9

Safety, Quality, and Value

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LEARNING OBJECTIVES

After reading this chapter the reader should be able to:

1. Define safety, quality, near miss, and unsafe action
2. List the safety and quality factors that justified the clinical implementation of electronic health record systems
3. Discuss three reasons why the electronic health record is central to safety, quality, and value
4. List three issues that clinicians have with the current electronic health record systems and discuss how these problems affect safety and quality
5. Describe a specific electronic patient safety measurement system and a specific electronic safety reporting system
6. Describe two integrated clinical decision support systems and discuss how they improve safety and quality

INTRODUCTION

Improving medical safety and quality is difficult because of the number of the patients, the number and variety of medical conditions, and the complexity of the patient's condition. For example, disease pervasiveness is reflected in the fact that, in 2020, 83.4% of adults had a visit with a healthcare professional and there were 860.4 million physician office visits.(1) Many of these patient encounters were complex and each encounter provided multiple opportunities for clinicians, healthcare systems, and even patients, to make mistakes. These mistakes can have many causes, including: clinician cognitive errors, the rarity and/or complexity of medical conditions, clinician time pressures and distractions, miscommunication and misunderstanding, 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 safety and quality issues. Our job is to reduce them to a minimum and health informatics plays a critical role in our efforts to do so.

Health informatics is the electronic acquisition, storage, analysis, and use of medical information to advance medical care, improve patient outcomes, and reduce costs. It can also increase the efficiency and effectiveness of the healthcare system. From a safety and quality perspective, health informatics: [1] provides the medical information required to properly manage patients, [2] generates accurate risk, diagnosis, and prognosis (including treatment) predictions that improve care and outcomes, [3] creates real-world simulations and other forms of online training that improves clinician safety and quality knowledge and performance, [4] performs real-time monitoring and clinician notification of activities that place patients at risk of a safety event or low quality activity, and [5] detects and notifies clinician of the occurrence of safety and quality events.

SAFETY, QUALITY, AND VALUE

Safety, quality, and value have been central to medicine since the beginning of recorded time. "Do no harm" is a prime example of the importance of preventing safety events. But western medicine, during the hegemony of Galen, from approximately 200 CE to 1600 CE, adopted the unsafe practice of bloodletting and the low-quality theory of the "four humors of the body" mechanism of disease. The rise of scientific medicine ended Galen's reign. Medicines shifted its attention to such areas as anatomy and physiology, surgical asepsis and anesthesia, and diagnostics and therapeutics. The 20th century witnessed the professionalization of medicine: physicians received formal training, they began handwriting patient information on pieces of paper, and they started using experimental data to inform their treatment decisions. Safety and quality, as a systematic and professional activity, began in the 1950s. The first entry of the phrase "patient safety program" in PubMed occurred in 1962.(2)

If we are to use health informatics to improve safety, quality, and value, we must discuss what safety, quality, and value are. To begin, safety and quality are asymmetrically related; a lapse in safety almost always lowers quality, but safe medicine is not always high-quality medicine. An important concept is that they have different definitions, depending on the viewer's perspective. From the physician's perspective, safety, quality, and value are: do good work, don't mess up, and don't charge a lot. From the clinical outcome perspective, safety, quality, and value are the ability of physicians to provide appropriate and affordable care that achieves the expected clinical outcomes and that doesn't harm the patient. From the patient's perspective safety, quality, and value are that: (1) they understand the care they are receiving; (2) their care takes into account their values, preferences, and expectations; (3) they affirmatively agreed to their care; (4) their care is appropriate for their medical condition; (5) their care meets the current medical standards; and (6) they can afford it.(3)

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.(4) Safe and effective care focuses on the physician; timely, efficient and patient-centered focuses on the healthcare system; and equitable focuses on societal values. 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."*(5) In other words, *"better health, better care, lower cost through improvement."*(5,6) 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."*(7)

As one might imagine, value is a difficult concept to define. Generally, value is the how important something is to us. It can be expressed in monetary terms, e.g., how much a person or organization is will pay, or accept, for something. In this sense, value is comparative because resources are finite and choices must be made regarding how to allocate those resources. In addition to value being quantitative, it can also be expressed in qualitative terms. For example, how much a person values health or recovering from an illness, and how much an organization values providing safe, high quality medical care.

It should come as no surprise that there are four perspectives to value, namely, the providers of care, the recipients of care, the payers of care, and the social norms associated with medical care. Furthermore, these perspectives are not the identical. For example, in a University of Utah survey of 5,031 patients, 687 physicians, and 538 employers, 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.(8)

The monetary value patients place on their health can vary depending on the medical situation. For example, patients usually attach little monetary value to prevention; they may engage in health prevention activities so long as they do not cost a great deal of money. But when people are sick, they are willing to pay more for their medical care. Furthermore, when someone else is paying for their care, patients and their families usually want everything done, no matter the cost. Finally, out-of-pocket costs are very effective in lowering U.S. healthcare utilization costs – many patients will decline medical care for non-acute, non-life-threatening illnesses if they must pay for that care.

There is little accurate information regarding medical cost because there is little available 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.(8) Is it the direct expense involved in delivering medical care to a specific patient? If so, this cost is rarely known by anyone in health care

because it is rare for there to be an accurate patient-level cost accounting. Is it the contractual payments of employers and government agencies? Other than Medicare and Medicaid, these contract payments are considered a trade secret by the third-party payers and physicians are rarely privy to these payments. In other words, other than the physician's own prices, it is unusual for a physician to know the list prices or payments for care. Furthermore, 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 insurance. Ironically, the patients who least afford health insurance were the patients who have paid the most for medical care.

