes. There is growing recognition that clinician adherence to practice guidelines may be improved if patients are more aware of evidence and educated and involved in treatment related decision-making.38 Patient education tools such as patient pathways may have potential for promoting adherence to clinical practice guidelines by increasing patient knowledge and ability to participate in informed decision-making.

For patients with cardiac illness, effective patient education involves teaching self-management skills and reinforcing behavioral strategies to promote lifestyle modification and risk reduction. Evidence supports the use of tailored educational interventions based on individual profiles to address multiple risk factors and lifelong habits of individuals that contribute to heart disease and acute myocardial infarction.37,38 Interventions that center on the self-management needs of the individual are most effective in focusing patients on lasting and meaningful behavior change.37,41-42 However, the reality of acute-care environments, particularly patients’ high acuity levels and shortened lengths of stay, necessitate comprehensive patient education tools that can be integrated into the workflow so they are available for patients when they are ready and willing to learn.

In the current fast-paced acute-care environment, systematic strategies are needed to translate and integrate evidence into patient education tools. The use of automated platforms such as bedside Web-TV facilitates tailoring of information based on individual patient characteristics. Customization of the information that is presented is a necessary component of education of patients with chronic illness because it supports meaningful behavior change and promotes positive self-management skills.37,38,40-43,44

Automated patient pathways integrated into a Web-TV platform have the potential to deliver effective patient education while addressing the current realities of the acute-care environment.

“Automated patient pathways made available through a bedside Web-TV application in acute-care hospitals could provide patients with access to information within an appropriate context…”

PEARLS explained

PEARLS is a Web-TV application currently under development. Its purpose is to educate patients after acute myocardial infarction about their anticipated length of stay and treatment plan. In addition, PEARLS is an interactive patient pathway designed to support patients in decision-making and lifestyle modification by supplying evaluated, tailored information related to symptom recognition, lifestyle modification, and medication management. The availability of PEARLS on the bedside television may address many of the patient-related barriers to dissemination of CPG recommendations because PEARLS delivers information at the point-of-need in a patient-friendly format over the course of hospitalization.

The conceptual underpinnings of the PEARLS pathway are the informatics infrastructure for evidence-based practice (IIEBP) proposed by Bakken46 and the collaborative self-management model set forth by Von Korff, Long, and others.37,40-43,44 IIEBP comprises eight building blocks that support applying evidence to practice and building evidence from practice. It includes the following elements: data acquisition methods, standardized terminologies,
The IIEBP and its eight building blocks provide the structural framework for the PEARLS patient pathway and a rich base of support for the evidence-based patient education and self-management tools. The collaborative self-management model focuses on teaching and reinforcing customized self-management skills and is associated with good outcomes in patients with chronic illness. The literature on collaborative self-management suggests that over time, strategies that flow from this model may reduce the vulnerability of patients with chronic illness as collaborative self-management reinforces the skills needed to face the multiple challenges associated with ongoing chronic illness management.40,42,44

Steps in Development

The shared vision of the PEARLS pathway was conceived out of a desire to provide a systematic means of educating and engaging patients with cardiac illness during their treatment in an acute-care setting. This vision includes the use of a Web-TV application designed to target a “TV-literate” bed-bound population.

Envision: For acute myocardial infarction, the vision for the PEARLS pathway includes the ability to do the following:

- To educate patients and caregivers regarding length of stay and expected plan of care after the medical event.
- To provide tailored educational content related to reportable signs and symptoms; lifestyle modifications, such as smoking cessation, diet and activity; medications; and pain management.
- To support tailoring of evidence to acknowledge age-related, cultural, and ethnic differences and the role of these factors in the healthcare decision-making process.
- To encourage patients to seek follow-up care.
- To establish a framework that fits within the informatics infrastructure from which to link structure, process, and outcome data from internal and external sources (such as PEARLS pathway, practice guidelines, and performance measures, including patient adherence).
- To use the informatics infrastructure to drive adherence to clinical practice guidelines and evidence-based practice.

Analyze: Users were analyzed to consider their perspective in the design of the PEARLS pathway. The demographics of patients admitted to Greenwich Hospital (the “local” population) with a diagnosis of acute myocardial infarction were analyzed. The mean patient age is 71.2 years old and mean length of hospitalization is 5.9 days for uncomplicated and complicated cases. Although this is slightly over the hospital goal of three to four days for uncomplicated cases, it compares favorably with a length of stay of 6.5 days for patients in the hospital peer group and a 6.8-day average for patients in other hospitals in Connecticut.

