Health Informatics

Practical Guide

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Safety, Quality and Value

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LEARNING OBJECTIVES

After reading this chapter the reader should be able to:

- Define safety, quality, near miss, and unsafe action
- List the safety and quality factors that justified the clinical implementation of EHR systems
- Discuss three reasons why the EHR is central to safety, quality, and value
- List three issues that clinicians have with the current EHR systems and discuss how these problems affect safety and quality
- Describe a specific electronic patient safety measurement system and a specific electronic safety reporting system
- Describe two integrated CDSSs and discuss how they improve safety and quality

INTRODUCTION

From a safety and quality perspective, health informatics is the electronic acquisition, storage, and use of medical information to improve medical care. Health informatics has profoundly changed the practice of medicine and significantly improved the safety and quality of clinical care.

Health informatics, formerly medical informatics, has a long and honorable history. In the 1960s hospitals started using mainframe computers for their accounting and billing, and for storing laboratory test results which were printed and put in the patient's paper chart. As early as 1972 the National Library of Medicine, a part of the National Institutes of Health, began funding informatics training programs whose main purpose was to train individuals to apply computer and information science to medicine.[1]

The federal government enacted legislation and established entities designed to develop health informatics in order to improve safety and quality. The Agency for Health Care Policy and Research was established under the Omnibus Budget Reconciliation Act of 1989 (103 Stat. 2159). It was reauthorized with its name changed to the Agency for Healthcare Research and Quality (AHRQ) under the Healthcare Research and Quality Act of 1999. Its mission is to "*produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable.*"[2] During this time health informatics, as a discipline, began to appreciate the centrality of the patient's medical record and to understand that if medicine was to improve its safety and quality it would have to computerize the medical record.

The Evolution of the EHR

At the turn of the 20th century, medical records were handwritten on index cards and stored in envelopes.[3] As the century progressed medicine became more complex and medical records became more complex. In addition, the demand for accurate medical information increased, which required that physicians write more detailed and complete notes.[4-6] These factors increased the size and scope of the medical record, thus it became a large, paper-based loose-leaf collection of clinical notes, laboratory values, radiology reports, and consultations.

As early as the mid-1960s, there were calls for computerizing outpatient clinic records.[7] Yet it was not until 1991, with the publication of the Institute of Medicine's *CPR Report – Computer-based Patient Record,* that there was an in-depth analysis of some of the potential benefits of EHRs, a discussion of issues related to implementation barriers including privacy and cost, and a national call for the adoption of a computer-based patient

record.[8] In 1996, President Clinton signed the Health Insurance Portability and Accountability Act (HIPAA) into law (Public Law 104 - 191). It was designed to make health insurance more affordable and accessible and it included important provisions to address the transmission and privacy issues related to electronic personal health information. It focused national attention on health information technology and the use of EHRs.

The increased national awareness of, and interest in, safety and quality, led the Institute of Medicine (now known as the National Academy of Medicine) to publish a series of landmark reports that shaped the national dialogue on healthcare safety, quality, and emphasized the importance of the electronic medical record:

- Published in 2000, To Err Is Human, Building a Safer Health System, focused on the safety and quality of care. It claimed that almost 100,000 hospital deaths were caused by medical errors. It asserted that that the problem was that good clinicians were working in a dysfunctional system and it set forth "a national agenda…for reducing medical errors and improving patient safety through the design of a safer health system."9
- Published in 2003, Key Capabilities of an EHR System discussed the basic functions of an EHR, database management, and data standards.10-11 It called for clinicians to abandon paper-based charts and move to electronic health systems and computer-aided decision support systems.
- Published in 2004, Patient Safety: Achieving a New Standard for Care, asserted that in order to prevent errors and to learn from the errors that do occur, a new health care delivery system was needed. It advocated for a radical restructuring of the medical system that had evolved over the last 100 years. The new system would be based on a culture of safety and the implementation of electronic information systems. In addition, it proposed the development of health care data standards for the exchange, reporting, and analysis of safety data.12

Yet, in the 13 years after the 1991 publication of *CPR Report – Computer-based Patient Record*, EHRs had not been widely adopted in clinical medicine.[13] There were few computers in outpatient examination rooms and hospital rooms, so there was little ability to use EHRs in the day-to-day practice of medicine.[14]

The widespread implementation and clinical use of electronic medical records in the United States began with President George Bush's 2004 State of the Union Address in which he said, "*By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care*."[15] This speech was followed by Executive Orders, by several major legislative initiatives, and by implementation rules and regulations:

- In 2004, the Office of National Coordinator for Health Information Technology was established by Executive Order. It was a national office whose mission was to promote and oversee the development of health information technology.
- In 2009, the American Recovery and Reinvestment Act was passed (H.R. 1, Pub. L. 111-5). It included the Health Information Technology for Economic and Clinical Health (HITECH) Act which authorized the use of financial incentives to promote the meaningful use of EHRs to improve safety and quality. It also mandated that the National Coordinator for Health Information Technology oversee the implementation of EHRs.16
- In 2010, the Patient Protection and Affordable Care Act (known colloquially as Obamacare) (H.R. 35-90, Pub. L. 111-148) included mandated financial incentives for hospitals and clinicians for improvements in the quality of care of Medicare patients.
- In 2015, the Medicare Access and CHIP Reauthorization Act (MACRA), (H.R. 2, Pub. L. 114–10), institutionalized the use of health informatics to assess quality, improve clinical care, and lower costs. It allowed the Centers for Medicare and Medicaid Services to financially incentivize clinicians and medical organizations to adopt electronic medical record systems and to demonstrate their "meaningful use."
- In 2017, the Merit-Based Incentive Program System (MIPS) was introduced along with the Alternative Payment Models (APMs), which replaced several prior initiatives including meaningful use, in order to better monitor and improve safety, quality, and value.

These federal initiatives have driven the transition from paper-based, to electronic, health records but several issues related to the EHR remain unresolved including: record portability, the transmission of records between EHR systems, and clinician acceptance. The EHR will be the basis for many of the advances in safety, quality, and value.

In parallel with the federal clinical improvement initiatives, the National Library of Medicine redoubled its support of health informatics education and training. It expanded its mission from creating computer-related medical applications to supporting sixteen graduate level biomedical informatics training programs in the areas of translational bioinformatics, clinical research informatics, healthcare informatics, and public health informatics.[17]

Many private and quasi-private organizations have been created to improve safety and quality. For example, the **National Quality Forum's** mission "*is to lead national collaboration to improve health and healthcare quality through measurement. We strive to achieve this mission by: Convening key public- and private-sector leaders to establish national priorities and goals to achieve healthcare that is safe, effective, patient-centered, timely, efficient, and equitable; Working to ensure that NQF-endorsed standards will be the primary standards used to measure and report on the quality and efficiency of healthcare in the United States; and By Serving as a major driving force for and facilitator of continuous quality improvement of American healthcare quality.*"[18] In addition, every major medical center has a robust safety and quality program.

Health Informatics Has Made Great Progress Over The Last Decade

The rise of health informatics in two domains has significantly improved safety and quality:

1. Clinical activities – (a) widespread installation of computers in outpatient examination rooms and hospital rooms, (b) adoption of EHR systems and their use during the clinical encounter, and (c) implementation and use of CDSSs; and
2. Monitoring and improvement activities – (a) auditing of EHRs in order to assess clinician performance and monitor patient safety, and (b) implementation of improvement initiatives.

The rest of this chapter explores these domains from the perspective of safety and quality.

The Enormity And Complexity Of Medicine In The United States

Improving safety and quality is a very difficult because of the pervasiveness of disease, the complexity of medicine, and the importance of health in everyone's life. Disease pervasiveness is reflected by the fact that 83.6% of adults had contact with a health care professional in 2015, there were 884.7 million physician office visits in 2015, 125.7 million hospital outpatient visits in 2011, 141.4 million emergency department visits in 2014, and 35 million hospital admissions in 2015.[19-23] Many of these patient encounters were complex and each provided multiple opportunities for clinicians, healthcare systems, and even patients, to make mistakes. These mistakes can have many causes, including: the rarity and/or complexity of the medical conditions and procedures, clinician time pressures and distractions, miscommunication and misunderstanding, patient personality characteristics, and defects in the healthcare system's delivery of medical care. The sheer number of encounters, and the fact that clinicians and patients are human, means that there will always be medical safety and quality issues. The job of health informatics is to minimize these issues by: (1) providing real-world simulations and other forms of training to improve clinician safety and quality performance, (2) the real-time monitoring and detection and clinician notification of activities that place patients at risk of a safety or quality event and the detection and clinician notification of the occurrence of safety and quality events, and (3) modifying the healthcare system in order to prevent the recurrence of unsafe actions or inactions. Health informatics plays an important role in safety, quality, and value.

QUALITY, SAFETY, AND VALUE

Quality And Safety

Safety and quality are related in the sense that a lapse in safety almost always lowers quality, but safe medicine is not always high-quality medicine.

From the physician's perspective, quality, safety, and value are: do good work, don't mess up, and don't charge a lot.

From the patient's perspective, quality, safety, and value are: (1) medical care that they understand, that takes into account their preferences and expectations, and that they agreed to; (2) that is appropriate for the medical condition and performed properly; and (3) that they can afford.[24]

From the Institute of Medicine's perspective, quality is a set of six aspirational goals: medical care should be safe, effective, timely, efficient, patient-centered, and equitable. [25] In this set of goals, safe and effective focuses on the physician; timely, efficient and patient-centered focuses on the healthcare system; and equitable focuses on societal virtues.