This situation has been changing. On January 1, 2021 Federal Rule (FR) 65524 took effect.(9) It mandated that all U.S. hospitals receiving federal funds publicly display their prices for 300 services. Five separate prices were required including the minimum and maximum negotiated price and the discounted cash price. A recent study examined the compliance of 20 US News and World Report honor roll hospitals.(10) Six months after the rule went into effect, they found that "Many highly respected U.S. hospitals are not in compliance with new price transparency legislation" (p. 1) and that only 30% posted both their cash and minimum and maximum negotiated prices. Furthermore, for hospitals where they could compare the cash price with the minimum negotiated price, the cash price was usually orders of magnitude higher. Finally, for cancer drugs, only 27 of the 61 National Cancer Institute-designated cancer centers disclosed private payer-specific prices for a least one top-selling therapy, and their markups on cancer drugs ranged from 118% to 664%.(11)

From a societal perspective, potential medical costs are almost infinite because there is essentially no limit to the amount of money that can be spent trying to achieve perfect clinical outcomes for all patients and all medical conditions. Therefore, all societies ration care, sometimes the rationing is explicit but it is usually implicit – hidden from view.(12) For example, the United Kingdom National Health Service practices explicit rationing(13) and, as British government's spending has declined, the rationing has increased.(12-14) 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 can be a two and one-half month wait to see a specialist and another two and one-half month wait to receive treatment.(15) Rationing is based on priorities and they depend on what societies are willing spend their money on. Government spending decisions are usually based on: (1) political budget decisions, (2) the overall cost of medical conditions (the number of patients times cost per patient), and (3) a cost-benefit justification.

In the U.S., the Centers for Medicare and Medicaid Services (CMS) uses financial incentives and disincentives to regulate the practice of medicine. CMS has established a "value-based" payment system that aims to obtain value for its money by eliminating "*inappropriate and unnecessary"* care and by applying quality metrics to improve the quality of care.(16) There are at least two important problem with this approach: (1) how to define inappropriate and unnecessary and (2) how to integrate new tests and treatments into the value equation. Furthermore, value-based payment systems may not result in significant reductions in the cost of care.(17-18) In addition, 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.(19) In other words, although we would like to lower costs by receiving value, there are countervailing factors, factors that meet the definition of value but drive up costs.

In recent years, the U.S. federal government has established organizations designed to drive safety and quality improvement. 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.*"(20) Federal organizations play an important role in stimulating safety and quality research and implementing safety and quality practices. For example, as early as 1972 the National Library of Medicine, a part of the National Institutes of Health, began funding informatics training programs. Its goal was to train individuals to apply computer and information science to medicine.(21)

Interestingly, one can ask, what is the value of health informatics? For example, what is the economic benefit of a clinical decision support system (CDSS) used for cardiovascular disease prevention? Jacob et al. recently undertook a systematic review to answer this question.(22) They 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." In other words, because of a paucity of data regarding the drivers of cost and benefit, and a lack of cost metrics, they were unable to determine if CDSSs were cost-effective for cardiovascular disease prevention. The problems Jacob et al. describe are not limited to clinical decision support systems; they apply to most medical cost-benefit calculations.

Finally, 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 systems (overhead costs and personnel) and on health information systems. Fortunately, health information technology (HIT) can improve the efficiency of health care while, at the same time, enhancing safety and quality. HIT can be able to accomplish this by monitoring and assessing care and by reporting the information that clinicians need to know in order to prevent unsafe actions and assist clinicians in their cognitive and procedural activities. This will have the effect of advancing safety and quality and, as a consequence, improving value.

USING COMPUTERS TO IMPROVE SAFETY, QUALITY, AND VALUE

Health informatics, formerly medical informatics, has a long and honorable history that began with meeting the needs of healthcare administrators. In the 1960s, hospitals started using mainframe computers for inventory control, for accounting and billing, and for laboratory results. Furthermore, as early as the mid-1960s, there were calls for computerizing outpatient clinic records (23) and, starting in the 1970s, and continuing to this day, there has been a keen interest in computer-based clinical decision support systems.

The first important computer-based clinical systems were designed to improve quality. They were diagnostic clinical decision support systems. The initial publication was the internal medicine diagnostic system Internist-1. (24,25) It consisted of a set of branching if-then rules and contained 570 diseases. There were two issues with Internist-1 and with similar computer-based systems. First, they did not solve a medical problem. In other words, internal medicine physicians were perfectly capable of making accurate diagnoses without Internist-1 and the program did not improve their diagnostic accuracy. Second, it could take many hours to manually input the clinical data into the program and no one wanted to perform that task. Internist-1 was transformed into Quick Medical Reference,(26-27) 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. Quick Medical Reference can function as a textbook and it can generate a rank order list of possible diagnoses. Additional diagnostic programs included: DXplain,(28-29) which contained 2,000 diseases, 5,000 clinical manifestations, and used a modified form of Bayesian statistics; Iliad,(30) which contained 930 diseases, 1,500 syndromes, 13,900 disease manifestations, and 90 simulated cases; and Isabel, which contained 11,000 diagnoses and 4,000 drugs and heuristics.(31-32) These programs, examples of clinical decision support systems, have the potential to improve the quality of care but they had to wait for the arrival of EHRs, and of computers in exam and hospital rooms, before they could be put to clinical use. Computer-based diagnostic prediction, as an example of clinical decision support systems, is still not widely used in medicine even though they can increase the likelihood of the inclusion of the correct diagnosis in the differential diagnosis list.(33)

Even in the earliest years, health informaticians understood that if medicine was to improve its safety and quality health informatics would have to be able to assess what was in the patient record in an electronic form. Yet it was not until 1991, with the publication of the Institute of Medicine's *CPR Report – Computer-based Patient Record,*(34) that there was an in-depth analysis of the potential benefits of the electronic health record (EHR) and of the issues related to implementation barriers – including privacy and cost. The report was a national call for the adoption of a computer-based patient record. Unfortunately, at that time, there was very little knowledge of, and experience with, EHRs.

The advent of the electronic health record

At the turn of the 20th century, medical records were handwritten on index cards and stored in envelopes. (35,36) As the century progressed medicine, and medical records, became more complex. In addition, as medical information increased, the need for physicians to write more detailed and complete notes increased.(37-39) These factors drove the increasing size and scope of the medical

record – medical records became a large, paper-based loose-leaf collection of clinical notes, treatments and procedures, laboratory and radiology reports, consultations, and other information.

