



Standards Insight

An Analysis of Health Information
Standards Development Initiatives

March 2003

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INTRODUCTION

HIMSS 2003 – a record year

HIMSS 2003 Annual Conference, like the HCIT industry in general, has rebounded from the Y2K hangover and dot-com slump of the last few years. There were near record numbers – almost 700 vendors and more than 19,000 attendees. The final tallies were likely reduced by the heightened “Orange” high alert status that went into effect the week before the conference. The HCIT market was up approximately 10 percent, led by clinical information systems vendors. The HIMSS conference is a good venue for visualizing the strategic outlook for the HCIT industry and how it affects the standards initiatives that we analyze.

HIMSS 2003 was less about new “hot” topics as it was about better defining key industry trends that were clear at HIMSS 2002. In our review last March, we noted:

- ? The dominant theme at HIMSS 2002 was reducing medical errors, improving clinical processes and operational efficiencies. The hot technology was computerized physician order entry.
- ? Leapfrog’s impact on HCIT will be to drive integrated clinical information systems, not just computerized physician order entry.
- ? HCIT security has been defined by compliance with the proposed HIPAA rules for the last four years, not as a business priority. That has changed after September 11. HIPAA still looms as motivator, but more business attention is being directed at contingency plans, disaster recovery plus system protection and not just maintaining privacy.

Reducing medical errors, Leapfrog and security continue to be the principle factors shaping the HCIT environment in 2003. With some variation, they represent the 18- to 24-month outlook for the industry. In this issue of the *Standards Insight*, we will step back from our direct analysis of interoperability standards to focus on primary business drivers. This is the context that gives priority and provides the resources to interoperability standards initiatives.

PATIENT SAFETY

Patient safety is now the top business issue facing healthcare, as identified in the 14th Annual HIMSS Leadership Survey of CIOs¹. Fifty-two percent of respondents identified reducing medical errors and promoting patient safety as the most important IT priority. It also is expected to be the most important IT priority over the next two years.

The Leapfrog Group is having an increasingly larger affect on healthcare, despite resistance from many provider organizations. Leapfrog is driving the response to the alarms raised by the IOM Report *To Err Is Human: Building a Safer Health System*.² Leapfrog’s value proposition is that quality care should be the most cost-effective care. It stresses that the current number of medical errors is unacceptable and that hospitals need to change. It has successfully made this case to large employers, other large payers and now to the public at large. However, provider organizations have resisted the Leapfrog specifics as too costly or infeasible.

¹ According to the CIOs, reducing medical errors and HIPAA compliance are the top two business issues facing healthcare, followed by cost pressures. The 14th Annual Health Information and Management Systems Society Leadership Survey sponsored by Superior Consulting.
www.himss.org

² Institute of Medicine *To Err is Human, Building a Safer Health System*. National Academies Press. 2000.

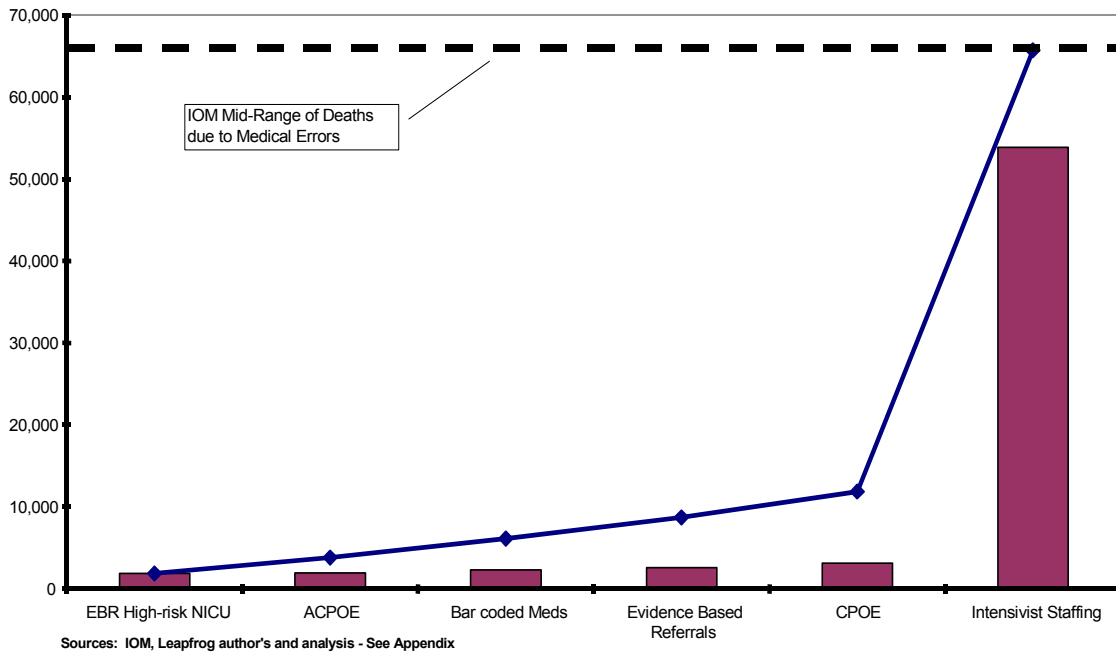
Still it would be impossible to understate the importance the HCIT industry is giving to reducing medical errors and improving patient safety. In the three and a half years since the IOM study was published, the HCIT industry has anticipated the report to be the catalyst to drive clinical information systems. Somehow Y2K and HIPAA have diverted resources and dollars from these patient-care initiatives. If HIMSS 2003 was indicative, the time for patient safety and reducing errors has come. This will translate into the need to invest in computerized physician order entry systems (CPOE), bar code-based medication management systems and the computer-based patient records. However as the HCIT industry awaits this double-digit growth in spending, we might want to examine the premises of these initiatives and their return on investment. The HIPAA experience should be a warning against accepting macroeconomic cost benefit analyses that were based on disputable evidence and without a microeconomic ROI case for those actually making the investment. While CPOE and related applications are still expected to grow rapidly, it is not clear that they will produce the ROI one might expect.