From the Center for Medicare and Medicaid Services' perspective, quality is a set of six aspirational goals: "(1) *make care safer by reducing harm caused in the delivery of care; (2) strengthen person and family engagement as partners in their care; (3) promote effective communication and coordination of care; (4) promote effective prevention and treatment of chronic disease; (5) work with communities to promote best practices of healthy living; and (6) care affordable."* As Medicaid states, this is *"better health, better care, lower cost through improvement."* [26-27]

From the Agency for Healthcare Research and Quality's perspective, quality is "*the degree to which health care services for individuals and populations*

increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[28]

From the clinical outcome perspective, quality, safety, and value are the ability of medical professionals to provide safe, affordable and appropriate care that achieves the expected clinical outcomes. Outcomes are usually risk adjusted and disease specific, and they take into account the dangers lurking in the side-effects of treatment.

Value

Value is the how important something is to us. It can be expressed in monetary terms; how much a person or organization will pay, or accept, for something they want to receive or give. In this sense, value is usually comparative because resources are almost always finite. At other times, it is expressed in qualitative terms, for example, how much a person "values" health, how much a patient "values" recovering from an illness, or how much an organization "values" providing high quality care.

There are at least four perspectives on medical value: (1) the physician and/or healthcare system that delivers the care (provider of care), (2) the patient and sometimes the patient's family (recipient of care), (3) the employer or government agency that either directly or indirectly pays for the care (payer for care), and (4) the norms of the society within which the care occurs. It should come as no surprise that these four perspectives are not identical. For example, in a University of Utah survey, conducted by Leavitt Partners in 2017, of 5,031 patients, 687 physicians, and 538 employers, they found that 88% of physicians equated value with the quality of care, 60% of employers ranked cost as the key component of value, and 45% of patients said that value was affordable out-of-pocket expenses.[29] Thus, there is a major conflict between the quantitative and qualitative views of value, depending on whether the respondent is the deliverer, recipient, or payer of medical care.

From the patient perspective, patients value health but the monetary value they place on healthcare varies with necessity. For example, patients usually attach little monetary value to prevention. In addition, they usually do not want to pay out of pocket, so requiring payments from patients can be a significant disincentive to their utilizing medical services. But when patients are sick, they are usually willing to pay more for their medical care and, when someone else is paying for that care, patients and their families tend to want everything done for them, no matter what the cost.

Another perspective is to frame value in terms of the net clinical benefit. For example, in terms of the net benefit of the treatment group in a clinical trial, where the next benefit is the sum of the clinical benefit and toxic effects, compared to the controls.[30] In cancer, the idea is that at least 20% of the control patients must still be alive and there must be at least a 50% improvement due to the treatment.[31-32] Of course, this is an oversimplification since it does not take into account the magnitude/duration of the improved outcome. Furthermore, it assumes a measurement outcome precision that does not exist, it may be unrealistically stringent, and it may not correspond to either the patient's or clinician's perception of a clinical benefit, especially since their expectations are rarely accurate.[33-35] Another type of net clinical benefit relates to low-value testing. For example, the view that there is little net clinical benefit in imaging patients who present with acute uncomplicated back pain.[36] Although reducing imaging utilization may appear to be a simple idea, it may have unintended consequences. For example, patients who are refused imaging may go to another clinician, they may experience a catastrophic outcome that could have been avoided by imaging, and they may no longer trust their clinician – which can lead to poor clinician-patient relationships and can affect other patient medical problems.

From a monetary perspective, there is little accurate information regarding the cost of care. Although 76% of physicians consider cost when making treatment decisions, it is not clear what "cost" they are considering.[29] Is it the direct expense involved in delivering medical care to a specific patient? If so, this cost is rarely known by anyone in healthcare because it is rare that there is accurate patient-level cost accounting. Is it the payments that employers and government agencies contractually make? Other than Medicare and Medicaid, these contract payments are considered a secret by the third-party payers, and physicians rarely know these payments. Other than the physician's own prices, it is unusual for a physician to know the list prices or payments for care. Patients almost never know the cost of care until they receive an explanation of benefits, reflecting the charges and payments for care. Finally, there is the list price of care, which is the price that a patient pays if he or she is not covered by a third-party contract or government agency. Historically, the patients who could not afford health insurance were the patients who have paid the most for medical care.

Another perspective is to employ a valuation method that combines the payments for specific services/therapies with predictions of patient future states. For example, one way to assess value is to use quality-adjusted life years (QALY), based EQ-5D utility estimates, either directly or through simulations, to determine value.[37] If the treatment does not produce sufficient quality-adjusted life years, then it is not of value. Although normative

systems are interesting they have several problems. First, the individual patient predictions are rarely accurate. Second, populations may provide different utility estimates.[37] Third, individual patients are quite variable in what they value and how much they value it, and their valuations can change over time.[38-39] Fourth, many patients with limited life expectancies do not even want to discuss their life expectancy.[40] Finally, patients rarely reject a treatment simply because it has a low quality-adjusted life year estimate.

There have been attempts to define value in terms of what a life is worth, i.e., how much society should pay to add one year to a person's life. But no one has been able to justify a specific number, for example, no one has been able to successfully argue that we should pay $50,000 to add one year but that we should not pay $51,000 to add one year to a person's life. When a patient is dying, these numbers appear meaningless to both the patient and the family.

Another monetary approach is to create equations, where value is equal to the [service/treatment] times [quality of the service/treatment] divided by [price of providing the service/treatment]. It is not clear that these are the only terms that should be in the equation. Furthermore, it turns out that the numerator and denominator are difficult to measure and that there is no method for weighting the importance of each of the terms in the equation. Finally, attempts have been made in the U.S. to rank order services and treatments from high value to low value, but none have been able to set and maintain a threshold below which they will not pay because; inevitably, more and more exceptions are made until the system ceases to effectively ration care.[41]

Interestingly, one can ask the question, what is the value of health informatics? For example, what is the economic benefit of a clinical decision support system (CDSS) that is used for cardiovascular disease prevention? Jacob et al. recently undertook a systematic review to answer this question. He found that, "*The symposium noted the difficulty in transitioning from judgments of economic value at the level of specific implementations to a judgment about the aggregate of the implementations: costs and benefits have to be summed over implementations with different organizational contexts, technologies, functions, outcomes, scales, and scope. This systematic economic review of one type of health information technology, namely CDSS, encountered similar difficulties among others in synthesizing the economic evidence from various implementation instances.*"[42] In other words, because of a paucity of information regarding the drivers of cost and benefit, and a lack of cost metrics, they were unable to determine if CDSSs were cost-beneficial or cost-effective for cardiovascular disease prevention. The problems Jacob et al. describe are not limited to CDSSs, they apply to most medical economic benefit calculations.

From a societal perspective, potential medical costs are almost infinite because there is no limit to the amount of money that can be spent trying to achieve perfect clinical outcomes for all patients and all conditions. Therefore, all societies ration care, sometimes the rationing is explicit but usually it is implicit and hidden from view.[43] For example, the United Kingdom National Health Service practices explicit rationing and, as British government's spending has declined, the rationing has increased.[44-45] Another form of rationing practiced by both the U.K. and Canada is to make people wait until they either give up, die, or go to the private healthcare system. In Canada, after a referral from a general practitioner, there is a two and one-half month wait to see a specialist and another two and one-half month wait to receive treatment.[46] Rationing priorities, what societies are willing spend their healthcare money for, is based on: (1) the medical conditions it is willing to treat, (2) the number of patients with those conditions, and (3) the cost, and sometimes efficacy of the treatment. Society achieves value by maximizing the impact of its resources on what it considers important; by treating the patients that society deems should receive medical care, by delivering that care at the lowest possible cost given the political situation, and by achieving the largest possible medical benefit for the most patients. In other words, societies choose who to include and who to exclude from care.

In the U.S., the Centers for Medicare and Medicaid Services (CMS) is using financial incentives and disincentives to regulate the practice of medicine. The Centers for Medicare and Medicaid Services has established a "value-based" payment system that aims to get value for its money by eliminating "*inappropriate and unnecessary"* care and by applying quality metrics to improve the quality of care.[47] The main thrust of this approach is to reduce costs; it assumes that improving safety and quality will reduce costs. But value-based payment systems, as they are currently implemented and without significant assistance from health informatics, may not result in significant reductions in the cost of care.[48-49] Furthermore, it is not clear that CMS's anticipated cost reductions will significantly offset the cost of improving safety and quality. For example, in a population of high-cost Medicare patients, it was found that only 4.8% of the spending was preventable.[50]

To be clear, safety and quality cost money, they require increased expenditures on clinician safety and quality training, they require that clinicians spend time on quality improvement activities rather than seeing

patients, and they require investments in healthcare personnel and information systems. On the other hand, in the future, health informatics and technology may be able to improve the efficiency of healthcare while, at the same time, enhance safety and quality, by monitoring and assessing care and reporting that information to clinicians in order to prevent unsafe actions from occurring and by directing clinicians to perform those actions (cognitive and procedural) that improve safety and quality – which should also improve value.