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, accessible, and included important provisions that addressed transmission and privacy issues related to electronic personal health information (PHI). HIPAA focused national attention on health information technology and the use of EHRs, in part to improve safety and quality. 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 and quality, and which emphasized the importance of the electronic medical record. These publications included:

- Published in 2000, *To Err Is Human, Building a Safer Health System,* focused on the safety and quality of care.(40) This publication claimed that almost 100,000 hospital deaths were caused by medical errors and asserted that that the problem was that good clinicians were working in a dysfunctional system. It set forth "*a national agenda…for reducing medical errors and improving patient safety through the design of a safer health system*."
- Published in 2003, *Key Capabilities of an Electronic Health Record System,* discussed the basic functions of an EHR, database management, and data standards.(41-42) 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 healthcare delivery system was needed. (43) 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 healthcare data standards for the exchange, reporting, and analysis of safety data.

Yet, in the 13 years after the 1991 publication of *CPR Report – Computer-based Patient Record*,(32) EHRs had not been widely adopted in clinical medicine.(44) Furthermore, 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.(36)

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*."(45) This was an aspirational rather than a scientific or empirical statement because there was little evidence for this statement at that time. His speech was followed by Executive Orders, by several major legislative initiatives, and by Federal implementation rules and regulations, including:

- In 2004, the Office of National Coordinator for Health Information Technology (ONC) was established by Executive Order. The ONC 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.(46)
- 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 medical 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 2018, the phrase "promoting interoperability" replaced "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 in order to better monitor and improve safety, quality, and value.

These federal initiatives drove the transition from paper-based records to electronic records. The EHR has become the foundation for many safety advances, for quality improvement projects, and for improved billing practices. But several issues related to the EHR

remained unresolved including record portability, the transmission of records between EHR systems, and clinician acceptance.

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.(47)

During this time many private and quasi-private organizations were 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 health care in the United States; and by serving as a major driving force for and facilitator of continuous quality improvement of American healthcare quality.*"(48) In addition, every major medical center has a robust safety and quality program.

Health informatics has taken great strides over the last decade in three important areas:

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 clinical decision support systems;
2. Monitoring activities – assessing EHRs in order to measure clinician performance and to monitor patient safety; and
3. Quality improvement activities – there has been a proliferation of quality improvement projects, but they have not always resulted in improved outcomes and they have not always been implemented within a medical system and across medical systems.

USING ELECTRONIC HEALTH RECORDS TO IMPROVE SAFETY, QUALITY, AND VALUE

From a health informatics perspective, an EHR system consists of: (1) a graphical user interface that the clinician uses to enter and view information, (2) a sophisticated relational database that acquires, stores, and retrieves information, and (3) powerful, extensible auditing and reporting systems. Prior to President Bush's speech 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.(36)

But paper records had at least six disadvantages. (36) First, it could be difficult to read the handwriting in some notes and they could contain handwriting errors and non-standard abbreviations. Second, the patient's current chart would occasionally 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 clerical personnel time and space. Fifth, it was very expensive to manually review charts. These factors meant that it was difficult for administrators to see what physicians were doing because they had to manually review individual charts and that was expensive. For example, the cost of a manual review varied from $74 to $350 per chart, depending on the amount of information extracted.(49) This meant that, except for peer reviews, charts were not routinely audited to determine physician and nurse performance and hospitals could not direct physicians to change their documentation practices in order to increase revenue. The EHR eliminated the cost of chart review. It is easily readable, it is usually available, 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. It was expected that it would take physicians the same amount of time to use an EHR as it took to use a paper chart and that the reduction in clerical and storage costs would more than pay for the adoption and use of EHRs. Both assumptions turned out to be incorrect and those errors had major effects on health care, including driving down physician satisfaction and driving up healthcare costs.

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. The rationale was that computers would significantly improve safety and quality. These programs were usually based on financial incentives and penalties. The American Recovery and

Reinvestment Act of 2009(50-51) 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.(52) In addition, CMS began introducing quality metrics that clinicians and hospitals had to meet in order to receive financial incentives and not incur financial penalties.

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. The relationship between EHRs and clinical quality has been investigated, usually in cross-sectional studies of process measures rather than clinical outcomes.(53-60) The results have been equivocal. No study has demonstrated a computerization benefit across all its quality measures. Some studies have shown a partial benefit,(56, 57, 60, 61) while others have not demonstrated a significant clinical impact on quality.(53-55, 58,59,62) Furthermore, one of the few retrospective longitudinal studies that used the quality measure hemoglobin A1c compared before and after the introduction of an EHR and did not find as significant quality improvement attributable to the use of an EHR.(63) Finally, it is unlikely that randomized prospective studies will ever be conducted because it would require half of the physicians in the study to return to handwritten notes.

From a system perspective, the conversion from paper charts to an EHR system created several problems. One was that moving from paper to the EHR, or moving from one EHR system to another, usually does not carry forward the 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 terms of EHR implementation, physicians should receive a great deal of expensive and time-consuming training, but most transitions provide relatively little training, and the training physician do receive usually consists of a short didactic related to the major features of the system – with little regard to how the EHR fits into the clinical workflow. Furthermore, there is no generally accepted method for training healthcare professionals and students on how to use EHR systems.(64-65) This situation causes clinicians frustration and requires them to develop "workarounds" to achieve their patient-related goals. These workarounds can lead to safety issues.(66)

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' patient records and, therefore, no assessment of their performance. Furthermore, the EHR creates opportunities 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, the addition of clinical decision support systems to EHRs has the potential to directly improve safety and quality.