The IOM Report and the Leapfrog Group

When it was first published in 1999, *To Err is Human* provoked a great deal of news attention and awareness among the public about the magnitude of the medical error problem. The number of deaths attributed to medical errors – ranging from 44,000 to 98,000 – was widely cited. Analogies equating unnecessary medical deaths to the deaths caused by crashing a 747 jet every day were easy to grasp. At the same time, several of the largest employers began meeting to discuss the quality and costs of the healthcare that they were purchasing for their employees. This became the Leapfrog Group. Coming from an industrial world where other suppliers were forced to meet stringent quality standards, Leapfrog, applying the purchasing power of its members, sought significant measures that would force hospitals and other healthcare providers to change. They chose three criteria, based on various empirical studies of factors that seemed to make a difference: CPOE, evidence-based hospital referrals (EBR - threshold minimum procedure volumes) and ICU physician staffing (IPS). Leapfrog estimates their initiatives, if adopted by all non-rural hospitals, could prevent up to 58,300 deaths and 522,000 medication errors. The figure below shows the impact of fully implementing the Leapfrog standards and two other key initiatives – bar coded medications administration and ambulatory CPOE – compared to the mid-range estimate of avoidable deaths because of medical errors using the IOM formula.³

³ Please refer to the appendix for more details about the data analysis used to develop the figure.

Patient Safety Initiatives Impact on Avoidable



Full implementation of the Leapfrog initiatives reduces the mid-range of avoidable deaths close to zero. It's also clear there's a very high proportion of avoidable deaths (about 75 percent) that are attributed to lack of intensivist management of ICU patients. So, it's possible there is some crossover between medication errors in general and medication errors in the ICU and between low-volume sites of coronary artery bypass or aortic aneurysm surgeries and subsequent deaths in the ICU.

In addition to the Leapfrog criteria, there were two other high visibility patient safety initiatives evident at HIMSS 2003: bar coded medications administration systems and ambulatory computerized physician order entry (ACPOE). The former closes the loop when paired with CPOE to eliminate the last source of error, and potential avoidable deaths, in medicating inpatients. ACPOE addresses prescribing and transcription errors that account for more than 60 percent of outpatient medication errors.

Thus, we have a set of patient safety initiatives, with which patients and payers could begin to evaluate hospitals and physicians. Implementing each of the initiatives has its own cost-benefit profile when applied to specific health systems, hospitals and practices. There are other estimates, not used by the IOM, for all of these outcomes, so one can generally make different cases for most of the initiatives. Finally, Leapfrog and IOM have focused on deaths caused by medical errors, the starkest endpoint and quality marker. However, the initiatives are aimed at reducing all process errors, going from three-sigma to six-sigma. Again each of the initiatives has its own profile in terms of number of observations and error rate, which in turn affect the cost-benefit of the mediation efforts.

What is going on?

All of the Leapfrog initiatives are disruptive to hospitals, disruptive to culture, processes and economics. This has led to two responses: one is from leaders, which quickly adopt these initiatives, and the other is from providers that seek alternative, less disruptive and expensive measures of quality.

During the Leapfrog presentation at the HIMSS 2003 conference, the speaker⁴ noted that Leapfrog was using CPOE, which has demonstrably the worst ROI of its three criteria, as a

⁴ de Brantes, F.. "The Leapfrog Group: 2003 Agenda". Session 112. HIMSS 2003

wedge to encourage integration of clinical systems. In fact, one cannot really automate physician order entry, regardless of its decision support capabilities, without a more complete clinical information system (CIS). For example, it is unlikely that physicians would review paper charts and reports, handwrite their notes and then turn to the computer to input orders. In the other case of decision support, without automating other clinical data sources and systems, such as history, labs, and pharmacy, there would be no data to validate a new order.

Not surprisingly CPOE has been enthusiastically embraced by the HCIT industry. It represents at least a 20 percent increase in market size over the next five to seven years and pulls through most of the rest of the enterprise CIS. Already, most leading health systems have begun investing in enterprise CIS. In the 14th Annual HIMSS Leadership Survey, 20 percent already have some level of enterprise CIS in place. However, this was accomplished based on voluntary decisions by health system executives reflecting their mission, available funding, culture and strategic priorities. Almost without exception, these “well-wired” organizations are and will continue to be the leaders in clinical and financial performance. The remaining 80 percent will come along. The problem we face as the HCIT industry is becoming part of the “unfunded mandate” crowd, particularly if we cannot show evidence that CPOE and enterprise CIS do improve patient safety and clinical outcomes at some affordable cost. We can embrace concepts such as “it’s just the cost of doing business” or “it’s infrastructure,” but healthcare provider management will demand and deserve a rigorous ROI analysis before making this level of investment.