USING THE EHR TO IMPROVE QUALITY, SAFETY AND VALUE

An EHR system consists of a graphical user interface for entering and viewing information, a sophisticated relational database that can acquire, store and retrieve information, and powerful, extensible auditing and reporting systems. Prior to President Bush's speech there had been a great deal of interest in EHRs and there were many small, primitive by today's standards, EHR systems – none of which were in widespread use. The main barrier to their acceptance was that few physicians used computers in their clinical practice, even fewer had computers in their exam rooms, and almost none used them routinely during their interactions with patients. The reason for this situation was that the paper chart had been optimized by clinicians over the previous hundred years and it was an extremely efficient clinical data acquisition, storage, and retrieval system.[51]

But paper records had at least five disadvantages. First, it could be difficult to read the handwriting in some notes, there could be errors and there could be non-standard abbreviations. Second, occasionally the patient's current chart would be checked out of medical records and it could take several hours to retrieve it. Third, charts were local and could not be accessed remotely. Fourth, paper records took up a great deal of clerical personnel time and a large amount of space. Fifth, and the most important disadvantage, was that it was very expensive to manually review charts.[51] For example, the cost of a manual review varied from $74 to $350 per chart, depending on the amount of information extracted.[52] This meant that, except for peer review, charts were not routinely audited to determine physician and nurse performance, and hospitals were not being evaluated and compared in terms of their performance. The EHR is easily readable, it is always available (except when it isn't), it takes up very little space (except in the exam room where it takes up a great deal of space), and it can be used to aggregate and analyze clinician and healthcare system performance.

Within a year of President Bush's speech, CMS began rolling out programs to financially encourage clinicians and hospitals to purchase computers and EHR programs and, later, to meaningfully use them. These programs were usually based on financial incentives and penalties. The American Recovery and Reinvestment Act of 2009 significantly increased physician adoption of EHRs and the Centers for Disease Control and Prevention reported that, by 2015, 87% of office-based physicians were using an EHR.[53-55] In addition, CMS began introducing quality metrics that clinicians and hospitals had to meet in order to continue to receive financial incentives and not incur financial penalties.

The relationship between EHRs and clinical quality has been investigated, usually in cross-sectional studies of process measures.[56-63] The results have been equivocal. No study has demonstrated a benefit across all its quality measures. Some have shown a partial benefit,[59-61, 64] while others have not demonstrated a significant clinical impact on quality.[56-58, 61-62, 65] Furthermore, one of the few retrospective longitudinal studies that used the quality measure hemoglobin A1c and compared before and after the introduction of an EHR did not find significant quality improvement attributable to the use of an EHR.[66] At the time President Bush spoke there were not, and to this day there have not been, any large scale randomized prospective studies that demonstrate significant improvements in safety and quality directly attributable to just the use of EHRs. Furthermore, it is unlikely that one will be conducted since it would require half of the physicians in the study to return to handwritten notes.

Although EHRs may not have a direct effect on safety and quality, they do allow administrative personnel to, for the first time, monitor clinician and healthcare system performance. Prior to EHRs individual physician charts were audited (usually as part of the peer review process) but there was no aggregation of a physicians' medical records, or healthcare system records, and, therefore, no assessment of their performance. Furthermore, the EHR allows for indirect safety and quality improvements related to: 1) determining the nature, frequency, and severity the safety and quality issues, 2) assessing quality and safety issues and implement solutions, and 3) determining if the implemented solutions had, in fact, improved medical care. Furthermore, adding CDSSs to EHRs has the potential to directly improve safety and quality.

Clinician Problems with EHRs

The conversion from paper charts to an EHR system has created several problems. One issue is that moving

from paper to the EHR or moving from one EHR to another, usually results in the loss of most of a patient's past medical information. Commonly, only medications, allergies, and problem lists are transferred to the new system. Access to the old system usually continues for a brief period of time, but the cumbersome use of two parallel systems usually ends rather quickly. In addition, the use of a new EHR requires a great deal of clinician training, but most transitions provide relatively little clinician training, and the training they do receive usually consists of a short didactic related to the major features of the system and workflow "cheat sheets", followed by clinician trial and error during patient encounters. The loss of patient medical histories and the inept use of EHR systems have created significant safety and quality issues.

Clinicians are currently experiencing problems related to their use of the EHR. One problem is clinician time and efficiency. In the past, clinicians quickly reviewed the patient's history, including the clinical information that had accrued since the last clinical note; they interacted with the patient; and they wrote a new narrative note that contained a summary of the patient's progress, an assessment of the clinical encounter, and a description and explanation of the clinical plan for the patient. Currently, clinicians sign into the computer, access the EHR, open the patient's record, and search the relevant patient information using pull-down menus, click boxes, and opening windows. Either during or after the patient encounter, clinicians add information to the patient's record using the same pull-down menus, click boxes, and opening windows. Furthermore, clinicians usually manually type the patient information into the EHR. Finally, physicians may not be allowed to write free text notes, they may be required to use template-based notes.[67] All of these activities require time, present a fragmented view of the patient, are opportunities for mistakes, and reduce clinician productivity.

Currently, physicians spend at least 5.9 hours out of an 11.4-hour work day using their EHR.[68-69] Typing into a computer and accessing information during the clinical encounter reduces the amount of time spent interacting with patients and distracts both the patient and clinician during the clinical encounter.[70] Over one-third of patients believe that the physician's use of a computer in the clinical encounter negatively affects physician-patient communication.[71] This means that clinicians may be less productive, they may see fewer patients, they may generate fewer relative value units (RVUs) and, due to computer-based distractions, they may find it difficult to communicate with their patients.

It is true that the EHR does improve the narrative note quality; physician notes are more complete.[72-73] But, in order to save time, clinicians have resorted to a shortcut that the EHR makes available to them. An unintended consequence of the EHR is that it allows clinicians to cut-and-paste from previous notes into the current note. This adds old, out-of-date information to the encounter note, it reduces the amount of current information in the note, and it makes it difficult to rapidly obtain an accurate understanding of the patient's current status.[74] Cutting and pasting does save time, but at the expense of the clinical quality of the note.

It is well known in human factors research that technology can cause human mistakes and there has been a growing recognition since 2005 that EHRs can cause mistakes.[75-88] Issues with system functionality, for example, poor user interfaces and fragmented displays, have delayed the delivery of care – which is a safety issue. There have been an increasing number of safety professional liability claims related to EHRs, including the use of copy and paste, insufficient area for documentation, poor drop-down menus, and improper templates.[88-89] In a recent health information technology review, 53% of the studies found that health information technology problems were associated with patient harm and death, and near-miss events were reported in 29% of the studies.[90] It is ironic that one of the main reasons for adopting EHR was because they would improve safety by eliminating mistakes, only to find that they have been replaced by health information technology-related mistakes. Furthermore, whereas handwriting mistakes were relatively easy to detect and correct, health information technology-related mistakes have been much more difficult to detect and correct.[90] Some have advocated for proactive detection of health information technology-related problems while others have advocated for the redesign of health information technology systems to reduce human error.[91-93] Both solutions are necessary, but both are expensive to implement.

A recent RAND report stated that, "*the current state of EHR technology significantly worsened professional satisfaction in multiple ways. Poor EHR usability, time-consuming data entry, interference with face-to-face patient care, inefficient and less fulfilling work content, inability to exchange health information between EHR products, and degradation of clinical documentation were prominent sources of professional dissatisfaction.*"[67] Furthermore, physicians complain that, because of shortcomings in the design and implementation of health information technology systems, current EHRs do not deliver sufficient clinical value to compensate for their difficulty and expense.[94] It was suggested in a recent review that we should rethink the definition of meaningful use, reduce EHR difficulty, and improve

their clinical utility.[95] In other words, EHRs may be necessary but they not sufficient, for increasing the safety and quality of medical care.

Finally, EHR systems, and their related hardware and software are, in their current form, very expensive to buy, maintain, and upgrade. In addition, they are very expensive to use because they slow down clinicians in terms of finding the relevant information, they require checking of boxes, and they necessitate typing into a computer. One of the primary goals of health informatics is to improve the usability and efficiency of EHRs.

Societal Perspective

Both the good and the bad aspects of clinicians being required to use EHRs have been discussed, but there is also a societal perspective. "*With rapid consolidation of American medicine into large-scale corporations, corporate strategies are coming to the forefront in health care delivery, requiring a dramatic increase in the amount and detail of documentation, implemented through use of EHRs (EHRs). EHRs are structured to prioritize the interests of a myriad of political and corporate stakeholders, resulting in a complex, multi-layered, and cumbersome health records system, largely not directly relevant to clinical care. Drawing on observations conducted in outpatient specialty clinics, we consider how EHRs prioritize institutional needs manifested as a long list of requisites that must be documented with each consultation. We argue that the EHR enforces the centrality of market principles in clinical medicine, redefining the clinician's role to be less of a medical expert and more of an administrative bureaucrat, and transforming the patient into a digital entity with standardized conditions, treatments, and goals, without a personal narrative.*"[96] Health informatics can be viewed as dehumanizing patients and the clinicians; it can be viewed as part of a larger effort to advance the interests of corporations and governments, at the expense of patients and clinicians. One way to humanize health informatics is to demonstrate its positive benefits to patients and clinicians, for example, by showing: (1) its ability to improve the delivery of medical services, (2) its ability to assist in the selection of the best therapy for an individual patient, and (3) its ability to improve patient outcomes.