The socioeconomic demographic data of the average senior citizen in Greenwich appears to be different than that of other geographic areas. The mean retirement income is $26,000 annually, compared with $18,000 for all Connecticut senior citizens. In addition, 60 percent of the population of Greenwich has a college level or higher...
education, compared with 30 percent of all senior citizens in the state. “Wired seniors” tend to be those who are in a high-income bracket and with a high level of education. The demographic profile of the local Greenwich population suggests that the acute myocardial infarction patients in this local population fit the “wired seniors” profile.

**Design**

A Web page prototype was created to illustrate the design concept of the PEARLS pathway. The collaborative self-management model was interwoven into the prototype while separating and defining user interfaces on separate Web pages. Web pages were created for the initial pathway screen (the PEARLS home page) with expected length of stay, day one of hospitalization, day two of hospitalization, and days three to four (discharge) of hospitalization (see Figure 1.). The PEARLS home page screen displays the benchmark length of stay for patients recovering from AMI. Clicking on a specific day of hospitalization with the bedside remote displays the treatment plan for that day (see Figure 2.).

The large care element “buttons” such as location, medications, and tests are linked to Web pages from MedlinePlus or other evidence-based or evaluated information. For example, the location button links the patient to the Greenwich Hospital Web page that describes the inpatient cardiology units. The tests button is linked to the Journal of the American Medical Association’s patient education page on electrocardiograms.

Additional Web pages were created to display questions designed to facilitate self-assessment of the major risk factors for heart disease and to display content and information linked to each question. Risk-factor assessment questions are set up as displayed in Figure 3. Individuals are asked to respond to questions and read content that is relevant to their own risk factors. Linked to each question is a brief, easy-to-read summary of the American Heart Association’s recommendations for prevention of heart disease. Under the summary are links to a brief video (less than four minutes in length) and reading material that enable the individual to get additional, evaluated information that is consistent with guideline recommendations. Individuals can choose to watch the video, read from a Web page, or do both, depending on the amount of information and their preferred mode of learning.

**Refine:** The information on the Web page prototypes was presented to elderly hospital volunteers and refined based on their feedback. The initial evaluations led to an overall simplification of language used throughout the PEARLS patient pathway and the addition of a screen that provided an overview and intent of the patient pathway. The volunteers recommended that the screen enable users to move on quickly if they do not desire additional information or if they were working with a clinician who had provided a similar overview.

To further refine the PEARLS pathway, a heuristic evaluation was conducted using the Neilson method. Neilson defines heuristic evaluation as “a usability engineering method for finding the suitability problems in a user interface design so that they can be attended to as part of an iterative process.” Neilson found that by using between three to six evaluators, 66 percent to 75 percent of usability problems could be identified.

Three elderly hospital volunteers with a range of computer literacy levels (one with no experience, one with some experience, including class at a senior center, and a self-described Web surfer) were asked to evaluate the PEARLS patient pathway. During the process, evaluators were given a television remote, and the PEARLS pathway was turned on. Evaluators were asked to navigate through the pathway using the remote without assistance and to use the PEARLS pathway help screen for guidance if needed.

The evaluators were observed, and notes were taken on usability issues. Their concerns included television remote-related issues, computer literacy issues, and PEARLS pathway problems.

All evaluators identified the remote as the largest source of difficulty in navigating the PEARLS pathway. The greatest differences in usability were noted between the self-described Web surfer and the other two users. The evaluators with some or no computer experience both needed to be cued regarding the use of the up and down arrows for navigating to pathway icons and the use of the “select” button for making selections.

In addition, they expected that the PEARLS pathway would respond immediately to clicking the remote, as is generally the case with a television remote. If there was a delay, the users would continue to click until the pathway responded. Because PEARLS is a Web-TV application, it behaves more like a computer than a television; users may experience a brief delay between making a selection and
seeing the computer response. After this concept was explained, the users were able to successfully navigate the pages and select content related to their cardiac risk factors. However, all users suggested that a “remote help page” be added as a link to the pathway index page. Users stated that this link could provide access to a brief tutorial on use of the remote and instruct users to click once to make a selection.

All three users reported that they enjoyed reading the content and watching the short video clips. They commented that the information was useful and had sufficient flexibility to allow for selection of content that is relevant to health status and easy to understand. The experienced user reported on the usefulness of the Web links for finding valid information. One user, who was a heart attack survivor, said she wished that PEARLS was available when she was hospitalized because she believed it would have helped her and her husband feel like they could do more to promote recovery than they believed when she was hospitalized.