Clinician Perspective on Electronic Health Records

In the U.S., the electronic medical record has been driven by federal rules and regulation, payer requirements, administrators and, to a lesser extent, by safety and quality. The way EHRs are designed and implemented has a dramatic impact on physician and nurse morale and performance. Many physicians believe that the EHRs were not designed for clinicians, which is why they are difficult for clinicians to use.(67-69) There is a perspective that supports the idea that EHRs were not designed for physicians. "*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 electronic health records (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."*(70) From this perspective, health informatics can be viewed as dehumanizing both patients and the clinicians and it can be seen as part of a larger effort to advance the interests of corporations and governments, at the expense of patients and clinicians.

Before EHRs, the clinical encounter began with physicians picking up the patient's chart before entering the exam or hospital room and quickly reviewing the clinical information that had accrued since their last visit. This process would usually take one or two minutes. They would then enter the room, sit across from, or next to, the patient. They would intermittently hand write their clinical note during the interaction. This all changed with the introduction of the computer, and its associated EHR, into the room.

Currently, physicians enter the exam or hospital room, sign into the computer, access the EHR, open the patient's record, and search for the current patient information using pull-down menus and click boxes, and by opening multiple windows. Once the clinician has found the relevant information the interaction begins. The clinician continues interacting with the computer in oreder to view the patient's alerts and reminders, to find additional information, and to enter encounter dropdown, click box, and free text information. On the positive side, it is true that the EHR improves the completeness of the clinical note.(36,71)

It is well known in human factors studies that technology can cause human mistakes and there has been a growing recognition, first documented in 2005, that EHRs can lead to mistakes.(72-85) For example, the EHR allows clinicians to cut-and-paste from previous notes into the current note. This adds out-of-date information to the encounter note, and it can reduces the amount of current information in the note. Out-of-date information makes it difficult to rapidly obtain an accurate understanding of the patient's current status.(86) Cutting and pasting does save clinician time, but at the expense of the clinical quality and the interpretability of the note. In a recent health information technology review, 53% of the studies found that HIT problems were associated with patient harm and death, and near-miss events were reported in 29% of the studies.(87) 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) In addition, it can be difficult to establish and maintain a physician-patient rapport when the visit is a three-way interaction between the physician, the computer, and the patient. Over one-third of patients believe that the physician's use of a computer in the clinical encounter negatively affects physician-patient communication.(88) Finally, the EHR's poor physician usability has increased physician cognitive load, emotional distress, and created an unfulfilling workplace environment.(89)

In terms of clinician time, in order for administrators to obtain the information they want, physicians must enter a great deal of information into the EHR.(90) Physicians find this documentation to be excessive and onerous, they find that it detracts from face time with patients, and they find that it causes them to burnout. (91-92) Electronic message volume is also a huge time problem, especially for primary care physicians, and can lead to exhaustion.(93-95) Furthermore, while cursive handwriting is fast, typing is slow. This means that clinicians spend a lot more time manually typing in the EHR than they would writing in a chart. Currently, physicians spend at least 5.9 hours out of an 11.4-hour work day using their EHR(96-97) and, for the years 2005– 2018, the mean annual per capita patient face time with primary care physicians fell from 33.8 to 30.4 minutes.(92) Furthermore, some of that face time was distracted time, it was typing into a computer and accessing information during the clinical encounter – which reduces the effective amount of time spent interacting with patients and distracts both the patient and clinician during the clinical encounter.(98) The amount of time demanded by the EHR means that clinicians : (1) may be less productive, they may see fewer patients, and they may generate fewer relative value units (RVUs), (2) due to computer-based distractions there can be more mistakes and (3), they may find it difficult to communicate with their patients. Finally, there is the direct effect of EHRs on clinicians. EHRs have created intense work place stress,(99) increased psychological and physiological fatigue,(100) and increased physician and nurse burnout.(101-107) It is little wonder that some physicians have negative feelings toward EHRs.(108)

In 2009, President Obama signed the Health Information Technology for Economic and Clinical Health (HITECH) Act. At that time, the American Medical Informatics Association (AMIA) held a 2009 Annual Health Policy Meeting that focused on the unanticipated consequence of EHR implementation. A recent study looked back at the AMIA meeting and found that it never anticipated the significant increase in physician burnout caused by EHRs.(109)

There are many inaccuracies in EHRs, which can affect clinical care.(110) Whereas handwriting mistakes were relatively easy to detect and correct, inaccuracies in EHRs are much more difficult to detect and correct. (111-112) Once an erroneous piece of information is entered into the EHR it can be very hard to notice it and even more difficult to delete it. Some have advocated for proactive detection of health information technology-related problems(113) while others have advocated for the redesign of HIT systems to reduce mistakes.(113-115)

Both solutions are necessary but both are expensive to implement. It is ironic that one of the main reasons for adopting EHRs was because they would improve safety by eliminating mistakes in the medical record only to find that EHRs have created their own mistakes that can be even more pernicious.(112, 116)

A recent RAND report stated that, "*the current state of EHR [electronic health record] 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*."(90) 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.(117) It was suggested that we should rethink the definition of meaningful use, reduce EHR difficulty, and improve their clinical utility.(118) In other words, EHRs may be necessary but they not sufficient, for increasing the safety and quality of medical care.

Importantly, it was not initially recognized how much EHR systems would cost. The hardware and software are very expensive to buy, maintain, and upgrade. For example, the cost of the U.S. Department of Veterans Affairs EHR implementation will be over $16 billion.(119) In addition, EHRs are very expensive to use because they reduce clinician productivity, lower morale, and increase burnout.

One way to humanize health informatics is to demonstrate its positive benefits to patients and clinicians 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. Furthermore, one of the most important goals of health informatics must be to improve the usability and efficiency of EHRs. Health informatics must develop EHRs that increase clinician productivity, improve morale, and lower burnout.

DIFFICULTY TO READ FREE TEXT HAS LIMITED QUALITY, SAFETY AND VALUE

EHRs contain medically meaningful information. Meaning is defined as any unit of information that is directly or indirectly related to patients. A meaning is one or more words, phrases, and numbers. We would like to extract meanings automatically and systematically from the EHR so that we can improve patient care, safety, quality, and value. In the past, to acquire medical information, an abstractor would have to be hired to audit paper charts. Unfortunately, today, an abstractor still must be hired, only now it is to audit electronic charts. The reason for this situation is because we cannot accurately and reliably read the free text in the clinical note.