THE INABILITY TO INTERPRET FREE TEXT HAS LIMITED QUALITY, SAFETY AND VALUE

In addition to the many problems clinicians encounter when using EHRs, administrators and researchers have their own problems with EHRs. They want to automatically extract meaningful information so that they can assess the safety, quality and value of medical care. "Meaningful" in this context is medical information that tells us what we want to know about the patient. For example, we may want to know if a patient was injured, the cause of the injury, where the injury is located, if the patient is in pain, what treatment was provided, and whether the treatment was effective. Furthermore, we may want to aggregate all the patients with this particular injury in order to perform an observational study of the effectiveness of a treatment. In other words, administrators and researchers want to automatically extract information from EHRs so they no longer have to perform manual chart reviews in order to determine how patients are being treated and their outcomes.

The problem is that the clinical information they are interested in is being typed into the EHR as free text and there is currently no automated way to read these notes with sufficient accuracy so that the extracted data are highly reliable. Because the clinician's narrative text cannot be automatically read with high accuracy, administrators have resorted to requiring that clinicians check boxes and fill in structured fields in the EHR – because this information can be automatically extracted and analyzed. In addition, administrators have used "administrative" data, usually data from the EHR that is used for billing, to assess performance. Unfortunately, administrative data does not contain important clinical information, it contains biases related to payer reimbursement, and there are significant challenges related to its use in assessing safety and quality.[97]

Binary Data: Check Boxes

There are three kinds of information in most EHRs; check boxes, structured and semi-structured text, and free text. Check boxes are labeled binary fields that the clinician checks. They can be one item or a list of items, any one or more of which may be relevant to the clinical problem. The boxes may be related to prevention, signs and symptoms, diagnosis, prognosis and treatment, outcomes. Check boxes are useful to administrative personnel because: (1) once the boxes are checked, the data can be easily and inexpensively acquired, (2) the data is already organized in terms of category/subcategory, e.g., prevention or the diagnosis and treatment of disease, and (3) the data can be aggregated.

Check boxes require a great deal of checking. For example, for each symptom, the clinician has to check some or all of the boxes related to onset, duration, frequency, location, setting, alleviating/aggravating factors, quality, intensity, severity, temporal trends, and

unique manifestations and, in terms of pain, paroxysmal pain (shooting, sharp, electric, hot, and radiating), superficial pain (itchy, cold, numb, sensitive, and tingling), and deep pain (aching, heavy, dull, cramping, and throbbing), and so forth. Furthermore, clinicians have to check the relevant boxes that show the reasons for: (1) working up the patient, (2) determining the diagnosis, and (3) selecting a specific treatment. They must also describe the outcome of the treatment. In addition, they must somehow communicate (1) their reasoning, (2) who the patient is and what his or her values are, and (3) why the patient and clinician, using shared decision making, selected a particular treatment plan. Finally, because of the many boxes, there are many possible box-checking errors.

In other words, check boxes can be useful for discrete, simple information. Unfortunately, they are of little use for more complex information because there is currently no way to combine and organize large disparate collections of check boxes in order to create meaningful clinical information. The more complex and detailed the meanings of interest, the more hierarchal and detailed the boxes must be, the more boxes that must be checked, and the more difficult it is to put all the box information together into an integrated, coherent and clinically useful medical description of the patient.

Alphanumeric Data: Structured and Semi-structured Fields

When we advance from binary (existence/nonexistence) data to alphanumeric data, we move from check boxes to structured and semi-structured data. Fully structured fields are fields that take specific values, for example, laboratory values and prescription orders. Structured data can also be exact text, for example, drop down menus that contain all the possible diagnoses in urological pathology. In this situation, every item on the menu has a corpus of text with a specific meaning. When an item is selected the exact same text is always inserted into the EHR.

Semi-structured fields are usually domain-specific and have limited, pre-specified vocabularies, for example, radiology reports. Although the text may vary slightly, the predefined vocabulary establishes the meaning. Because the words and phrases are already known, a key word or key phrase search can be used to find the meanings in the text.

In both structured and semi-structured fields, the type of information is already known by the label of the field, and what we want to know is the token for the patient. For example, for laboratory data, the type is already known, e.g., the field is labeled HbA1c, and we want to know the token, namely, the patient's numeric value in the A1c field. In other words, we search a specific field and the information in the field is the meaning.

Alphanumeric Data: Unstructured Fields

The problem with using just check boxes and structured fields is the paucity of information they to provide. Check boxes and structured fields cannot fully represent the complexity and individuality of patients, their diseases, and their treatments. Unstructured fields allow clinicians to generate free text, so that they can properly describe the patient and the patient's condition, explore possible diagnoses and the reasons for selecting one diagnosis over another, and justify the treatment that was selected for an individual patient. The need to automatically find the meanings expressed in free text has long been recognized as one of the most important goals of health informatics. The automatic search for meaning in free text is the province of natural language processing.

Natural Language Processing

Natural language processing (NLP) is a computer program that takes as its input the clinician's electronic free text and it returns as its output the meaning of the text. In order to determine the meaning of text one needs to label (named entities) the medical concepts relating to patient signs and symptoms, tests and imaging, risk assessment, diagnosis, prognosis, treatment, and outcome and then determine the relationship between the named entities one is interested in. For example, if one wanted to know if the patient had had chest pain [named entity] associated with his myocardial infarction [named entity], one would determine if both terms were present (usually but not always in the same sentence) and if a relationship between the two was described in the free text.

The main problems with finding meaning in text is that: (1) there are many ways to say the same meaning, (2) the meaning can depend on the context, and (3) much of the medical free text is written in a telegraphic style that does not obey the rules of English. Furthermore, meaning can cross sentence boundaries, for example, there can be co-reference.[98]

There are many approaches to natural language processing; the three most commonly used are key word, rule-based, and machine learning. A recent review of natural language processing methods found that 24% used key word, 67% used rule-based, and 9% used statistical methods.[99] Since that review the number of statistical methods has increased dramatically. Common information extraction methods include: MedLEE, HITEx, and cTAKES.[100-102]

Key word, or key phrase, are searches for an exact word or phrase in the text. Since the meaning of the key word is known, if the word is found in the text, then the meaning of the text is also known. It can also search for the root form of the word, for variations of the word including abbreviations and plurals, and for synonyms. The major drawback of this approach is that it is too specific. One must perform a search for every way the word can be written. Furthermore, (1) it does not include modifiers such as "not," (2) it does not include predicates, and (3) it does not take context into account. In other words, just knowing that a word is present is not usually sufficient for determining the meaning of the text.

Rule-based systems are more flexible. They allow for searching text in terms of subject-predicate statements; if X is in the text, then search for Y, if both X and Y are found then you have found the meaning of the text. For example, if the term "pain" is in the text, then search for an anatomic location, such as leg. If you find both, then you infer that the patient has leg pain. Clearly, this is superior to a key word search, but many of the problems inherent in the key word search remain. For example, (1) you must specify all possible variations of the subject and predicate, (2) it does not take into account modifiers, and (3) its view of context is limited to the predicate.

Machine learning (based on statistical methods) defines the search for meaning in free text as a classification task. The ways that a meaning can be written are called patterns and patterns can be learned. For example, the relationship between a patient having an A1c and the value of the A1c can be written many different ways including, "*the patient's A1c is 6.7,"* and "*the patient's A1c is well controlled at 6.7*." Words sets are coded as patterns and trained on text that both contains these patterns (positive) and text that does not contain these patterns (negative). The better machine learning is at distinguishing positive patterns from negative patterns (and non-patterns) the more accurate it is. The idea is that during training machine learning will learn to create classes of patterns and to generalize these classes to patterns it has not seen before, where the generalized pattern is not an exact set of words, rather, it is the features in the text that indicate the existence or nonexistence of the searched for meaning. In other words, the trained model will be able to use a set of features to define the target meaning and it will use this set to detect the existence of the target meaning in the sentence. Many machine learning algorithms have been used, including support vector machines, Bayesian conditional probability models, and artificial neural networks (also called deep learning).

Currently, no key word, rule-based, or machine learning method has performed with a sufficiently high accuracy that it can be used to reliably find any meaning in any medical free text.

SAFETY AND QUALITY DETECTION AND REPORTING

In most situations, an EHR system will not, by itself, improve the safety and quality of medical care but the clinical use of an EHR is a necessary prerequisite for quality and safety improvement. Furthermore, EHR systems assist and are, many times, essential for: (1) detecting and reporting of adverse events, (2) safety and quality improvement initiatives, and (3) prevention programs.

Focus On Actions Rather Than Events

An adverse event is "*An unexpected and undesired incident directly associated with the care or services provided to the patient.*"[103] In other words, an adverse event is a safety event that reached the patient. "*A near miss is any event that could have had an adverse patient consequence but did not and was indistinguishable from a full-fledged adverse event in all but outcome*."[104] A near miss event and an adverse event can have the same cause and this can result in their being confounded. Essentially, a near miss event and an adverse event only differ in that one reached the patient and the other did not.[105]

Historically, safety has focused on events, such as near miss events and adverse events, rather than on the unsafe actions that cause these events – even though almost every near miss event and adverse event is caused by at least one unsafe action. If we are to prevent the occurrence of safety events, we must focus on the causes of the events, i.e., the unsafe actions or unsafe inactions that give rise to the event because, once an unsafe event occurs, it is too late to prevent it. All that can be done is to ameliorate any resulting patient harm and try to prevent that specific adverse event from recurring. If we can prevent near misses by preventing unsafe actions, then we can prevent adverse events. An unsafe action is any action (or inaction) that has the potential to cause an adverse event. Once an unsafe action occurs steps must be taken to eliminate its recurrence and the recurrence of any unsafe actions associated with the proximate unsafe action. Furthermore, unsafe conditions are usually caused by unsafe actions. If an unsafe condition is observed, it must be eliminated and the unsafe actions associated with it must be identified and eliminated.