Business and Politics

The American Hospital Association has reacted vigorously to the Leapfrog initiative. By some accounts, more than 80 percent of AHA member hospitals could not afford to meet the Leapfrog criteria, even excluding the few very specialized procedures. They would argue that such criteria are not feasible but that other “better” quality criteria and patient safety measures are needed. We have no shortage of such “standards” from which to choose. These include the ORYX measures from Joint Commission on the Accreditation Healthcare Organizations, the National Quality Forum’s Hospital Performance Measures and the Agency for Healthcare Research and Quality, which sponsored 90 plus indicators developed by the University of California San Francisco.

Obviously many of these “standards” overlap or address the same problem from a different perspective, e.g., Adverse Drug Events viewed through the CPOE prism of Leapfrog or the Root Cause prism of JCAHO’s sentinel events. While we in HCIT believe that integrated clinical information systems are ultimately a necessary part of any solution that improves outcomes and patient safety cost-effectively, we may not be a sufficient solution. Thus, entering into the national debate about the value of CPOE or bar coding or telemedicine ICU services should be approached with caution. We offer technical systems that enable organizations to change and improve. Our systems are not sufficient by themselves to create positive change or improvements. The well-publicized takedown of the CPOE system at Cedars-Sinai is certainly an acute reminder of the vulnerability of technology to organization and culture.

Recall the lessons of Y2K and HIPAA, our two most recent experiences with “mandated” IT investments that executive management “had” to make. Both were based on uncertain premises (not unusual in dealing with the future) of low risk of very catastrophic things (Y2K) or low probability of very high returns (HIPAA), and both have not been widely viewed as good investments. Both might be considered the “cost of doing business,” but they provide no measurable return on investment or improvement in patient care. While the new patient safety-related technologies aim at enabling improved patient care, their investment case is not yet made, particularly in the absence of clinician acceptance. As we have seen the underlying numbers defining the problem are uncertain, subject to interpretation and not readily translated to individual healthcare organizations’ actual performance. Moreover, we once again see the problem of misalignment between those that pay and those that benefit economically.

The Leapfrog Group, to its credit, has recognized this gap in financial returns, particularly associated with CPOE. At the 2003 Annual Conference, they announced a new “profit-sharing” program for providers that invest in CPOE and IPS. That is, to the extent that the healthcare buyers can benefit from reductions in costs for adverse events, they will share this “windfall” with participating providers. The direct financial benefit of reducing adverse events goes to the charge or per diem based payers in shorter lengths of stay and lower intensity care. Most Leapfrog payer arrangements are of this type rather than full capitation or DRG rates, such as Medicare. Conversely, the hospital loses revenue saved by error avoidance. It will be interesting to see if Leapfrog and its members can figure out how to accomplish this. It will be more interesting to see how Medicare responds, because it is the hospital that captures the savings from preventing adverse events for Medicare beneficiaries.

What is clear is that there will be a growing acceptance of integrated clinical information systems supporting advanced care processes and workflow throughout and among healthcare enterprises. What is needed is the analysis that helps set technology priorities within the context of the larger mission, operations, culture and resources of each healthcare organization.

FINAL SECURITY RULES PUBLISHED

HIPAA, particularly security, still remains a very high priority for providers. According to the HIMSS Leadership Survey HIPAA security and privacy compliance are the next two highest IT priorities after patient safety. Coincidentally, HHS released the preview text of the final security rules on the closing day of HIMSS 2003 and officially published them on February 20, which implies that covered entities must be in compliance by April 2005. But even without the final rule, IT security has taken on new meaning and urgency since 9/11. While internal security threats remain the most prevalent, external threats must be considered. In the interim since the proposed security rules, the federal government has adopted a National Strategy for Securing Cyberspace that it wants government agencies to adopt and private organizations to consider. The HIPAA Privacy rules that go into effect in April already require system security in place to ensure confidentiality. Thus, the release of the final security rules seems, in many respects, anti-climatic. Nevertheless they are important in what they say and in what they do not say.

The final rules are less detailed and prescriptive than the proposed rule, putting more responsibility on individual IT management. This is both good and bad. It does reflect the general strategy of the federal government for securing cyberspace, making each entity responsible for its own security. It is bad to the extent that different organizations will interpret their risks and resulting mitigation steps differently. This will complicate both the exchange of information between entities as well as implementation of new systems within organizations that have selected different security methods and technology. Today, most HCIT applications implement their own security methods for authentication, authorization and system integrity. There are no interoperability standards at this level in healthcare software.

The final rules reflect sound security practices that make each healthcare enterprise responsible for its own IT security. The rules provide no safe harbors that say if you do this, you are okay. They require ongoing vigilance, not a one-time compliance effort. They do not specify technology nor how much to spend on mitigation. They very much reflect the rethinking of national IT security for a highly distributed, self-managed system.

There will be many commentaries and detailed analysis of the final Security rules. However, there are a few points worth highlighting:

- ? The rules apply only to securing electronic protected health information (PHI). Thus they do not match the scope of the privacy rules, which cover PHI in all formats.

- ? Their explicit stated purpose is adoption of national standards to protect the confidentiality, integrity and availability of electronic PHI (in transit or in stores/custody) without actually specifying an explicit standard.
- ? They conform the old concept of chain of trust agreements to the privacy rule's Business Associate (BA) term. However, technically the BA concept may represent different challenges if one were ever going to move to establishing automated trust relationships, e.g. using ebXML or Web Services. Nor does this reduce the need for trading partner agreements as best practice for communications and security protocols.
- ? They simplify requirements into standards and implementation specifications without prescribing specific methods.