The Future of PEARLS

Currently, the PEARLS pathway is being refined, based on the results of the heuristic evaluation. Additional help screens are being added and will require evaluation before the pathway is ready for use with patients. In addition, the feedback regarding the remote has been shared with the Web-TV company, and they have been asked to make some simple changes that will make the remote better for patients using the PEARLS pathway, as well as for patients using the television.

After resolution of usability problems identified through the heuristic evaluation, PEARLS may be expanded to target other chronic illness populations, including heart failure, chronic obstructive pulmonary disease, and diabetes. By providing a means to access information about length of stay, the treatment plan, and risk factor modification at the point of care, Web-TV provides a platform for the PEARLS pathway that drives patient-centered informatics processes for evidence-based practice.

The PEARLS pathway utilizes collaborative self-management strategies with known effectiveness by using an automated platform to tailor educational content with the intent of supporting behavioral change. Developers hope that the PEARLS pathway will drive evidence-based practice as data is collected on information viewed by patients and their response to that information. Over time, this will enable measurement of the impact of PEARLS on patient outcomes such as knowledge, length of stay, and rehospitalization.

In the face of current acute care challenges, patients with chronic illness require ongoing, tailored education to promote self-management skills and improve functioning and quality of life after discharge. The PEARLS application is a patient-centered, evidence-based practice tool designed to drive these outcomes while advancing evidence-based practice.

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Applications of Ecological Interface Design in Supporting the Nursing Process

Kathryn Momtahan, RN, PhD; and Catherine Burns

ABSTRACT

Today's nursing environment is complex, with many sources of data that are often poorly displayed. Ecological interface design (EID) is a systematic approach to designing interfaces to complex systems. EID has been used to design interfaces for aviation displays, power plant monitoring and control, human hemodynamic monitoring, anesthesia monitoring, and neonatal intensive care monitoring and diagnosis. EID makes critical relationships easily visible, eliminating the mental workload of integrating, calculating, or remembering multiple values. This paper reviews past experimental studies of EID in healthcare applications and discusses the application of EID to a decision-support tool for diabetic patients using personal digital assistants. The authors also discuss other contributions that EID could make to the nursing process in the areas of physiological monitoring, decision support, database design, and the measurement and analysis of nurse-sensitive outcomes, including patient safety outcomes.

KEYWORDS

- Ecological interface design
- Cognitive work analysis
- Nursing process
- Personal digital assistants

Introduction

Since the publication of the Institute of Medicine report “To Err is Human: Building a Safer Health System” and the subsequent report, “Crossing the Quality Chasm,” there has been a growing understanding of the role that human factors can play in preventing errors and improving healthcare delivery. The latest Institute of Medicine report, “Keeping Patients Safe: Transforming the Work Environment of Nurses,” recommends an increase in the development and use of computer-supported clinical decision-support systems as a way to improve patient safety.

A recent large-scale project by O’Neill et al. called “The Nurse Computer Decision Support Project” (N-CODES) describes a prototype for a prospective decision-support system that integrates the best available evidence into the decision-making process. The project staff consists of four senior researchers, two computer engineers, two nurses, and seven research assistants (three engineering graduate students and four nursing graduate students). The project has not yet produced a working prototype, although the groundwork has been completed and presumably the task of integrating and presenting the information now will be addressed.

One approach that can be used to design interfaces for complex systems is the ecological interface design approach. This paper will describe ecological interface design (EID); the underlying cognitive work analysis (CWA) that is done before the design phase; an overview of work that has been done in this area in the last two decades, with an emphasis on work in the healthcare environment; and a discussion of four possible applications of EID to the nursing process: patient monitoring, database design, decision support tools, and the measurement and analysis of nurse-sensitive outcomes. The challenges facing the application of EID to the nursing process also are reviewed.
Overview of Ecological Interface Design

Ecological interface design is a systematic approach to interface design for complex systems. EID uses a method called work domain analysis to determine the information requirements for ecological displays. Work domain analysis is an important component of cognitive work analysis.

Work domain analysis results in a five-level hierarchical model of the system of interest or work domain. This five-level hierarchy is called an abstraction hierarchy, originally conceptualized by Rasmussen.8,9 This model ranges from the concrete, with a description of equipment and its capabilities, to the abstract, with a description of purposes to be achieved with that equipment. In this way, work domain analysis specifies information requirements in a way that is relevant to goals.