Although we normally think of unsafe actions as being produced by clinicians in hospitals, everyone involved in a patient's care, including the patient, can produce unsafe

actions and these actions can occur in clinics, independent living situations (with or without home care), and residential care, including assisted living and nursing facilities. In addition, although we have been examining safety from the clinician and healthcare system perspective, it is important to understand that patients can feel unsafe due to actions that the clinician and healthcare system may not recognize as unsafe.[106]

When we move away from events and to actions, we can recognize the importance of unsafe inactions. Unsafe inactions are missed care.[107] Missed care is "*any aspect of required care that is omitted either in part or in whole or delayed*."[108] They are not always mistakes, many times they are actions that are selectively not performed, usually due to time pressure, because it is believed that the inaction will not create a safety risk. In addition, primary care physicians may omit patient teaching, follow-up, emotional support, and mental health needs because of time constraints and administrative burdens.[109] Inactions can create safety risks and they must be recognized and incorporated in a safety program.[107, 109] Currently, it is very difficult to detect unsafe inactions but, in the future, it may be possible for CDSSs to be trained to detect unsafe inactions.

In terms of hospitals, it is well known that unsafe actions occur frequently throughout hospitals.[110] Many are not reported, and from a system perspective, they go unnoticed.[111] The essential questions are: how are unsafe actions to be detected, which unsafe actions should be reported, and how are unsafe actions to be prevented? One approach to detecting unsafe actions is for an automatic clinician decision support system to monitor performance. Such a system requires: (1) an electronic safety detection system, (2) all actions are entered into the system in real time, and (3) the system analyzes the entered information and reports safety issues in real time. With this system in place an unsafe action that was not noticed by the performing clinician will be detected and reported by the system. The system will send a safety message to the clinician and to safety personnel that an unsafe action either has, or is, occurring. This will provide an opportunity for clinicians to truncate, and perhaps even prevent, the unsafe action. A limited version of this system exists in pharmacy CPOEs.

Reporting Unsafe Events and Actions

Currently, it is the responsibility of individuals to detect, report, and correct most unsafe actions. How good are individuals at reporting unsafe actions? Westbrook found that of the 218.9/1,000 clinically important prescribing errors, only 13.0/1,000 errors were reported by the clinical staff.[112] Another study also found that few adverse event medication errors were recorded in the EHR.[113] Furthermore, two-thirds of near miss events were reported by a witness and one-third were self-reported.[114] Given that most near miss events are probably not witnessed, this suggests that many, if not most, near miss events are not reported. Further support for not reporting near misses comes from residents who preferred to discuss an adverse event with their supervisor and at department-led conferences, rather than reporting the event.[115]

The current safety systems are retrospective, they operate on a case-by-case basis, they detect few errors, their incident evaluation and resolution process can miss the correct causes, the process takes a long time and can be expensive, and long-delayed corrective action can be ineffective. Furthermore, other than the aggregation of individual event reports, the current system does not have the ability to perform systematic, patient-level safety assessments across the medical system and it does not have the ability to aggregate that information to detect systemic problems.

Currently, the proximate individual is usually blamed for an unsafe action. It is said that the individual made a mistake, forgot, exhibited poor communication, did not comply with policies and procedures, and much more.[114,116] In reality, a properly trained medical professional has safely performed that action many times in the past. But people are not perfect; there are random mistakes in human performance. In other words, on any given day, every individual has a probability of making a mistake. On this day, the mistake was made by this person – on another day it may be made by another person. The real problem is that there was no recognition of the fallibility of man and of the risk inherent in each medical activity and, as a consequence, there were no processes in place to prevent most mistakes from occurring.

One approach to mistakes is punitive – blame the individual. For example, administrative personnel may believe that they must educate the "offending attending physician and his or her staff."[117] But competent individuals feel that it is unfair to blame them for the mistake and denigrating the physician and his or her staff is counterproductive.[91] Although punitive measures can lead to anger, resentment, and a negative culture – playing the "blame game" is still prevalent in many healthcare systems. Most researchers who have assessed the utility of the punitive approach have rejected it. Instead, they have called for the option of anonymous reporting; for an expert, objective, systematic standardized process to analyze and understand unsafe actions; and for feedback

regarding that changes were made in the system so that clinicians can feel that they are a part of the safety improvement process. [37, 91, 115, 118-125]

Near miss events and adverse events are often blamed on individuals because their unsafe actions are usually the proximate cause. Previous unsafe actions related to the near miss or adverse event, and the conditions surrounding the event, may be noted but are typically not considered part of the primary cause of the event. Furthermore, in an investigation of a near miss it is rarely recognized that the individual is part of a healthcare system and that it is the system that allowed the individual to produce an unsafe action. Finally, there is a failure to understand that the real cause of the unsafe action may be: (1) inadequate training and/or supervision by the system, (2) overwork and stressful conditions within the system, or (3) the system's inability to manage the clinical environment. For example, in hospital settings, interruptions are associated with more than 80% of the orders entered into the wrong EHR.[118] Unfortunately, by far the most common response to an unsafe action is to try to change people rather than to improve the system.[114,116, 126-127] There is a critical need for health information systems that can monitor clinician actions and report problems before they occur, so we do not blame competent health care professionals.

Finally, in most systems, the safety personnel are usually reactive, they spend most of their time filling out patient safety reports, investigating events, and providing documentation. It is the frontline supervisors and clinicians who must find the time and resources required to proactively improve safety.[128] It must be recognized that the safety personnel and the frontline clinicians need improved health informatics systems in order to efficiently and effectively perform their jobs.

Activity Related to Near Miss Events

When a near miss has been detected several things can happen. According to Jeffs there are three possible responses to a near miss. There is the "*quick fix*," where the effect of the near miss is dealt with but nothing else is done. There is the "*going into a black hole*," where the near miss is dealt with and reported to the system, but clinicians never learn if it was fixed and, if so, how it was fixed. There is the "*closing off the Swiss-cheese holes*," where the near miss is dealt with and reported to the system, the system takes corrective action to prevent its recurrence, and the relevant information is returned to the clinicians.[110]

It is difficult to select and mount a systematic response to near miss events because, although there are approaches to categorizing the severity of close calls and adverse events for comparative analysis, for example, the Safety Assessment Code Matrix, there is currently no consensus regarding which near miss events should be reported and how they should be dealt with.[129-131] Furthermore, even the reporting or harm is fraught with difficulty. The Agency for Healthcare Research and Quality released version 1.2 of its Harm Scale in April 2012. It has a two-part harm assessment process for harm, namely, the degree and duration of harm. Degree of harm consists of a five-point scale: death, severe harm, moderate harm, mild harm, and no harm. Duration of harm consists of a two-point scale: permanent (at least one year) and temporary harm.[132] A consistent problem in safety is the creation of scales that have low interrater agreement. For example, the AHRQ Harm Scale v1.2 has kappa's of around 0.50 and raters have a great deal of difficulty distinguishing between severe, moderate, and mild harm.[133]

One reason for the quick fix is that it is the expedient solution. Another reason for the prevalence of quick fixes is that the person who produced the unsafe action does not want to be blamed for it, so fixing but not reporting it becomes the preferred solution. In addition, clinicians are over committed, and they have competing priorities; taking the time to report an unsafe action may not be their highest priority.[110]

For reporting and acting on unsafe actions, one can take a Safety Assessment Code Matrix approach, namely, to prioritize unsafe actions in terms of the combination of their probability of causing an adverse event and the degree of severity of a resulting adverse event.[129] But the scoring system should not be based on subjective judgments, rather, it should be an evidence-based quantitative assessment. Using a data-driven expert system for guidance, some low risk unsafe actions can be quickly fixed, while more serious unsafe actions require a report, systemic corrective action, and feedback to the clinicians. Furthermore, reporting should be electronic and standardized so that the reported information can be properly analyzed, effectively acted upon, and electronically transmitted across the healthcare system. Finally, there must be: (1) a non-punitive response to the report, (2) an effective organizational response including change management (learning) within a facility and across the healthcare organization, and (3) feedback to leadership, safety personnel, and clinicians regarding the organizational response.[119,123]

In addition to assessing risk, health informatics can assist in evaluating and eliminating unsafe actions by collecting the necessary data. These data should be analyzed as a ratio, where the numerator is the number

of detected unsafe actions (and inactions) and the denominator is the opportunity for an unsafe action (and inaction), over a specified time interval. The opportunity for an unsafe action is, for a properly trained person, the product of the complexity of the action, the complexity of the activity within which the action occurs, the frequency of the action, the frequency of the activity, and person's activation, over the specified time interval. Person activation is his or her arousal.[134] The expected level of activation is equal to 1.0 when the performer has a normal arousal, to <1.0 when the performer has too low an arousal (usually when the task is repetitive and/or boring), and to >1.0 when performer has too high an arousal (usually when under a great deal of stress). In other words, every medical activity will have a denominator, which may be somewhat imperfect, but which allows for the identification of those activities that have the highest chance of unsafe actions and which adjusts for the observed rate of unsafe actions, thus placing the observed unsafe actions in the context of their probability of occurrence. This should be calculated by an expert system and the results should be the targets of a learning healthcare system.