In clearly leaving full responsibility with each covered entity to make its own risk assessment and mitigation plan, the security rule invites many different interpretations and plans and certainly implementations. Over time, these will coalesce around best practices, with further guidance, eventual standards and ultimately court decisions. In the meantime, both individual IT departments and HCIT vendors will face a lot of uncertainty and variations. Based on the industry horror stories, we could see a lot of project delays and product reconfigurations until things sort out. We expect that vendors have or will develop their preferred technical implementations with which they will attempt to influence their clients. Incumbent systems, particularly the core legacy systems, are what they are, but new systems and applications coming into an enterprise with new security can expect to meet stiffer and varied requirements and technology implementations.

As expected, electronic and digital signature requirements were omitted from the final security rule. Within the standards development community, we soon will see an audit message standard but no audit repository standard. As noted later, Integrating the Healthcare Enterprise (IHE) is developing an integration profile for user authentication. But we have not seen movement in developing a standard trust framework or standard roles, privileges and authorization methods. Wireless networking is still considered highly vulnerable. Meanwhile, the state of the hacker art is rapidly moving past perimeter defenses, such as firewalls, towards encrypted attacks at the applications level. Thus, we can only view the final Security rule as one step, not a defining moment, in a long-term struggle.

INTEGRATED CLINICAL INFORMATION SYSTEMS

Just behind patient safety and HIPAA in IT priority are clinical information systems. In fact, the six most important applications over the next two years are CPOE, general CIS, bar coded medications management, point of care decision support, the clinical data repository (CDR) and the computer-based patient record.

Integrated clinical information systems are enterprise-wide systems built on a clinical data repository fed by departmental systems and supporting clinician access and workflow. Prototypically, such an integrated CIS can be provided by a single vendor or assembled from a best-of-breed collection of systems. However, the latter solution is threatened by both economics and an inability to integrate processes.

Those vendors that can offer a credible enterprise-wide integrated clinical solution have a significant technical and economic advantage over vendors with less complete or best-of-breed solutions. The former can and do marginally price incremental applications as necessary to maintain account control. A second vendor without that economic leverage in an account cannot match the core vendor in price or in implementation and support costs. Because clinical workflow process and decision support integration are not yet supported by "standards," the technical capabilities of data messaging interfaces cannot equal an integrated application's automation of process workflow. While some aspect of a best-of-breed solution must, by definition, be better

than the single source integrated solution, this functional advantage is offset by the value of system integration and lower implementation and maintenance costs.

There is a gap between interfacing different applications at the data messaging level and at the process level. HL7 Version 2.x messages are suitable for ADT messages, orders and results communications and simple queries. They are not as well suited to support processes, such as CPOE and medications administration with decision support. While there has been interest within HL7 to define packages of messages as part of an application profile, HL7 still is addressing more fundamental issues concerning templates and conformance profiles. It is one of the reasons that we have expressed concern over the “lateness” of HL7 Version 3.0 at a time when healthcare enterprises are making strategic commitments to their clinical system architectures.⁵ Other standards initiatives, such as OMG, tried without much market acceptance to organize common processes as services, such as their patient identifier service. IHE has organized its radiology centric integration profiles around workflow. These profiles fully define the messages, triggers and content that must be support by an actor/role in the profile. This comes close to plug and play to automate workflow within a radiology department. Now, IHE has announced its intention to extend its integration profiles to enterprise-wide functions. However, neither its initial set nor any other current standards’ work will be able to compete with single-vendor solutions to clinical workflow, at least within our 18 to 24 month horizon.

Ultimately, these trends come together in the national healthcare infrastructure and the electronic health record (EHR). System integration within and without the healthcare enterprise is the real challenge, both for the healthcare enterprises themselves, for the HCIT industry and for standards developers. Security is the great disabler and interoperability standards, the enablers, are in danger of fragmentation and delay. Interoperability standards, necessary for a best-of-breed strategy, have not kept pace with the movement to workflow and processes rather than data exchange. These trends drive the market back toward vendors of single integrated solutions.

THE STATE OF INTEROPERABILITY STANDARDS

The two major priorities in HCIT right now are using CIS to improve patient safety and implementing appropriate security and privacy measures, in both cases with an eye to ROI and relative cost benefits. In both cases, interoperability is a critical success factor in implementing integrated CIS and in securely deploying such systems within and without the enterprise. In the first instance, integrated CIS to improve patient safety, we must address workflow and processes, not just data interfacing. In the second case, we need to overcome the anarchy of individual application-based security within the enterprise and automating the complex administrative and technical security issues of exchanging information outside the enterprise. In most cases, our present standards fall short, which reinforce the single-vendor solution in the first case and create many barriers to a national healthcare infrastructure and EHR in the second case.

Two important standards initiatives, Health Level 7 (HL7) and IHE, participated in HIMSS 2003 and are worthy of note.

HL7

As is its long-standing custom, HL7 presented a live demonstration of the interoperability possible from implementing its standards. The demo included four scenarios, 19 participating vendors with contribution and support from eight others. The latter included the CDC and FDA; both have become very interested in interoperability standards as enablers for national tracking of public

⁵ One can ask what percentage of the 79 percent of CIO respondents in the 14th Annual HIMSS Leadership Survey who reported evaluating, implementing or operating a CDR, the core of an enterprise CIS, have incorporated any aspect of HL7 Version 3.0 into their enterprise CIS planning.

health issues, such as disease outbreaks, as well as adverse drug events and medical device complications. Both contributed to the scenarios involving an outpatient or clinic encounters with message or document interchange with hospitals and the external agencies. The demo showcased most HL7 standards, including both Version 2 and Version 3 messaging, the clinical document architecture (CDA), Arden Syntax, CCOW for context management, HIPAA claims attachment and the Java API for Version 3. Despite the heavy use of interface engine technology to intermediate and transform the various messages, one gets a glimpse of where HL7 is going.