Figure 1 outlines the levels of the abstraction hierarchy. The functional purpose layer describes the purpose for which the system is to be built. In computer-based systems for which this theoretical framework has been developed, this layer most commonly will map to the application layer of the system. The abstract function level maps out the causal structure of the system. The generalized function level provides a view of the processes by which the abstract functions are carried out. The physical function layer describes the components and physical implementations of the processes in the generalized function layer. In the physical form layer, the components are described by their appearance, location, and physical form.

This work domain analysis is used to guide the computer interface design. Originally designed to support the design of process control displays,10 it more recently has been used to develop aviation displays,11 displays for a document-retrieval system for public libraries,12,13 network management,14 hemodynamic monitoring,15 neonatal intensive care monitoring,16 and anesthesia monitoring.17,18,19 Most of the analyses in the medical domain have modified the hierarchy somewhat, dispensing with generic-level labeling, such as abstract function and generalized function, in favor of levels more tightly tailored to medical applications. Table 1 shows these modifications by comparing the layers of the abstraction hierarchy developed for designing displays for power plant monitoring, aviation, and anesthesia.

Until now, the investigation of the application of EID to healthcare has been limited to several studies in anesthesiology monitoring, hemodynamic monitoring, and neonatal monitoring. These environments relate well to the power plant and aviation domains because they require extensive monitoring and highly trained personnel. Table 2 summarizes these studies and their findings.

<table>
<thead>
<tr>
<th>Power Plant</th>
<th>Aviation</th>
<th>Anesthesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Purpose</td>
<td>Produce electrical energy</td>
<td>Fuel system: Provide fuel to get aircraft to its destination</td>
</tr>
<tr>
<td>Abstract Function</td>
<td>Mass and energy transfers</td>
<td>Mass and energy conservation</td>
</tr>
<tr>
<td>Generalized Function Processes</td>
<td>Temperature and pressure changes</td>
<td>Flow and storage of different liquids, gases and heat</td>
</tr>
<tr>
<td>Physical Function</td>
<td>Actions and behaviors of heaters, boilers and turbines</td>
<td>Engine and fuel action and behavior</td>
</tr>
<tr>
<td>Physical Form</td>
<td>Power plant equipment location, appearance and condition</td>
<td>Airplane engine and equipment location, appearance and condition</td>
</tr>
</tbody>
</table>

Table 1. Comparison of the layers of the abstraction hierarchy produced for three different domains (power plants, aviation and anesthesia).
Patient Monitoring

While some researchers using the EID framework have focused on hemodynamic monitoring of critically ill patients that may be performed by nurses or physicians, some others have focused on the role of the anesthetist and the anesthesia workstation. Although these patient monitoring activities seem fairly similar, in fact, there are several differences. In the operating room, the anesthetist is the sole monitor of one patient. In the intensive care setting, although the nurse is the main monitor, others may be involved in the care of a patient, such as the intensivist. The nurse also may be monitoring more than one patient; for example, in a recovery room setting, a nurse may take care of several patients at once. In addition, the anesthetist is actively inducing a state of disequilibrium (the anesthesia) so the operation can proceed. In an intensive care situation, the intent is for the patient to achieve and maintain a steady state. The EID displays in the studies presented in Table 2 were compared against existing displays in use in those areas at the time of the studies.

Diabetic Monitoring

EID was used to design a tool for diabetic monitoring for patients using personal digital assistants (PDAs). While not yet tested for its performance, it provides a good demonstration that EID concepts may be useful at the patient level and applicable to small screen displays.

Novel visualizations for diabetic health monitoring were developed, concentrating on visually portraying the key relationships for overall health by showing energy balances between exercise, basal metabolic rate and carbohydrate intake. The monitor shows insulin action curves and the relationship between insulin injections and blood insulin levels. Both of these relationships are difficult for patients to understand for various reasons; for example, the energy balance requires multiple calculations, and the blood insulin level involves the prediction of a time lag. Current patient tools, such as log books or digital applications, do not provide this type of calculated and predictive information even though both of these relationships are also important if the patient is to maintain tight control of their metabolic system.