Patient Safety Systems

Currently, medical personnel report safety events by manually filling in either a paper-based or electronic reporting form, for example, in the Patient Safety Reporting System.[135] The safety event information is sent to safety personnel where the event is documented and, if it is a Joint Commission sentinel event, and sometimes even if it isn't, it is investigated and reported.[136] The safety report can be deficient in several ways: (1) it may lack standardization of data, (2) it may not include of all the relevant data, and (3) it may contain analysis biases.[137] That said, patient safety reporting programs have been successful in medicine.[119, 125, 138-139] But attempts to adapt industry safety approaches to medicine have resulted in numerous practical problems.[140] An important problem is that most industry systems use a total reporting approach which, in medicine, means that "*any unintended or unexpected incident that could have or did lead to a harm*" must be reported.[141] This is based on the belief that increased reporting will increase safety. This assumption can lead to a focus on quantity rather than quality. To take notice of every event, to mandate that each one must be properly reported, and to require that corrective action be taken for each reported event, will overwhelm most safety programs.[110] For example, an oncology practice implemented a reporting program and in its first three years it received 688 reports, each of which had to undergo a "*plan, do, study, act*" quality improvement cycle.[37] In a radiation department, over a two-year period 1,897 near misses were reported though their voluntary, electronic incident system. This represented an average of one near miss for every patient treated.[122] In a diverse group of primary care practices, over a nine-month period, 632 near misses were reported but only 32 quality improvement projects could be initiated.[121] It is well known that "*the frequency of near misses in daily practice does make it impractical for clinicians to report every near miss, or for the organization to respond to every near miss.*"[110]

Most safety programs are not integrated into the EHR system. Their reports are usually not automatically filled in and the investigation is not automatically conducted, and the investigation results written. Health informatics needs to develop and implement an automated safety reporting system that is a part of the EHR. In the future, a large part of quality and safety will be triggered electronically, much of the data will auto populate the form, much of the investigation will be performed by a data-driven expert system, and the report will be automatically written.

Root Cause Analysis

A root cause analysis is usually a reactive process that attempts to discover the prior causal event or events that gave rise to a specific safety event. In addition, it attempts to determine how to prevent the safety event from recurring. The usual methodology is to assess the safety event and infer the cause of the event. The problem is that this approach commits the *post hoc, ergo propter hoc* ("*After this, therefore because of this*") logical fallacy. As David Hume pointed out in *Of Miracles*, the effect does not contain within it its cause; for any effect, there are many possible causes and the effect cannot prove its cause. Furthermore, there are almost always a cascade of causes that result in an observed effect.[142] The outcome of most root cause analyses is to point to the proximate clinician, even though there are usually several unsafe actions leading up to the clinician being involved in the safety event. One way to solve this problem is to use health informatics. One can use information in the EHR to: (1) determine all antecedent actions, (2) create a decision model that uses these antecedents, the unsafe action, and other relevant EHR information, and (3) run the model to determine the probably of each of the possible sequences causing the safety event. In other words, set-up the variables, simulate the situation, find the most probable causes, and fix those causes.

Safety and Quality Measurement

There are many quality measurement systems. One of the most utilized is the National Committee for Quality Assurance's Healthcare Effectiveness Data and Information Set (HEDIS) measures.[143] In 2017, it consisted of a set of 91 measures that assessed how well patients were being cared for by clinicians and healthcare systems. The system uses defined and structured field searches, surveys, and self-reporting. In addition, the Centers for Medicare and Medicaid Services currently has 271 quality measures that are used to justify payment.[144] Finally, the Agency for Healthcare Research and Quality's National Guideline Clearinghouse is a database that contains thousands of clinical practice guidelines, most of which measure quality of care.[145] Unfortunately, the explosion of measures has led to inefficiencies and imbalances, including poorly defined measures, duplicate and overlapping measures, and an over representation of measures in some areas.[146]

Measurement is a necessary component of all quality improvement projects. Unfortunately, too many projects are *ad hoc* and local. The editors of JAMA Internal Medicine critically appraised the quality improvement studies that they receive for publication and they found that many of them were of poor quality for the following reasons: (1) they were not generalizable, the problem existed only at one center or the intervention was only performed at a limited number of centers, (2) many studies only focused on changes in health care processes, use, or cost rather than on clinical outcomes, (3) they did not assess, in addition to benefits, potential adverse effects, (4) value, in terms of cost savings, did not reflect the costs associated with the intervention, (5) it was rare for there to be a control group, (6) no attempt was made to use statistical methods that approximated randomization, and (7) even when blinding was possible it was not done.[147]

Most medical organizations are collecting EHR data and manual data that can be used to construct process and outcome measures.[148] Although process measures are not very reliable, they tend to be more reliable than outcome measures because the healthcare system directly controls processes, but outcomes are affected by patient behaviors.[149-153] In fact, it has been suggested that outcomes, at least in cancer, are not a good measure of quality.[154]

These data are periodically aggregated in order to assess and improve the organization's performance. The aggregate results can be presented numerically or graphically, or a combination of the two. The display of these measures is usually called a dashboard. For example, a Veterans Integrated Services Network, in order to improve the quality, safety, and value of its care of veterans, developed 300 dashboards and reports.[155]

Although apparently a very simple task, in reality, the communication of actionable safety and quality information is devilishly difficult. What to display, how to display it, and what it means are very challenging issues. In the past, the development of dashboards and reports has been primarily *ad hoc*. Administrators usually targeted specific measures for performance assessment and the targeted measures drove the creation of dashboards. Typically, there was no explicit plan regarding how to operationalize the organization's safety and quality objectives in terms of an integrated set of aggregated measures and there was little recognition whether the dashboard is for strategic, tactical and operational use.[156] Furthermore, there was no evaluation method to determine if the organization's dashboard goals had been met. For example, Karami et al. identified seven evaluative categories for dashboards, namely, user customization, knowledge discovery, security, information delivery, alerting, visual design, and integration and system connectivity – few of which are systematically evaluated during the development, and use of, a dashboard.[157] In addition, there was little understanding of significant intellectual, financial, and personnel resources necessary to create an effective dashboard.[156] Finally, the evidence for the utility of dashboards is slight. A recent review found that most of the dashboard literature consisted of dashboard descriptions and individual case reports rather than empirical studies.[156] In other words, it is not yet known whether dashboards, as opposed to other methods of understanding safety and quality results, are effective at improving safety and quality. Information technology is at its best when it operates in real time and when its information drives immediate actions that prevent or ameliorate an unsafe action.[158]

The federal government, as one of the largest U.S. medical payers, has long been interested in knowing the safety of the care provided to its beneficiaries by its payee hospitals. In 2001, the Centers for Medicare and Medicaid Services created the Medicare Patient Safety Monitoring System, which, in 2009, was transferred to the Agency for Healthcare Research and Quality. The Medicare Patient Safety Monitoring System performs manual chart reviews to determine the national rates for 21 types of adverse events and it creates a baseline for evaluating national patient safety initiatives.[159] Shortly after its creation, in 2003, the Agency for Healthcare Research and Quality developed its 27 item Patient Safety Indicators that screen for adverse events that are likely to be preventable.[160]

Individual reporting and Patient Safety Indicators underreport safety events. They fail to detect approximately 90% of the hospital events.[161] The Global Trigger Tool, developed by the Institute for Healthcare Improvement in 2003, assesses the safety of care provided by individual hospitals. It can detect up to 90% of adverse events, in comparison to approximately 1% using voluntary reporting systems and 9% using the Patient Safety Indicators.[161]

The Global Trigger Tool process involves randomly selecting ten discharged patient medical records every two weeks at a hospital. Two reviewers independently review the same charts for the presence of one or more of 53 "*triggers*," which are entries in the medical record that require further investigation to determine whether an adverse event occurred and, if so, its severity. Regardless of the size of the chart and the complexity of the patient's medical problems, each chart review is limited to 20 minutes. The two reviewers arrive at a consensus regarding triggers, adverse events, and severity. A physician adjudicator, the final arbitrator, and the reviewers then come to a final determination regarding the number, type, and severity of events. The physician does not review the records; he/she only assesses the reviewers' results.

The Global Trigger Tool has improved the safety event detection process by defining a set of triggers and providing a systematic process for their evaluation. There is a substantial body of evidence that supports the fact that the Global Trigger Tool significantly improves safety.[161-175] But the manual Global Trigger Tool does have important limitations: (1) because it is not risk adjusted, it cannot be used to compare different types of hospitals, (2) it is very labor intensive and expensive, (3) it exhibits low abstractor agreement, (4) it does not examine all inpatients, and (5) a physician must adjudicate the abstractor's findings for each putative adverse event.