Because physicians' free text narrative notes cannot be accurately and reliably read, administrators have resorted to creating boxes that clinicians must check, drop down menus, and structured fields. This fragments the clinical narrative and makes it difficult to find information and to understand patients, their medical condition, and their treatment. In addition, administrative billing/claims data is used to understand physician activity and performance. Unfortunately, administrative data can be incorrect because it misses important clinical information(120) and because it is affected by to payer reimbursement requirements. In addition, there are significant challenges associated with using administrative data for assessing safety and quality.(121) For example, post-op adverse event detection is 12.5% using administrative data and chart review, 24% using chart review.(122) For hospital adverse event detection: administrative data revealed, 171 events whereas chart review revealed 456 events.(123)

Binary Data: Check Boxes

There are three types of information formats in most EHRs: check boxes; structured and semi-structured text (including drop down prespecified text); and free text. Check boxes are labeled binary (present/absent) fields that consist of one or more items related to a clinical problem. The boxes may be related to prevention, signs and symptoms, diagnosis, prognosis and treatment, and outcomes. Check boxes are useful to administrative personnel because: (1) once the boxes are checked, the data can be easily and inexpensively acquired and summed and, (2) the data is already organized in terms of the category or subcategory of the check box.

Check boxes can require a great deal of checking. For example, when a patient present with a medical condition, then 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. In terms of pain, they must check, 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 may 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 may also have to 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. Furthermore, the check boxes may not properly or fully capture the patient's condition. Finally, the more boxes that have to be checked the more possible errors that can occur.

Check boxes can be useful for discrete, simple information but 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 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 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 inserted into the EHR. Semi-structured fields are usually domain-specific limited, pre-specified vocabularies, for example, radiology and pathology reports. Although the text may vary slightly, the predefined vocabulary establishes the meaning.

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 field. In other words, we search a specific meaning 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 limited amount and type 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 write free text, so that they can properly describe the patient, 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 systematic 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, it searches the free text for a target meaning, and it returns as its output a report of the existence or non-existence of the target meaning. There are several problems with finding meaning in text: [1] there are many ways to write or say a meaning, [2] a meaning usually depends on the context, including the adjacent words, and the location in the sentence/paragraph/document, [3] additions to root forms (e.g., prefixes, suffixes), abbreviations, negation, temporal relations, and meanings that span sentence boundaries such as co-reference,(124) and [4] much of the medical free text is written in a telegraphic style that does not follow the canonical rules of English.

There are many approaches to NLP. The three most common are key word, rule-based, and statistical. Note that when the term "word" is used, it can also mean a phrase. Key word and rule-based approaches look for words in the text that match to the target words, whereas, statistical methods rely on learning patterns of words that correspond to the target meaning. A review of NLP methods in 2016 found that 24% used key word, 67% used rule-based, and 9% used statistical methods. (125) Since then the number of statistical methods has increased dramatically and they are now the predominant NLP method.

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 key word is found in the text, then that meaning is present in the text. It can also search for variations of the word, for example, its root form or with a prefix or suffix. The major drawback of this approach is obvious, namely, it is too specific. One must perform a search for every way the word can be written. Furthermore, it does not take into account the adjacent words, such as negation, or its location in the sentence.

In other words, just knowing that a word is present is many times not sufficient for determining its meaning of the text.

Rule-based methods 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.

Statistical methods view the search for meaning in free text as a classification task. Many statistical methods have been used for NLP, including support vector machines, Bayesian conditional probability models, and artificial neural networks (also called artificial intelligence, machine learning, and deep learning). The ways that a meaning can be written are called patterns and these methods learn the patterns associated with a meaning. If a learned pattern is present in the text then we can say that the meaning is present. The patterns can be any combinations of words that correspond to the target meaning. The statistical method trains on text that has is known to have or not have target meaning (supervised learning). The dependent variable is the target meaning. Words or sets of words that are repeated and that are associated with the target meaning (patterns) are learned. The idea is that during training the statistical method will learn to use features in the text to create classes of patterns and to generalize these classes to patterns. The trained statistical model is presented with new free text set and it searches the free text for all the patterns it has learned. If it detects one of its patterns, it reports that the meaning is present in the text. The advantage of this approach is that one does not have to list all the possible ways of representing a meaning in the text, they can be found automatically as patterns.

The main problem with statistical methods is that there is a tradeoff between sensitivity and specificity. The more patterns of words the algorithm accepts the more true positives it finds, but the more patterns it accepts the more false positives it also accepts. In other words, there is a tradeoff between saying that a meaning is present when it is present (true positive) and saying a meaning is present when it is not present (false positive). One can lower the detection threshold for a positive pattern, which will increase the true positive rate, but this will also increase the false positive rate. This means that there is a limit to the accuracy of the resulting model. One way to observe the maximum sensitivity-specificity pair is to calculate Youden's J statistic which relates sensitivity to specificity or by assessing the receiver operating characteristic (ROC).

The maximum sensitivity-specificity pair depends on the difficulty of the problem. Medical free text is very difficult. Currently, the upper limit of accuracy on medical free text is always less that 90% on routine clinical notes. To date, the most accurate NLP is a neural network approach called "transformer."(126-127) Several investigators have applied statistical NLP methods to the detection of adverse events. Fan et al.(128) and Chopard(129) used algorithms to detect named entity adverse events. Both studies achieved moderately high accuracies but both were easy NLP tasks. To date, no published key word, rule-based, or statistical method has performed with a sufficiently high accuracy and reliability that it can be routinely used across all medical free text.