<table>
<thead>
<tr>
<th>Study</th>
<th>Tested with</th>
<th>Improved performance with EID display?</th>
<th>Experts or novices performed better?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Accuracy</td>
<td>Speed</td>
</tr>
<tr>
<td>Hemodynamic Monitoring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effkin et al. (1997)</td>
<td>19 undergraduate psychology students</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Experiment 1</td>
<td>Between subject design</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effkin et al. (1997)</td>
<td>13 undergraduate psychology students</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Experiment 2</td>
<td>Within subject design</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effkin et al. (1997)</td>
<td>6 experienced critical care nurses</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Experiment 3</td>
<td>6 nursing students</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sharp and Helmicki (1998)</td>
<td>16 anesthetists (attending fellows and residents)</td>
<td>Yes</td>
<td>Not measured</td>
</tr>
<tr>
<td>Anesthesia Monitoring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jungk (2000)</td>
<td>20 anesthetists</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Blike (1999)</td>
<td>3 anesthesia residents, 8 anesthetists</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Blike (2001)</td>
<td>5 anesthesia residents, 2 anesthetists</td>
<td>Mixed results</td>
<td>Mixed results</td>
</tr>
<tr>
<td>Jungk (2001)</td>
<td>16 anesthetists</td>
<td>No</td>
<td>Mixed results</td>
</tr>
<tr>
<td>Experiment 1</td>
<td>2 anesthetists</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jungk (2001)</td>
<td>8 anesthetists</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Experiment 2</td>
<td>Mixed results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zhang (2002)</td>
<td>12 anesthetists</td>
<td>Mixed results</td>
<td>Mixed results</td>
</tr>
<tr>
<td>Study 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zhang (2002)</td>
<td>12 undergraduate bioengineering students</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Study 2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Summary of the results of healthcare-related studies where the EID display was compared with conventional displays.
These variables appear when a work domain analysis of blood glucose metabolism is conducted, and, notably, they appear at the higher levels where processes, balances, and purposes are described. Table 3 shows some of the variables that are identified. Many of these variables—while they can be calculated, estimated, or predicted with a decision aid—are never available at the patient level (see Table 4). Figure 2 shows the interface developed for this system.

The menu includes entries for energy balance and body mass index, which are unique to the EID approach. Overall blood glucose state is quickly shown through too high (left), normal (middle), and too low (right) with color and shape coding.

**Applications of EID to Nursing**

The nursing process involves the evaluation of a patient’s condition, the identification of problems, and the implementation of interventions by nurses. Problems are identified based on the patient interview and physical assessment, prior knowledge, the patient’s medical information (such as the admitting diagnosis), and tests and procedures performed to determine a course of action. This process is recursive.

The frequency with which re-assessments are performed and interventions evaluated and modified will depend on a patient’s acuity level. In an intensive care unit, the process may occur every 15 minutes; in a stable patient ready to go home from the hospital, the process may occur perhaps every 12 hours and with less intensity.

The nursing process now also incorporates best evidence and practice. The nurse must collect and analyze data about the individual patient and then cognitively integrate that information with what they understand to be the best evidence to determine an intervention.

As with all healthcare-related processes, the nursing

---

**Table 3. Some variables identified from the work domain model.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Units</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body weight</td>
<td>kg or lb</td>
<td>Purpose</td>
</tr>
<tr>
<td>Blood glucose (plasma glucose)</td>
<td>mmol/l or mg/dl</td>
<td>Purpose, Physiology</td>
</tr>
<tr>
<td>Energy (in and out)</td>
<td>calories or kJ</td>
<td>Balances</td>
</tr>
<tr>
<td>Glucose absorption rate (gut)</td>
<td>mmol/h</td>
<td>Processes</td>
</tr>
<tr>
<td>Net hepatic glucose balance</td>
<td>mmol/h/kg</td>
<td>Processes</td>
</tr>
<tr>
<td>Rate of peripheral (insulin-dependent) glucose uptake</td>
<td>mmol/h/kg</td>
<td>Processes</td>
</tr>
<tr>
<td>Rate of insulin-independent glucose uptake</td>
<td>mmol/h/kg</td>
<td>Processes</td>
</tr>
<tr>
<td>Urinary glucose excretion rate</td>
<td>mmol/h</td>
<td>Processes</td>
</tr>
<tr>
<td>Plasma insulin</td>
<td>mU/l</td>
<td>Physiology</td>
</tr>
<tr>
<td>Amount of injectable insulin</td>
<td>Units (U)</td>
<td>Physiology</td>
</tr>
<tr>
<td>Type of injectable insulin</td>
<td></td>
<td>Physiology</td>
</tr>
<tr>
<td>Time since each insulin injection</td>
<td>hours</td>
<td>Physiology</td>
</tr>
<tr>
<td>Action curves of the types of insulin</td>
<td></td>
<td>Physiology</td>
</tr>
<tr>
<td>Amount of food ingested</td>
<td>grams or volume</td>
<td>Physiology</td>
</tr>
<tr>
<td>Type of food ingested</td>
<td></td>
<td>Physiology</td>
</tr>
<tr>
<td>Time since food ingested</td>
<td>hours</td>
<td>Physiology</td>
</tr>
<tr>
<td>Unit carbohydrate (CHO) value of food ingested</td>
<td>ratio of grams CHO to food amount</td>
<td>Physiology</td>
</tr>
<tr>
<td>Ketone level</td>
<td>mmol/l or mg/dl</td>
<td>Physiology</td>
</tr>
<tr>
<td>Renal threshold of glucose</td>
<td>mmol/l</td>
<td>Physiology</td>
</tr>
<tr>
<td>Creatinine clearance rate</td>
<td>ml/min</td>
<td>Physiology</td>
</tr>
<tr>
<td>Peripheral insulin sensitivity ($S_p$)</td>
<td></td>
<td>Physiology</td>
</tr>
<tr>
<td>Hepatic insulin sensitivity ($S_h$)</td>
<td></td>
<td>Physiology</td>
</tr>
</tbody>
</table>
As Burns and Hajdukiewicz\textsuperscript{5} point out, there are several challenges to applying EID to a healthcare domain. These challenges include:

- Choosing the system boundary.
- Deciding when to stop decomposing of the part-whole analysis.
- Integrating medical information.
- Dealing with issues associated with sensor limitations and availability.
- Determining information requirements for different roles in the medical environment.
- Extending EID to other sensory modes (such as auditory).

There are several opportunities to apply ecological interface design to the nursing process. Four possible applications will be discussed—physiological monitoring, decision support, database design, and measuring and analyzing nursing-sensitive outcomes.

To focus on a design, however, a cognitive work analysis first needs to be done in the area of interest. The focus here will mainly be on hospital-based nursing, but these applications of EID to physiological monitoring, decision support, and the measuring and analyzing of nursing-sensitive outcomes could all be used in primary care as well, particularly if the applications were to be developed for use with PDAs, which are popularly used as portable computerized devices.

### Analysis of the Work that Nurses Do

Until recently, the major focus of the efforts to measure the work that nurses do has focused on nursing workload measurement, so nursing productivity levels—sometimes referred to as utilization levels—could be calculated based on time-motion studies to facilitate the adjustment of staffing levels. For a comparison of four workload measurement systems developed for this purpose,

<table>
<thead>
<tr>
<th>Measured</th>
<th>Estimated</th>
<th>Calculated</th>
<th>Simulated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood glucose</td>
<td>Carbohydrate from food</td>
<td>Basal Energy Expenditure</td>
<td>Plasma insulin</td>
</tr>
<tr>
<td>Urine/blood ketones</td>
<td>Calories from food</td>
<td>Body Mass Index</td>
<td>Blood glucose</td>
</tr>
<tr>
<td>Insulin type &amp; dose</td>
<td>Calories burned from exercise</td>
<td></td>
<td>Net hepatic glucose balance</td>
</tr>
<tr>
<td>Height</td>
<td></td>
<td></td>
<td>Glucose uptake</td>
</tr>
<tr>
<td>Weight</td>
<td></td>
<td></td>
<td>Glucose absorption</td>
</tr>
<tr>
<td>Blood pressure</td>
<td></td>
<td></td>
<td>Renal excretion</td>
</tr>
<tr>
<td>Amount of food x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration &amp; intensity of exercise</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cholesterol, HDL and LDL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood triglycerides</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microalbumin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine clearance rate</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 4. Variables identified from the work domain model, with availability.**

![Figure 2. Menu for EID on a mobile device, diabetes project.](image_url)
Malloch21,22 and Conovaloff33 have reviewed the evolution of these systems.

It is now the norm for hospitals to have patient classification systems and nursing workload measures. Originally designed as an economic tool to optimize staff-mix ratios, there has been a shift toward optimizing staff-mix and nurse-patient ratios to improve patient outcomes,34,35,36 including patient safety outcomes.27

Nursing work also has been measured in the past to determine the percentage of time that nurses spend doing paperwork versus providing patient care. For example, such measurements are typical before and after implementation of a clinical information system so healthcare executives can measure the potential decrease in the amount of time nurses do paperwork after a CIS is implemented. Typically, either work-sampling methods28 or a combination of time-motion and work-sampling methods29 are used to measure the impact on nursing work before, after, and during the implementation of a CIS.