In the presentation about this year's demonstration, the HL7 spokesperson frankly noted that they had uncovered several problem areas in applying the HL7 standards in these inter-enterprise scenarios. Specifically, they noted the need for technical and business layer infrastructures. They were limited by not having a common patient index or method to share patient identities and by not having common privacy policies and security technologies. There were no well-defined triggers for reporting processes. Most of these problems have been defined as out of scope for HL7, but they clearly need to be solved in a standards-based manner if HL7 or the industry ever expects to move to the next level of interoperability.

Integrating the Healthcare Enterprise

Meanwhile, IHE did not offer a Year 4 interoperability demonstration but rather theater presentations about their methods and their success stories in radiology. More interestingly, the gaps in interoperability identified by the HL7 demo are partially addressed by IHE, which announced its new integration profiles for Year 5. IHE is expanding beyond the radiology domain to additional areas of the healthcare enterprise. These included:

? Clinical Query/Display Profiles

They are of two types: for existing reports in well-known presentation formats, such as CDA, PDF, RTF, and query for well-known key data, such as allergies, current medications and lab panels. These profiles are linked to both user authentication and EMPI services.

? Patient-Synchronized Applications Profile

This supports viewing the same patient while moving among applications on a desktop. It also is linked to user authentication and EMPI services.

? Advanced Security - Common User Authentication Profile

This is a standards based (Kerberos) user login for workstation and applications

? EMPI - Patient Identity Cross-Referencing Profile

This supports mapping a patient's multiple identities across registration domains to enable access to clinical information across domain boundaries.

One should note that CCOW, an HL7 standard, is prominently featured in all of the IHE profiles. It is the context manager for single user sign-on, calling the authentication service; it is the patient context manager for managing multiple applications on a desktop; and it underlies the mechanism for query for well-known reports and data. This broad support by IHE should give CCOW a further measure of acceptance. These are first steps directed at a specific problem rather than an enterprise framework or roadmap. If IHE succeeds in developing these enterprise-wide profiles with strong support from HCIT vendors and not just radiology vendors, then it may become an important focus for interoperability. Finally, IHE, like HL7, is strongly supported by best-of-breed vendors because the integration profiles facilitate interfacing to other vendors.

NEXT ISSUE

Building on the business and IT priorities discussed in this issue, we will look in more detail at the interoperability issues associated with integrating workflow and processes across systems and enterprises and at the electronic health record.

Late HL7 News Item

On February 27, HL7 announced that it had been advised by GE Medical Systems Information Technologies that GEMIT holds two patents that might be infringed by software products that implement HL7 Version 3.0. This disclosure by GE is required of any HL7 member if the member believes that it has intellectual property rights that overlap the standards being developed. While GE appears to be committed to a reasonable and non-discriminatory license policy, this is truly chilling if the patents are judged valid. We will take a closer look next issue. However, in light of the sensitivity of the matter and the resources of GE, everyone is treading very cautiously.

Please direct any questions, suggestions or comments regarding *Standards Insight* to Joyce Sensmeier (jsensmeier@himss.org) or its author, Ed Larsen (erlarsen@erlinc.com).

APPENDIX – DETAILED ANALYSIS

*The IOM Report and Adverse Events*⁶

Using two studies of hospital discharges, one from New York and the other from Colorado and Utah, *To Err Is Human* posited an adverse event rate of 3.7 and 2.9 percent of admissions, respectively. Of these, more than half (58 and 53 percent, respectively) were caused by errors. A little more than half again can be attributed to negligence. Finally 13.6 and 6.6 percent, respectively, of adverse events led to death. Based on 33.6 million annual admissions in 1997, the IOM Report calculated that there are as many as 98,000 or as few as 44,000 avoidable hospital deaths.⁷ Using the mid-range of the above, one can calculate an adverse event rate of 3.3 percent of admissions. Of these, 55.5 percent are a result of medical errors, of which 51 percent were a result of negligence. If we roll this mid-range analysis forward to 2001 admissions, we can estimate that there were 66,000 avoidable deaths *if no other factors have changed*.⁸

	Mid-Range	High	Low
2001 Admissions	35,600,000	35,600,000	35,600,000
Adverse Event Rate	3.3%	3.7%	2.9%
Deaths as Percent of AE	10.1%	13.6%	6.6%
Errors as Percent of AE	55.5%	58.0%	53.0%
Avoidable Deaths	65,853	103,901	36,113

The 66,000 hospital deaths as a result of medical error in 2001 translate into 1.7 avoidable deaths per 1,000 admissions or 1,700 per million (~4 sigma or 99.8% defect free as measured by death).⁹ The data suggests that serious injury (disability extending beyond 6 months) occurred at

⁶ An adverse event is an injury caused by medical management or mismanagement rather than by the underlying condition of the patient. An error is the failure to take a planned action or planning and taking the wrong action. All adverse events are not caused by errors. All errors do not cause adverse events, i.e., injuries. However, when adverse events are caused by errors, they are preventable adverse events. The assumption is that by reducing all errors and by improving system processes, preventable adverse events also will be reduced.