USING HEALTH INFORMATICS TO DETECT, REPORT, INVESTIGATE AND IMPROVE SAFETY AND QUALITY

In most situations, EHRs will not, by themselves, improve the safety and quality of medical care but EHRs are a necessary prerequisite for quality and safety improvement. They are essential for: (1) detecting and reporting adverse events, (2) safety and quality improvement initiatives, and (3) for effective prevention programs.

Although safety events are usually associated with clinicians, outpatient clinics, hospitals, and healthcare systems, they can occur anywhere including in patient's homes, in independent living situations (with or without home care), and in residential care including in assisted living and nursing facilities.(134-135) Finally, we must also focus on the patients and their actions and environments.

Focus on actions rather than events

An adverse event is "*Adverse events are untoward incidents, therapeutic misadventures, iatrogenic injuries or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic or other facility.*"(130) 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.*"(131) A near miss event and an adverse event can have the same cause, which 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.(132)

Historically, safety has focused on events, such as near miss events and adverse events, rather than on the preceding unsafe actions that gave rise to these events. Furthermore, a safety event is usually the result of more than one prior action or inaction and, many times it is the result of a prior triple failure. Thus, one can suggest that the error is really due to a system failure. If we are to prevent the occurrence of safety events, we must focus on the system that allowed the unsafe actions or unsafe inactions that gave rise to the event to occur because once an unsafe event occurs it is too late to prevent it. In other words, the proximal unsafe action was influenced by a series of upstream unsafe actions/conditions/environments. Furthermore, the upstream causes of downstream events may not be known to the clinician and healthcare system as unsafe.(133)

When we move away from focusing on events and shift our focus to actions, we can begin recognizing the importance of unsafe inactions. Unsafe inactions are missed care.(136) Missed care is "*any aspect of required care that is omitted either in part or in whole, or delayed*."(137) 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., or to a workaround to a problem. Because inactions can create safety risks, they must be recognized and incorporated in a safety program.(136,138) Currently, it is very difficult to detect unsafe inactions but, in the future, it may be possible for clinical decision support systems to be trained to detect unsafe inactions.

In terms of hospitals, it is well known that unsafe actions occur frequently throughout hospitals.(139) Many are not reported and, from a system perspective, they go unnoticed.(140) 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 can propose a way to detecting unsafe actions using an automatic clinician decision support system to monitor performance across clinicians. Such a system requires: (1) an electronic safety detection system, (2) that all actions are entered into the system in real time, and (3) that the system analyzes the entered information and reports safety issues in real time. With this system in place an unsafe action or inaction (perhaps not noticed by the performing clinician) will be detected and reported by the system. The system would send a safety message to the clinician and to safety personnel that an unsafe action either has, or is, occurring. This would provide an opportunity for clinicians to truncate, and perhaps even prevent, the unsafe action and for healthcare systems to be improved. A limited version of this system exists in pharmacy computerized provider order entry systems (discussed later). Finally, electronic medical management systems have been investigated in terms of system-related errors. Kinlay et al. found that, for example, such a system failed to properly check for duplicate orders and it was overly relied upon, which also caused errors.(112)

Reporting Safety Events and Actions

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. In the current system, the focus is on 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.(141) Another study also found that few adverse event medication errors were recorded in the EHR.(142) Furthermore, two-thirds of near miss events were reported by a witness and one-third were self-reported.(143) Given that most near miss events are probably not witnessed, this suggests that many, if not most, near miss events are not reported; they are either ignored or dealt with by workarounds. Further support for near misses not being reported comes from medical residents who preferred to discuss an adverse event with their supervisor and at department-led conferences, rather than reporting the event.(144) Psychological safety increases the chance that a near miss will be reported, but the rate of reporting is still low.(145)

The current individual reporting approach is retrospective: it operates on a case-by-case basis, it detects few errors, its incident evaluation and resolution process can miss the correct causes, its process takes a long time and can be expensive, and its long-delayed corrective action can be ineffective. In the current system, the focus is on individuals to detect, report, and correct most unsafe actions.

The opportunity for an unsafe action is, for a properly trained clinician, 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.(146) 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).

Currently, the actions of the most proximate-to-the-event individual is usually blamed for the event. It is said that the individual made a mistake, forgot, exhibited poor communication, did not comply with policies and procedures, and much more.(143,147) In reality, a properly trained medical professional has usually performed the action safely 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 humans and of the many risks inherent in every medical activity. Thus, the event occurred because of several system failures, of which the performer's error was just the last in the series of errors.

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."(148) 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.(113) 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: (1) the option of anonymous reporting; (2) an expert, objective, systematic standardized process to analyze and understand unsafe actions; and (3) feedback regarding that changes were made in the system so that clinicians can feel that they are a part of the safety improvement process.(113,149-156) For physicians to use this feedback they must be well-versed in terms of safety and quality but most healthcare systems do not provide physicians with the time they need to improve their knowledge.(157)

In other words, there is a failure to understand that the real causes of the unsafe action may be: (1) inadequate training and/or supervision by the system, (2) overwork and stressful conditions within the system, (3) distractions and interruptions, or (4) the system's inability to maintain a safe clinical environment. For example, in hospital settings, interruptions are associated with more than 80% of the orders entered into the wrong EHR.(150) Unfortunately, by far the most common response to an unsafe action is to try to change people rather than to improve the system.(143,147,158-159) It is clear that 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. (150,154) There is a critical need for health informatics systems that can monitor healthcare systems and report problems before they occur, rather than blaming competent healthcare professionals.

Quantifying the severity of the reported event, for example, harm, has been difficult. AHRQ 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.(160) A consistent problem in safety is that many of its scales have low interrater agreement. For example, the AHRQ Harm Scale v1.2 has a Cohen's kappa of around 0.50 and raters have a great deal of difficulty distinguishing between severe, moderate, and mild harm.(161)

Finally, in most healthcare systems, the safety personnel are reactive, they spend most of their time filling out patient safety reports, investigating events, and providing documentation. Safety, must become proactive, it must anticipate and ameliorate unsafe situations. It must enlist the frontline clinicians and it must give them the necessary time and resources.(157,162) In conclusion, safety personnel and frontline clinicians must work together using health informatics in order to provide safe high-quality care.