More recently, there has been some work done to account for other factors involved in the work that nurses do. Potter et al30 combined a time-motion analysis with a descriptive analysis of nursing work. By combining this data with a link analysis, the authors developed what they call a “cognitive pathway.” Other researchers have incorporated a measure of environmental complexity into their nursing work measurement and analysis.31,32 On a more global scale, there are recent efforts to identify nurse-sensitive outcomes,33 integrate reference terminology in nursing,34, and move this forward by mapping the nursing process to facilitate nursing information capture and utilization within HL7 standards.35

Physiological Monitoring

The most obvious application of EID to physiological monitoring based on cognitive work analysis is hemodynamic monitoring of critically ill patients in operating rooms and intensive care units, which has already been reviewed. The developing application of EID to diabetic monitoring also was discussed earlier. However, although this has been intended for use by diabetics themselves, this information could be shared with the diabetic’s physician or the advanced practice nurse in the diabetic clinic.

Diabetics are not the only group of patients whose condition requires continuous monitoring and adjustment of actions and treatment. Heart failure patients are another large group of patients whose physiological state needs to be closely watched. The monitoring of this information alone is important, but being able to share the information with physicians and heart failure clinic nurses would be very valuable.

In a six-month prospective interventional crossover study of 19 patients, Tsang et al36 were able to demonstrate a significant improvement in glycemic control when patients used a monitoring system with a handheld, touchscreen electronic diary (with a mean HbA1C reduction of 0.825 percent). Electronic diaries, which are becoming popular for the management of diabetes mellitus,37 cannot by themselves be considered a computerized decision support tool if they are used solely for logging patient information.

Decision Support

Although far from common, computerized decision support for clinical practice has been used long enough so that systematic reviews of their implementation and use are available.

In their systematic review of 63 controlled trials of computer-based clinical decision support systems on physician performance and patient outcomes, Hunt et al38 concluded that “published studies of CDSSs are increasing rapidly and their quality is improving. The CDSSs can enhance clinical performance for drug dosing, preventive care, and other aspects of medical care, but not convincingly for diagnosis. The effects of CDSSs on patient outcomes have been insufficiently studied.”

In a more recent assessment of the situation following their review of the literature, Trowbridge and Weingarten39 concluded that, “The preponderance of evidence suggests that clinical decision support systems are at least somewhat effective. Their highest utility has been demonstrated in the prevention of medical errors, especially when coupled with a computerized medical record and directly intercalated into the care process.”

Computerized decision support for clinical nursing practice is less common,40 although there are some promising results related to the implementation and use of decision support in nursing. Mueller et al41 reported the positive impact of a decision support tool—a diuretic treatment algorithm, designed and implemented for managing heart failure patients—used by advanced practice nurses. Researchers were able to demonstrate a significant reduction in the 30-day readmission rate and a 50 percent reduction in heart failure-related hospitalizations in 271 patients during a four-year period.

There is a growing interest in the integration of information from diverse sources to develop decision support tools that support the nursing process. Brekke et al42 describe an interesting approach to integrating population-based statistics to estimate the impact of coronary heart disease treatments on disease outcomes for populations. They created event-decision-intervention-outcome flow pathways to simulate risk of a clinical event and expected intervention outcome for heart failure, tachyarrhythmia, stable angina pectoris, acute coronary syndrome, bradycardia, post-myocardial infarction, and post-coronary artery bypass grafting. This type of modeling using population-based statistics for nursing interventions could enhance decision support tools for nurses and policy makers.
Database Design

In a recent paper, Burns and Zhou reported on a project using work domain analysis as a foundation for the design of a health information database for blood glucose management. They compared the content of four existing commercial databases for blood glucose management with the database they had designed. The study's benchmark was the sum of the data elements generated from the five databases, for a total of 300 possible unique data elements.

The database generated through work domain analysis covered 81.7 percent of the elements. The next closest database contained 45 percent of the elements. Importantly, some of the elements that the work domain analysis-generated database did not cover were related to events such as fasting, because the work domain analysis would record energy balances and calculate whether or not the patient was losing mass.

Event-based knowledge will need to be accounted for in future designs of health-related databases. Similarly, the contributions of other sources of data must be factored in. The tracking and treating of patients usually includes input from the patients themselves but also from a variety of healthcare professionals. In the case of hospital databases, the main source of information about the patient will be received from the healthcare professionals.

The ubiquity of data sources brings up another important point in using cognitive work analysis and the results of this analysis to support the design of interfaces to integrate and display information: how to account for interdisciplinary work. A good example of shared documentation in a hospital is the patient problem list; patients' problems can be added or removed by any healthcare professional.

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Another example is clinical pathways. Dykes et al. recently studied the adequacy of national standardized terminologies in the United States for interdisciplinary coded concepts in an automated clinical pathway for heart failure. They found that of the 260 unique pathway concepts identified, 239 of them—or 91.9 percent—were represented by one or more of the standardized coding systems.