⁷ Note that the IOM report did not use the same methodology to calculate avoidable deaths based on the Colorado/Utah projections as it did on the New York projections.

	New York Study	Colorado/Utah Study
1997 Admissions	33,600,000	33,600,000
Adverse Event Rate	3.7%	2.9%
Deaths as Percent of AE	13.6%	6.6%
Errors as Percent of AE	58.0%	53.0%
Avoidable Deaths	98,064	34,085

It appears as if they used the New York rate of AE's per admission and then the Colorado/Utah rates for deaths and errors.

⁸ This is an important point, and a weakness of all evidence-based projections. The two underlying studies were based on 1984 and 1992 data, respectively. To use these studies to shape current policy, one must assume that all the quality and process re-engineering efforts of the last 10-plus years have had no positive effect or that lower nurse staffing ratios have had no negative effect. Rather than assuming that the 1992 study reinforces the 1984 study, one might conclude that there were fewer adverse events, fewer errors (without a lower rate) and fewer deaths caused by AE. We simply do not know how representative the data is of today's adverse event and error rates.

⁹ A sigma calculator and further discussion of six-sigma can be found at www.isixsigma.com.

least as frequently as death. Using the number of adverse events caused by errors, i.e., 652,000, then there are 18,000 defects per million or 3.6 sigma. The actual rate of errors is much higher, but many of these do not result in patient injury. Finally, we should consider the number and complexity of events and processes that go into a single hospitalization. The frequency of errors and preventable adverse events, when compared with number of medications dispensed, lab tests run, chart entries made and so forth, is spread over a much larger number of activities. In the final analysis, this does not matter in terms of patient safety. It does not make any difference how many things went right if one thing goes wrong and kills the patient. However, it is important as a perspective on “fixing” the system. Like any other new investment, some things have a bigger payback than others – a necessary economic and investment calculation.

Estimated Number of Deaths From Medical Errors

While the IOM estimate of total deaths from medical errors raised alarm, of itself no course of action is apparent. Thus we have attempted to use the IOM report, a detailed analysis from Leapfrog¹⁰ and other sources to estimate the primary sources of these avoidable deaths. These were shown in the earlier graphic. The estimates for regional NICU and the other evidence-based referrals are directly from the Leapfrog analysis and discussed below. So too is the estimated number of deaths that could be avoided by intensivist management of ICU patients. These three sources account for 58,000 avoidable deaths. We also know that the IOM estimated that approximately 7,400 deaths are caused by medication errors. Medication errors appear to account for somewhere around 11 percent of the total avoidable deaths. Here we need to make some further estimates and assumptions to align deaths to those that could be prevented by CPOE and medication administration and those by ambulatory CPOE. This does not account for other sources of errors such as pharmacy errors. ADE caused deaths are further detailed in the following sections.

Adverse Drug Events and Medication Errors

An Adverse Drug Event (ADE) is a special case of an AE. Like AEs in general, some are caused by error, specifically a medication error. An ADE is generally classified as an error of prescribing, of communication, of dispensing or of administration.

The distribution of medication errors

A 1995 study by Leape et al.¹¹ found that errors related to physician ordering and transcription/communications represented 39 percent and 12 percent, respectively, of medication errors. Another 38 percent of the errors occur during drug administration. The remaining 11 percent are a result of pharmacy and dispensing errors. A perfect system would automate the entire process from order to administration. In allocating scarce resources, focusing on CPOE appears justified. However, this ignores the fact that some percentage of physician errors are caught downstream by the pharmacist or nurse. Conversely, an error made during medication administration has no backstop.

The IOM Report estimated that medication errors occur at a rate of 7.6 to 10.7 per 1,000 patient days (3.9 sigma). This translates into a 3 to 5 percent incidence rate per admission. The Leapfrog

¹⁰ Birkmeyer, J., et. al. “Leapfrog Patient Safety Standards” at www.leapfroggroup.org/PressEvent/birkmeyer.pdf

¹¹ Leape, L., et. al. “Systems Analysis of Adverse Drug Events”, JAMA 1995: 274+

Group, analyzing the impact of ADEs in making the case for CPOE, calculated that there are 949,000 serious medication errors per year in non-rural hospitals.¹²

Here things become a little less clear. Recall that the IOM estimated that 7,400 deaths occurred in 1993 from medication errors, a figure that includes both inpatient and outpatient. Leapfrog estimated that 20 percent of the serious inpatient medication errors were life threatening, i.e., 190,000. Obviously, few of these cause death or serious injury unless the IOM number 7,400 is incorrect. Consistent clinical reports peg the incidence of fatal ADEs as very low – less than one percent of total ADEs. Thus we will estimate that hospital deaths caused by ADEs are 5,500 or 0.6 percent of serious medication errors. The remaining ADE caused deaths are attributed to outpatients. With this in mind, let's address CPOE.

CPOE

Based on studies primarily at a Harvard teaching hospital, Leapfrog assumes that CPOE with error checking will reduce medication errors by 55 percent.¹³

If, as discussed above, this reduces life-threatening ADEs by 100,000, we still have no estimate of how many deaths and serious injuries are avoided. In its analysis, Leapfrog refrains from hard estimates but suggests the number could be 500 to 5,000 avoidable deaths per year. Alternatively, in this year's Leapfrog presentation at HIMSS 2003¹⁴, one could extrapolate their analysis of avoidable deaths that could be prevented by CPOE to be 10 percent of the total number of avoidable deaths, i.e., 4,000 to 10,000 annually. We estimate that CPOE can prevent approximately 3,100 deaths or about 56 percent of hospital deaths from medication errors.