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.(139) 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.

There is currently no consensus regarding which near miss events should be reported and how they should be dealt with.(87, 149) One response is the quick fix because 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 worked and they have competing priorities; taking the time to report an unsafe action may not be their highest priority.(139)

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.(163) 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.

In addition to assessing risk, expert systems can assist in evaluating and eliminating unsafe events by prospectively collecting data on unsafe actions. 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. This 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. This places 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 Reporting

There are several ways to report an adverse event. These include an individual reporting an incident (paper or electronic), auditor-based structured chart review, and safety briefings.(164) Few events are reported by incident or safety briefing, most are reported by structured chart review.(164) The detected events are usually entered into a patient safety reporting system(165) such as the Joint Patient Safety Reporting system.(166) The reporting of incident safety events used to require filling out a paper-based record. This has been supplanted by electronic reporting system forms, for example, reporting in the Patient Safety Reporting System.(167) The electronic safety event report is sent to safety personnel where the event is documented and, if it is a Joint Commission sentinel event,(168) and sometimes even if it isn't, it is investigated and reported.(168) Many factors must be taken into account when developing, implementing and using a patient safety reporting system. They include what should be reported, why it should be reported, how it should be reported, and what should be done with the report.(165,169)

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.(170) That said, patient safety reporting programs have been successful in medicine.(150,156,171-172) But attempts to adapt industry safety approaches to medicine have resulted in numerous practical problems.(173) An important issue 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.(174) This is based on the belief that increased reporting will result in 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. (139) 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.(149) 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.(153) 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.(152) 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."(139) Thus, total reporting is probably not a viable approach in medicine.

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 (CMS) created the Medicare Patient Safety Monitoring System,(175) which, in 2009, was transferred to AHRQ. 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.(175) Shortly after its creation, in 2003, AHRQ developed its 27 item Patient Safety Indicators that screen for adverse events that are likely to be preventable.(176)

Unfortunately, individual reporting and Patient Safety Indicators underreport safety events. They fail

to detect approximately 90% of the hospital events.(177) The Global Trigger Tool (GTT), 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.(177) The GTT 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 GTT has improved the safety event detection process by defining a set of triggers. There is a substantial body of evidence that supports the fact that the GTT significantly improves safety.(177-191) But the GTT is a manual process that has 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 GTT, using information from the EHR, including check boxes and structured fields.(192) 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 an adverse event – 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 GTT's lack of comprehensiveness, GTT does not assess all hospitalized patients. It employs an *ad hoc* search process for the triggers and 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.(193) 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.(194)

AHRQ has begun development of the Quality and Safety Review System (QSRS) to replace the Medicare Patient Safety Monitoring System.(195) 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 QSRS directs reviewers to look for specific information. 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 QSRS 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 (AHRQ Common Formats), and it uses validated rule-based (if-then) algorithms to detect adverse events. The QSRS 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 safety reporting systems is their reliance on human reporters and reviewers. What is needed is for the reporting system to have the ability to detect meaning in free text using a natural language processing program. Furthermore, it needs to operate in real time and to have the capability of notifying clinicians regarding potentially unsafe actions so they can be prevented from becoming adverse events.(195)

Medicine is changing and reporting must keep up with it. For example, the frequency of virtual health (VH), which includes telehealth and telemedicine, has increased over the last few years.(196-197) Unfortunately, although there are efforts to learn more about VH safety and quality,(198) other than mental health, little is known about the safety and quality of VH. Another area of change is the shift from inpatient surgery to ambulatory and outpatient surgery.(199) CMS maintains two separate reporting systems, namely, the Hospital Outpatient Quality Reporting system and the Ambulatory Surgery Center Quality Reporting system – and they only share two quality metrics. In addition, these systems do not consider the difficulty in dealing with infrequent and

low risk procedures. Currently, CMS pays for reporting rather than outcomes.

Many safety program activities and reports are not yet fully integrated into the EHR. Health informatics needs to develop and implement an automated safety reporting system that: (1) is a part of the EHR, (2) can be triggered electronically, (3) automatically populates the safety report, (4) contains a safety expert system to guide the assessment of the event, (5) allows the investigation to be entered into the final safety report, and (6) expands its focus from reporting to assessing pattens of care and outcomes.

Root Cause Analysis

A root cause analysis is a reactive process performed by a safety team that attempts to discover the prior causal events that gave rise to a observed safety event. In addition, it recommends steps that can be taken to prevent the safety event from recurring. TapRoot®(200) is a commercial root cause analysis system. The problem with the root cause analysis approach is that it commits the *post hoc, ergo propter hoc* ("*Since event Y followed event X, event Y must have been caused by event X*.") logical fallacy. As David Hume pointed out in *Of Miracles*, for any effect, there are many possible causes and the effect does not directly point to its cause.(201) Furthermore, in medicine, there are almost always a cascade of causes that result in an observed safety effect.

One way to solve this problem is to use health informatics. A health informatics system can monitor some of the actions occurring in the healthcare system and, when a safety event occurs, prospectively link those prior actions to the subsequent event. Another approach is to create a comprehensive list of all the antecedents, regardless of their possible relationship to the event, and place them in an algorithm that models the event and provides the probability of each antecedent being related to the event.