Nurse-Sensitive Outcomes

There is a great deal of interest in the measurement and analysis of nursing-sensitive outcomes. Although this is an important activity for researchers who want to link the work that nurses do with patient outcomes, it is essential to find ways to not only capture and categorize this information but to integrate and present the information back to nurses to enhance their practice. The standardization of terminology and the capturing of information are necessary parts of this process.

The current interest in improving patient safety while under the care of medical professionals has resulted in a discussion of nurse-sensitive patient safety indicators, a subset of nurse-sensitive patient outcomes. In their review of the literature, White and McGillis Hall found medication errors, nosocomial infections, patient falls, pressure ulcers, and mortality to be the most common safety outcomes linked to nursing practice.

Conclusion

Other than the cognitive work analysis that has been done related to hemodynamic monitoring, there has yet to be a cognitive work analysis performed to model the work that nurses do to design computerized systems that would facilitate the nursing process.

The task analysis and redesign of an intravenous infusion pump interface performed by Lin et al. is a good example of how an interface design can affect cognitive workload and patient safety, even though it is a simple example and is not based on a cognitive work analysis and EID because it deals with a single piece of equipment and not a complex system. Lin et al. were able to demonstrate an increase in the speed and accuracy of the programming of an intravenous infusion pump by experienced nurses when the interface was redesigned.

Before the introduction and universal use of intravenous infusion pumps, nurses counted the number of drops per minute when they set up and monitored intravenous infusions for patients. Now, not only are almost all intravenous fluids infused through programmed pumps, but hospitals typically have a variety of pumps that are in use from several different manufacturers. It can be assumed that the human factors design of at least some of these pumps is not optimal. What is needed to design better computerized systems to support nurses is cognitive work analysis and the design of interfaces that integrate all the information that nurses use and need in a way that decreases their cognitive workload. The expectation is that the speed and accuracy with which nurses perform their work would be enhanced and that this, in turn, would lead to a safer environment and improved outcomes for patients.

There are many challenges involved in using ecological interface design to support the nursing process. In terms of design, there has been a sparse amount of work domain analyses, except for research that has been done for physiological monitoring of patients. Most of the work to date has been tested on few subjects, and there is at least some
evidence that individual differences exist in the way people process information from displays. Elements of the design that affect the performance of novices versus expert users is still largely unknown and may differ depending on the domain and the user group. The role of the visual designer has not previously been taken into account. Because display design is partly an analytic and partly an artistic endeavor, it is conceivable the same type of display designed by two different visual designers might yield different results.

On the nursing side, the emerging classification of data elements means that a system designed now may not conform to the eventual form of the final standard. Also, because visual display interpretation has not been as extensively tested with nurses, little is known about the best way to present information to nurses.

About the Authors

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Catherine Burns directs the Advanced Interface Design Lab at the University of Waterloo in Ontario, Canada. Her research looks at human performance support through EID and advanced visualization.

References


43. Burns CM, Zhou Y. Work domain analysis as a step in a systematic database design methodology.


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Authors should submit a one-page proposal including:

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- Complete name, title, address, telephone number, fax number, and e-mail address of all potential authors

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- Technology Overview: Articles surveying and defining the key enabling technologies and/or business methodologies for the industry or its components (mobile computing, relational databases, handwriting/voice recognition, etc.), formulas for budgeting and/or needs assessment.
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Length

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- Technology Overview: Articles surveying and defining the key enabling technologies and/or business methodologies for the industry or its components (mobile computing, relational databases, handwriting/voice recognition, etc.), formulas for budgeting and/or needs assessment.
- Case Studies: Articles explaining the who, what, when, how, and why of a particular problem or challenge, and how it was solved or solution proposal. These include consumer-focused case studies. We discourage any type of marketing article, but allow for the name of the product to be mentioned once in the article. Generally, the product should be described in generic terms. The study should include some testimonial from the provider describing the provider’s experience with the product. We strongly suggest that these articles be co-authored by the provider and vendor.
- Data-driven research, pilot studies, and studies in conjunction with universities. These should follow the general format for a scientific article: Introduction, Methods, Results, and Comments.
- Book/Literature/Resource Review: In-depth articles reviewing a book or resource (including online products and services), articles surveying a variety of resources to further readers’ understanding of the field.

Send to Nancy Vitucci, Senior Editor, HIMSS, 230 E. Ohio Street, Suite 500, Chicago, IL 60611-3269.

Manuscript Submission
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