Many organizations have partially implemented an electronic version of the Global Trigger Tool, using information from the EHR, including check boxes and structured fields.[176] The problem with this approach is that it generates a huge number of triggers, each of which must be assessed by a reviewer for the existence of adverse events, which is very time consuming and expensive. Furthermore, many of the triggers are not captured by the check boxes and structured fields, so this approach does not eliminate the need for a reviewer checking the medical records.

In addition to the Global Trigger Tool's lack of comprehensiveness, it does not assess all hospitalized patients, it employs an *ad hoc* search process for the triggers, each reviewer examines the chart in his or her own way. This may be one of the reasons for the low agreement between raters in terms of the triggers and for the adverse events.[177] The low agreement means that there is a substantial amount of error in the number of triggers and which triggers are detected. Another issue is that the review of the patient's medical record is limited to 20 minutes. It is well known that the longer the patent is in the hospital the greater the chance of mistake, thus the limited chart review underestimates the number of errors and biases the types of errors detected.[178]

The Agency for Healthcare Research and Quality has begun development of the Quality and Safety Review System to replace the Medicare Patient Safety Monitoring System.[179] The new system is designed to overcome one of the main limitations of previous measurement systems, namely, the *ad hoc* search for safety event information in the chart. The Quality and Safety Review System directs reviewers to look for specific information based on questions automatically generated by its evidence-based expert system. The system uses existing information in the EHR, including age, sex, diagnoses, procedures, and potential adverse events as the basis for asking reviewers to acquire additional information from the chart. Based on what the reviewer reports, the expert system may ask additional questions before determining whether an adverse event had occurred. The expert system uses explicit, standardized definitions of the variables and of adverse events, and it uses human generated, validated rule-based (if-then) algorithms to ask questions and detect adverse events. The Quality and Safety Review System has a broad scope, its goal is to detect most of the adverse events that occur in hospitals, i.e., to measure "*all cause harm*." This standardized approach will allow reported rates to be compared across hospitals because they will be based on the same definitions and a standardized methodology.

Clearly, the major limitation of the Quality and Safety Review System is its reliance on human reviewers. What is needed in order for it to be maximally effective is for it to have the ability to detect meaning in free text. When this occurs, the system will become automatic, inexpensive, highly reliable, comprehensive (it will scan all patients), and accurate. Furthermore, it will operate in real time and have the capability of notifying clinicians regarding potentially unsafe actions, so they can be prevented from becoming adverse events.[179]

CLINICAL DECISION SUPPORT SYSTEMS

Although it was asserted that the elimination of the paper chart would significantly reduce errors and improve quality, that claim was made before the widespread

adoption of the EHR. Since its implementation it has become clear that, although there is no longer any illegible handwriting and the chart is readily available, the EHR produces its own errors, the cut-and-paste function has made the available patient record less intelligible, and clinicians are having a hard time using EHR systems. But all is not lost, for the EHR is a precondition for the development and use of most CDSSs. In the last decade, advances in safety and quality have largely been due to CDSSs that have been built into, and rely upon, the electronic record.

CDSSs have been defined as, "*any software designed to directly aid in clinical decision making in which characteristics of individual patients are matched to a computerized knowledge base for the purpose of generating patient-specific assessments or recommendations that are then presented to clinicians for consideration.*"[180] Full-fledged CDSSs have a graphical user interface, contain an algorithm, and display the output of the algorithm. The algorithm can be a human-constructed, rule-based system or, more recently, a trained statistical/probabilistic model. It takes as its input individual patient clinical information and provides as its output predictions regarding an individual patient's: risk of disease including prevention, or diagnosis, or prognosis including treatment and outcome.[181] The basic idea is that CDSSs can be used to prevent or ameliorate unsafe actions or inactions and provide information that can improve the quality of care. CDSSs have also been called expert systems and the use of trained statistical/probabilistic programs to make predictions has been called predictive analytics.

In terms of data acquisition, there are two main types of CDSSs.

1. Free-standing systems: they operate independently of the EHR. They require that an individual manually input the data and receive the results. The main type of autonomous systems has been for diagnosis.
2. Integrated systems: they interact directly with the patient's EHR. They access and analyze the clinical data and report their results. Currently, the main types of integrated systems are: (a) computerized provider order entry for medications, laboratory and radiographic tests and, (b) clinician alerts, reminders, and checklists. In addition, automated detection systems can discover potentially unsafe actions in order to prevent their occurrence or ameliorate their effects. An integrated system can operate in one of two modes, batch, where it periodically accesses, analyzes and reports its results and real-time, where it continuously accesses, analyzes, and reports its results.

The early CDSSs were free-standing because there was no EHR. Other than the importation of laboratory data, all data entry was performed manually by clinicians. With the advent of the EHR, CDSSs can automatically acquire data from the health record database but, because free text is usually not reliably read, these data are usually acquired from checkboxes and structured fields.

Currently, CDSSs are limited to demographic and anatomic/cellular data, both of which have limited predictive power. Molecular biomarkers, which are constative of the disease process, have the potential to allow us to better understand, predict, and treat disease. In the future, when molecular biomarkers (which include gene expression) are routinely included in the patient's medical record, CDSSs will become much more powerful – and the era of personalized medicine (also known as precision medicine) will have begun.[181]

Free-Standing Systems

The early CDSSs were free-standing. Clinicians manually entered the patient's data into the system and received the patient's risk of disease, or a rank order list of possible diseases, or a rank order list of treatments for a disease. The earliest CDSSs were diagnostic, and many supported some form of text data. Although an obvious target, the selection of diagnosis was unfortunate because the most difficult predictions in medicine tend to be those related to the diagnosis of disease.

The first diagnostic CDDS to gain widespread attention was the Internal Medicine diagnostic system Internist-1.[182-183] It consisted of a set of branching if-then rules and contained 570 diseases. There were two issues with Internist-1 and with similar free-standing systems. First, it did not solve a medical problem. In other words, Internal Medicine physicians were perfectly capable of making these diagnoses without Internist-1 and the program did not improve on their diagnostic accuracy. Second, it could take hours to manually input the clinical data into the program and no one wanted to perform that task. Internist-1 morphed into Quick Medical Reference, which was more of an information tool that a diagnostic program. It allowed clinicians to review the diagnostic information in the program's knowledge base. It contained 700 diseases and 5,000 signs, symptoms, and laboratory values. It could function as a textbook and it could generate a rank order list of possible diagnoses.[184-185] Unfortunately, it is no longer commercially available. Additional diagnostic programs included: DXplain, which contains 2,000 diseases, 5,000 clinical manifestations, and uses

a modified form of Bayesian statistics; Iliad, which contains 930 diseases, 1,500 syndromes, 13,900 disease manifestations, and 90 simulated cases; and Isabel, which contains 11,000 diagnoses and 4,000 drugs and heuristics.[186-188]

In some diagnostic situations, the primary source of data is the image. In 2006, Tleyjeh et al. created a program, VisualDx, into which clinicians entered descriptors and lesion morphologies and it provided a dermatologic differential diagnosis. Tleyjeh et al. suggested that the program could increase "*clinician awareness of, knowledge about, and skills in the recognition of chemical warfare, bioterrorism, and radiation injuries*."[189] More recently, they developed an app that can build a dermatologic differential diagnosis based on images.[190] The clinician takes a picture of the dermatologic lesion and enters relevant factors such as age, travel, medical and social history, and the location, distribution, and appearance of the lesion into the program. The program, based on a simple matching criterion, lists the possible diagnosis in rank order by likelihood. The program claims to contain more than 2,800 conditions and more than 40,000 images. Chou found that VisualDx could improve the dermatologic diagnostic accuracy of medical students and residents by 19%.[191]

Over the last 10 years there has been a great deal of interest in reducing diagnostic errors. In 2015, the National Academies of Sciences, Engineering and Medicine published *Improving Diagnosis in Health Care*. It described many of the current diagnostic problems and it recommended ways to improve diagnostic accuracy. CDSSs were an integral part of their diagnostic improvement strategy. They stated that "*Diagnostic decision support tools can provide support to clinicians and patients throughout each stage of the diagnostic process, such as during information acquisition, information integration and interpretation, the formation of a working diagnosis, and the making of a diagnosis*."[192] In order to achieve the envisaged automated clinical decision support system an effective, operational natural language processing system will have to be in place.

Integrated Systems

With the advent of the EHR, CDSSs could operate autonomously on check boxes, and on laboratory, radiology, and pathology information without human data entry. Furthermore, the clinical decision support system can be running in the background in real time during the patient encounter, assessing and responding to the information the clinician enters into the EHR. The clinical decision support system's real-time monitoring and response system is what makes it a powerful safety and quality tool.