In addition to causing avoidable deaths and serious injury, ADEs add hospital costs of \$2 billion (IOM cited studies) annually. These are based on extended lengths of stay, additional tests and procedures and so forth. Of course, depending on the reimbursement mix, many of these costs are reimbursed. In other words, providing care required by medical errors may be a source of revenue to providers. No one should use offsetting revenue as a justification for continuing error-prone processes. Moreover, the IOM also calculates a much greater societal cost of ADEs in terms of lives lost, wages lost, disability and so forth.

Let's look at the investment and operating costs involved in a CPOE system. We estimate the acquisition and operating costs of CPOE deployed in all non-rural hospitals to be \$8 billion year. This figure is based on the assumption that a typical hospital will have to invest \$5 million on the CPOE system, amortized over 5 years, and some amount of CIS infrastructure as well as annual operating costs of \$2 million.¹⁵

As much as we inherently believe in the benefits of CPOE, there is an economic problem. Hospitals will incur aggregate costs of \$8 billion a year for an uncertain financial return based on how much of the \$2 billion savings can be realized, given their payer mix. If increased operating costs and capital spending were not questions, then this spending decision would be easy. However, this spending must be weighed against other priorities including stemming operating losses, adding more nursing staff, disaster preparedness, new diagnostic and therapeutic systems, other IT investments and new or remodeled facilities. We should expect the executive management and boards of healthcare enterprises will carefully examine the improvement in patient care and financial consequences of their enterprise's investment in CPOE.

¹² Leapfrog decided that it was unlikely that rural hospitals could support a CPOE system. They calculated that 80 percent of admissions are in non-rural hospitals.

¹³ Recall the earlier point concerning the distribution of errors and the confounding impact of medication errors downstream from the CPOE system.

¹⁴ de Brantes, F.. Ibid.

¹⁵ Recently the AHA reported that it cost a 500-bed hospital \$7.9 million plus \$1.35 million a year to operate. WSJ

Leapfrog Analysis

Before completing the analysis of patient safety, we should review the complete Leapfrog initiative and two related concepts. Sponsored by the Business Roundtable, The Leapfrog Group is a coalition of large employers, e.g., Fortune 50, and other affiliated large buyers of healthcare, including CMS and Blue Cross/Blue Shield. Its purpose is to provide better healthcare value to its members by “buying” quality care. It has adopted three proxy measures of quality that it promotes to hospitals through selective contracting and by channeling consumers through education. It has fundamentally applied the six-sigma thinking to buying healthcare. The clearly observable defect for customers is an adverse event. Leapfrog is probably the most powerful animation of To Err is Human and has provoked real change in voluntary quality initiatives.

Besides CPOE, Leapfrog Group has advanced two other proxy quality indicators: evidence-based hospital referrals (EHR) and ICU Physician Staffing (IPS).

Evidence Based Hospital Referrals

Leapfrog selected six high-risk conditions where there is evidence that annual volume is directly linked to successful outcomes. Several, such as coronary artery bypass graft surgery and angioplasty, are relatively high-volume procedures performed at many larger hospitals. A few, such as esophageal cancer surgery, are relatively rare. In all cases Leapfrog wanted to direct patients to facilities that perform relatively higher volumes. Such referral would not raise direct costs to hospitals although some hospitals would lose business with resulting negative impact. In all, these six EBR procedures contribute 15 percent of deaths avoided, with NICU and CABG accounting for three quarters of these.

ICU Physician Staffing

Leapfrog estimates that of the 4 million patients admitted to intensive care units, there are 53,000 deaths that could be avoided if ICUs were adequately staffed by critical care medicine specialists, called intensivists. This represents fully 75 percent of the total avoidable deaths targeted by Leapfrog.¹⁶ The Leapfrog analysis is based on many studies that show that full-time intensivists/closed ICU have lower risk-adjusted mortality (approximately 15 percent lower), than open ICUs without full time intensivists or intensivists as consultants. The problem with the recommendation is the inadequate number of intensivists and the lack of economies of scale in ICUs.¹⁷

Bar Coding and Ambulatory CPOE

There are two additional vested interests vying with CPOE for space in the patient safety marketplace: bar coded based medications administration and ambulatory computerized physician order entry.

¹⁶ Again there is the problem of reconciling various estimates of avoidable deaths caused by medical errors. Other studies of ICU mortality suggest that the number of deaths resulting from medical errors could be as high as 175,000 – well above the Leapfrog number or the IOM estimate of total avoidable deaths.

¹⁷ If 10 percent of total hospital beds are in intensive care units, and the median size hospital is 150 beds, then one would be devoting at least one or two and as many as four or five intensivists for full-time coverage of 10 to 12 ICU patients. It is estimated that there would need to be five to six times the current number of critical care specialists to actually staff all ICUs. This makes part of the case for the ICU telemedicine approach.

Bar Code-Based Medications Administration

As we discussed above, almost 40 percent of medication errors occur during administration. However, the number of medication administration errors that lead to an adverse drug event is a smaller subset. Many errors are those of timing and some of omission, which may not have serious impact on the patient. However, the wrong drug, wrong dose and wrong route often contribute to causing more serious ADEs. In particular, intravenous medications are thought to be a major source of ADEs. Note that many of the potent IV meds, such as vasopressors, are administered in the ICU, confounding the analysis of ICU staffing vs. medication errors. Based on our estimate of the number of in-hospital deaths due to medication errors and their distribution, we can estimate that medication administration errors cause approximately 2,400 deaths per year. We assume that there are a much higher number of other serious outcomes.