Computerized Provider Order Entry Systems (CPOEs)

Published in 2007, the Institute of Medicine's *Preventing Medication Errors,* presented information regarding the incidence and cost of medication mistakes, and it offered strategies for reducing them.[193] They pointed out that paper-based prescribing was one of the most common sources of medical mistakes and adverse events. These mistakes were due to many factors, including: (1) illegible handwriting and the use of abbreviations in prescription orders, (2) incomplete and incorrect prescriptions (e.g., incorrect dose calculation, drug name confusion, restarting a discontinued medication), (3) adverse drug-drug interactions, and (4) prescribing a medication that the patient was allergic to.[194-195]

CPOEs are electronic systems that are integrated into the EHR and that allow physicians to electronically order medications. They contain expert systems that evaluate the safety of the order using rules and information in the patient's EHR and they transmit alerts to the clinician when a potentially unsafe action (medication order) is occurring. CPOEs have been shown to reduce duplicate medications, drug overdoses, adverse drug-drug interactions, and the prescribing medications that patients are allergic to.[196-201] A recent systematic review and meta-analysis of CPOEs in the intensive care unit found an 85% reduction in medication errors by clinicians and a 12% reduction in mortality associated with CPOEs.[202] But computer-based systems are not perfect, they can make mistakes.[90] CPOEs can create duplicate prescriptions, miss wrong dose and wrong drug, generate mistakes related to drop down menus, and alerts can malfunction.[194, 203-206] It had been thought that adding additional clinical decision support capabilities to a computerized provider order entry system would offer additional safety and quality benefits, but it did not provide any additional benefit.[207-210] Furthermore, it is not always the case that all aspects of a safety solution need be electronic. A common outpatient medication mistake is dispensing a medication to the wrong patient, which occurs in 1.22 per 1,000 dispensed prescriptions.[200] Simple measures, such as checking the prescription with the patient at the point of sale, can reduce these mistakes by 56%.[211]

Another form of CPOE deals with the ordering of laboratory tests. Whereas, ordering medications dealt with safety, laboratory test ordering systems deal with reducing unnecessary testing in order to reduce the volume of tests and the cost of testing. A recent study

used a CDDS to detect tests with a high repetition probability, or great complexity, or which were mutually incompatible within the same order.[212] The system would either cancel the test with no recourse or cancel it but allow the test after a written justification. They found that the provider order entry system reduced testing by 16% and costs by 17%. In a similar manner, radiology testing was reduced when CDSSs reviewed information in the patient's chart and denied testing. [213] Unfortunately, clinicians complained that the system was: (1) not easy to use, (2) too slow, (3) presented a high risk of error, and (4) required frequent interactions between the clinical staff. The investigators concluded that user acceptance and satisfaction were critical to system success. If clinicians did not find that the system benefited them, then they would either not use the system or they would use it in a suboptimal manner.

How well the computer-based clinical systems are implemented can have a profound effect on their acceptance and use.[131, 214-216] For example, in an odd twist of fate, the CPOE system used at a major teaching hospital in France crashed and they had to return to a paper-based order system.[217] The residents were given a satisfaction and user survey for both the electronic and paper order systems. They were almost four times more satisfied with the paper than the electronic system and they did not detect an increase in errors. In other words, computer-based systems that are not user-friendly, not efficient, and do not add clinical value can be detrimental to medical practice. User feedback should be solicited, and the acquired information acted upon, in the creation and deployment of computer-based clinical systems.[131, 218] Finally, because CDSSs have become part of the clinician work-flow, it is important to design them so that they seamlessly integrate into the clinician-patient clinical encounter.[219]

Clinician Alerts, Reminders and Checklists

Alerts are very useful in reducing medication mistakes. Most alerts are for drug-drug interactions. Unfortunately, currently there are far too many alerts, which blunts their effectiveness. Frequent alerts regarding co-administration incompatibilities negatively influenced adherence to the alerts – which resulted in many alerts being either ignored or overridden.[220-226] Alert fatigue has significantly reduced clinician enthusiasm for medication alerts.[226] In other words, there can be too much of a good thing when it comes to safety.

Another kind of alert, a patient-specific electronic reminder, occurs less frequently and has been shown to be an effective safety tool. Reminders that were integrated into an EHR increased clinician adherence to recommended care for diabetes and coronary artery disease.[227] In addition, a recent systematic review showed that reminders were effective in increasing clinician's ordering diabetes testing in women with a history of gestational diabetes.[228] But not all reminders are equally effective. Reminders for appropriate laboratory monitoring had no impact on rates of receiving appropriate testing for creatinine, potassium, liver function, renal function, or therapeutic drug level monitoring.[229] It appears that the efficacy of a reminder depends, in part, on whether there is a clinical problem that the reminder solves.

Safety checklists are activity-specific ordered lists of the actions that must be performed to successfully accomplish the task.[230] They have been useful in reducing preventable medical mistakes.[230-234] They are used in situations where an obligatory sequence of actions must be performed and where, if an action is omitted or an incorrect action is added, there is the potential for an unsafe inaction or action to occur – which could result in an adverse event. Checklists are especially useful in situations where several clinicians are performing coordinated actions on a patient in a complex, multi-stimuli environment. Checklists sequentially focus clinicians' attention on specific tasks. Recently, computer-based interactive, dynamic, adaptive safety checklists have been developed, many of which are linked to EHRs.[235-239] Interactive means that when an item is checked as completed, the system is updated, dynamic means that the checklist advances as the items on the checklist are completed, and adaptive means that the checklist can change based on changing conditions in the clinical workflow. These capabilities are based on the checklist's if-then algorithms and data-driven expert systems. The major limitations of checklists are: (1) they can tell if an action was done or not done but cannot tell if what was done was what was supposed to be done and cannot tell whether it was done correctly, (2) checklists are time consuming, and (3) checklists can disrupt an established workflow. Finally, checklist adherence tends to drop off over time. For example, the use of a childbirth checklist declined from 100% initially, to 72.8% at 2 months, to 61.7% at 12 months.[240]

Real-Time Systems

Although medication ordering and reminder systems operate in real time, they are just the initial steps in real time CDSSs. A long-term system-level step that is necessary to improve safety is to develop and implement sophisticated real-time CDSSs.

1. Clinician-patient clinical encounter: This system takes as its input the real time natural language information written into the EHR by the clinician during the clinician-patient interaction and existing check box and structured data already in the medical record. The CDSS continuously monitors this input in real time, in order to detect unsafe actions and conditions and to report unsafe actions and conditions to the clinician while the interaction is in progress, so a safety event can be prevented. This means that clinicians will have to write in their EHR during the clinical encounter.[241]
2. Medical procedure: This system takes as its input audiovisual information produced in real time during the procedure and existing check box and structured data already in the medical record. The CDSS continuously monitors this input in real time, in order to detect unsafe actions and conditions and to report unsafe actions and conditions to the clinician while the procedure is in progress so that a safety event can be prevented.

Decision Aids

CDSSs can be, and should be, used as decision aids. They provide predictions regarding the risks and benefits of a treatment for an individual patient. These estimates can be discussed with the patient as part of shared decision making. For example, they have been used to decide whether the patient should undergo an elective joint replacement.[242] The use of decision aids has been shown to reduce the rate of hip and knee surgery, thus reducing medical utilization and costs.[243-244]

Regulatory Environment and a Cautionary Note

Although the Centers for Medicare and Medicaid Services and the Agency for Health Care Research and Quality has been the driving forces behind the implementation and use of EHRs and related systems, the U.S. Food and Drug Administration is the federal agency responsible for the regulation of medical devices, including software. The Food and Drug Administration has been interested in medical software for many years, including CDSSs. It held hearings and provided guidance in 1998, 1999, and 2002.[245-247] In 2016, Congress passed the 21st Century Cures Act (Public Law No. 114-255, FDCA § 520(o)(1)(E)), which exempts from regulation software designed for: *"(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines); (ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and (iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient*." Many of the current health informatics tools existed without FDA approval. This law not only makes them legal, but it also opens the field to additional innovation.

FUTURE TRENDS

Health informatics will likely develop an accurate natural language processing program. This advance will allow for the automatic detection of meaning in free text. Furthermore, it will drive the redesign of the EHR, thus reducing the number of check boxes and structured data and resurrecting the narrative clinical note. It will be easier for clinicians to use the EHR and for administrators to aggregate and analyze medical data.

Safety and quality will consist of systematic, evidence-based electronic detection and reporting programs. Furthermore, CDSSs will operate in real-time and alert clinicians to actions that may place patients at risk of harm.

KEY POINTS

- It is clear that safety, quality and value are becoming defining characteristics of medical practice
- The U.S. government has, and will continue to, drive safety, quality and value
- Safety must shift its focus from safety events to the unsafe actions that cause the events, for it is only then that we have a real chance to prevent safety events
- The EHR is necessary but not sufficient for improving safety and quality
- In order to achieve their full potential, EHR systems must have the capability to read free text
- Health informatics will be building real-time CDSSs into the EHR and these systems will significantly improve safety, quality and value

CONCLUSIONS

Health informatics must be properly socialized within the medical community. Currently, is exists mostly by fiat. The usual situation is that clinicians are told that a health information technology product is being implemented and they better get used to it. But this mode of implementation does not have long term viability. A recent editorial in Lancet Oncology stated, "*What has become evident over the past two decades or longer is that vast amounts of data have now infiltrated every aspect of our daily lives. From data analytics to artificial intelligence, to predictive modelling and machine learning, we are now seeing these systems being incorporated into all aspects of health, including those found in oncology. But as now shown by the JAMIA study, physicians are not always willing to accept the changes that these systems bring. Although big data offers the promise of easing workflows, ensuring treatment adherence according to guidelines, the analysis of large datasets, maintenance of a centralised records system, improving diagnostic accuracy, and monitoring disease or drug safety surveillance—all of which could be hugely beneficial for the future of health care—clearly a delicate balance is needed when integrating those promises into the clinical decision-making process.*"[248]

Health informatics must not just be an administrative endeavor designed to reduce costs. It must become an integrated strategy supported by clinicians and focused on improving safety, quality, and value.

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