While automated dispensing carts have addressed some of the sources of errors, point of care systems, usually involving bar code readers, are seen as the most effective means of reducing medication administration errors. This requires an online link to the dispensing/pharmacy system that can verify that the right patient is getting the right drug at the correct time. To enable this closed loop, hospitals need unit-dose medications with individual bar codes. This has been a major stumbling block because CliniCom (now part of McKesson) introduced bedside medication bar coding in 1986.¹⁸ Then, as now, to deploy such a system, a hospital was forced to package and bar code many of its own unit doses. To address this issue, the National Alliance for Health Information Technology (NAHIT), the industry consortium convened by the AHA, made bar coded unit dose packaging its No. 1 issue. In general, the pharmaceutical industry has been reluctant to voluntarily create bar coded unit dose packaging due to higher costs, lack of standards and/or impending regulations and uncertain demand. The FDA had announced its intention to publish bar coding rules by the end of last year. It still has not done so.

IV medications require a more sophisticated system. While monitoring and IV device vendors have offered controller and pump networking for more than 10 years, there has been no compelling medication administration application. These networked devices could report alarm conditions as well as flow rates, but there was no automated link to the actual drug being given. New systems that automate IV medication delivery appear to be addressing these issues.

Ambulatory CPOE

In past HIMSS conferences, you may recall the enthusiasm for PDA-based prescription-writing products, one manifestation of dot-com mania. It became apparent that such devices, in the absence of a robust infrastructure linking the script application to clinical data as well as pharmacies, were relatively useless. At HIMSS 2003, the Center for Information Technology Leadership (CITL), chartered by Partners Health and partnering with HIMSS, previewed its more comprehensive study of ACPOE.¹⁹

CITL estimates that there are 8 million ADEs per year among outpatients. As a point of comparison, there are 1.3 billion drugs prescribed annually. It is estimated that 62 percent of ambulatory medication errors occur at ordering and transcribing. Thus, the error rate is 6,000 defects per million observations (4 sigma). This overstates the process quality, because some patients take more than one drug and thus are more likely to have an ADE. CITL also estimates that about 6.5 percent of the ADEs are life threatening, i.e., 520,000.

¹⁸ The February 10 issue of Inside Healthcare Computing (www.insidehealth.com) reported that McKesson has asserted a CliniCom patent on the use of bar code readers at the point of care for medications administration. If valid, this would greatly alter the industry rush to this technology.

¹⁹ Middleton, B. from CITL (www.citl.org)

CITL goes on to estimate that ACPOE can avoid 2 million of these ADEs (a 25 percent reduction). This would represent a similar percentage reduction of life-threatening ADEs by 130,000. Note that we do not have an estimate of the number of life-threatening ADEs that result in death or permanent disability. A just-published study of preventable ADEs in the ambulatory Medicare population found a 0.7 percent death rate and a 0.3 percent rate of permanent disability among detected ADEs.²⁰ Again if we use the IOM estimate of 7,400 ADE-caused avoidable deaths per year and subtract the 5,500 we calculated for inpatient deaths, we can estimate that there are around 1,900 medication error-related deaths in the ambulatory setting. It is not clear if this represents all preventable ADE-related deaths or the 60 percent one might ascribe to ordering and communication errors.

To improve patient safety by this amount, CITL estimates that a national investment of \$14 billion to \$30 billion would be necessary. They posit three levels of ACPOE from the most basic system, which produces legible scripts with rudimentary, non-patient specific references to a fully integrated CIS system. The former, close to the simple script-writing applications that failed, is estimated to cost \$11,500 per physician over five years, independent of practice size. The latter systems would cost from \$45,000 to \$122,000 per physician over 5 years, based on practice size.²¹

CITL further projects that widespread implementation of ACPOE could result in savings of \$44 billion a year. Of this, perhaps 20 to 25 percent would be directly realized in direct healthcare costs. However, we again must note that the healthcare savings are a result of avoiding 1.3 million outpatient visits and 190,000 hospital admissions. Using average cost per visit and per admission, we can calculate a savings to *payers and patients* of approximately \$2 billion.

Without seeing the full analysis, it would appear that the economic benefits might be off by a factor of 10. Moreover, we are back to the fundamental problem of who pays and who gains. While we would not suggest that either physicians or hospitals would not want to address the problem of medication errors and adverse drug events, we can clearly see the perverse incentives, particularly with ACPOE. The physician practice invests but sees no direct economic return. Lower malpractice rates might be a theoretic benefit, but are much too abstract and caught up in much larger issues to influence investment. In fact, lower errors might reduce the number of future visits. Hospitals have no direct incentive to help fund this physician practice investment because its most immediate effect would be to reduce outpatient visits and admissions. Again, we do not suggest that physicians or hospitals should accept any rate of preventable injury and death to patients. However, neither physicians nor hospitals have access to unlimited capital and funds and thus must allocate resources where they can provide the highest return in terms of improved safety, clinical outcomes and financial benefit.

²⁰ Gurwitz, J. et. al. Incidence and preventability of adverse drug events among older patients in the ambulatory setting. JAMA 289:9 (March 5, 2003).

? ²¹ It is not clear from the data presented how the per-physician costs translate into the total estimated costs. It appears that it is based on proportion of practicing physicians in practices of different sizes. The final study from CITL will be available in April.
www.citl.org