Safety and Quality Measurement and Information Display

Measurement is based on the Ancient Greek idea that if something cannot be named it cannot be controlled – quality management has accepted this idea with a twist – if it cannot be measured it cannot be improved. 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.(202) It consists of a set of quality measures that assess how well patients are being cared for by clinicians and healthcare systems. HEDIS uses defined and structured field searches, surveys, and self-reporting. In addition, the CMS Quality Payment Program (QPP) uses quality measures to justify payment.(203) Unfortunately, many small and medium medical practices cannot afford to comply with the CMS requirements. They must either accept less revenue or form cooperatives in order to provide the required information. Richardson found that many practices are joined cooperatives in order to meet eCQM reporting requirements.(204)

Most medical organizations collect EHR data that is the basis for process and outcome measures.(205) But electronic clinical quality measures (eCQM) from EHRs are not always reliable.(206-208) Schmaltz assessed the reliability of EHR-extracted data elements to chart-abstracted data and found only moderate agreement.(209) Although process measures are not always reliable, they tend to be more controllable than outcome measures because the healthcare system can directly control processes of care, whereas, outcomes are affected by many factors including patient behaviors.(206-208,201-211) In fact, it has been suggested that outcomes, at least in cancer, are not a good measure of quality.(212)

The data for these measures are periodically aggregated 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.(213) Although apparently a very simple task, in reality, the communication of actionable safety and quality information is devilishly difficult. There are intense issues regarding what to display, how to display it, and what the display means.

In the past, the development of electronic dashboards has been primarily *ad hoc*. Administrators usually targeted specific measures for performance assessment and the targeted measures drove the creation of dashboards. Initially, dashboards represented the monitoring of administrative activities such as resource utilization, but over time they were expanded to include safety and quality measures. Typically, there was no explicit plan regarding how to operationalize the organization's safety and quality objectives in terms of an integrated systematic set of aggregated measures and there was little recognition regarding whether the dashboard was for strategic, tactical and operational use.(214) Furthermore, an evaluation method to determine whether the organization's dashboard goals had been met was rarely present.(215) 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.(157,216) In addition, there was little understanding of significant intellectual, financial, and personnel resources necessary to create an effective dashboard.(214) Finally, there is little empirical evidence for the utility of dashboards. (215) Recent reviews have found that most of the dashboard literature consists of dashboard descriptions and individual case reports rather than empirical studies.(214-215) A review of dashboard effectiveness concluded that there is limited evidence that dashboards integrated into electronic medical records systems, and used as feedback or decision support tools, are associated with improvements in medical use and test ordering.(217) 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. Finally, health informatics is at its best when it operates in real time and when its information drives immediate actions that prevent or ameliorate an unsafe action.(218) Unfortunately, dashboards rarely provide real-time data and it is even rarer that they drive immediate action.(215)

Clearly, there are tens of thousands of medical activities that can be measured to determine if the activities deliver safe, high quality, high value medical care. All of which can be targets of a quality improvement project if they do not deliver safe, high-quality care. For example, for safety, we can assess the rate of unintended retained foreign objects after surgery; for quality, we can assess the frequency of indwelling urinary catheters in hospitalized patients; and, for value, we can assess the rate of MRI testing in the context of lower back pain. One can ask, what was the rationale for the selection of each of these measures and for the 20, or 50, or 100 other measures that comprise their dashboard? Perhaps it was to assess the most frequent activities, or to assess the most easily measured activities, or to assess the most expensive activities, or to assess what the government, for whatever reason, chose to be assessed. Let us now suppose that, after years of work and a great deal of time and money, we drive down the frequency of one or more of these activities. What is the next step? Is it to focus on another activity, and then another, until we have measured and changed thousands of activities? This is best described as a whack-a-mole process. Once a mole is whacked another pops up and we whack it, and then another and we whack it, ad infinitum.

A better approach is based on the type-token distinction. The idea is that a specific medical activity is a token of a type of medical process. The goal is to use the token to learn about, and improve, the type. In other words, an activity would be selected that indexed a medical process and what is learned by improving the activity will be used to improve all the activities that are within the domain of that process of care.

QUALITY IMPROVEMENT PROJECTS

The goal of most, if not all quality improvement projects is to reduce the rate of a measured safety event to zero.(219) 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 healthcare 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.(220) Furthermore, the American College of Surgeons pointed out that, although many reported quality improvement projects involve large organization, most projects are local, occurring within one hospital, most are poorly funded or unfunded, and they are run by front line clinicians rather than by quality professionals.(221) The American College of Surgeons proposed a framework for small local quality improvement projects. Finally, few studies that assess the project's potential for success and discover its unintended consequences are performed prior to starting a quality improvement project. Interestingly, neither the JAMA Internal Medicine study nor the American College of Surgeons framework even mentioned the critical role that health informatics plays in quality improvement.

CLINICAL DECISION SUPPORT SYSTEMS

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*.(229) It described many of the current diagnostic problems and it recommended ways to improve diagnostic accuracy. Clinical decision support systems 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.*" It should be pointed out that, in order to achieve the envisaged automated clinical decision support system, a highly accurate natural language processing system will have to be in place.

Although it was asserted that the elimination of the paper chart by the EHR 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 is not without its own problems. For example, the cut-and-paste function has made the patient record less intelligible, there are typing errors, and clinicians are having a hard time using EHR systems. But the EHR cannot be abandoned, instead it must be improved, because it is necessary for the development and use of most clinical decision support systems (CDSS). In the last decade, advances in safety and quality have largely been due to quality improvement projects and CDSSs that have been built into, and rely upon, the EHR.

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.*"(222) Full-fledged CDSSs have a graphical user interface, contain a functional algorithm, and display the output of the algorithm. The algorithm can be a human-constructed system of it can be a trained statistical/probabilistic model that 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) From a safety and quality perspective, the basic idea is that CDSSs provide physicians with information that can be used to prevent or ameliorate unsafe actions or inactions and they can provide the healthcare system with information that can be used to improve overall quality of care.

Early clinical decision support systems were autonomous because there was no EHR for them to be integrated into. Other than the importation of laboratory data, all data entry had to be performed manually by clinicians. With the advent of the EHR, CDSSs have sifted to integrated systems that acquire data from the health record database. Unfortunately, because free text is usually not reliably read, these data are usually acquired from checkboxes and structured fields.

Today, autonomous or semi-autonomous CDSSs exist for some medical tasks, for example, in dermatology, where 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.(223) More recently, they developed an app that can provide a dermatologic differential diagnosis based on images.(224) 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 contains 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%.(225) CDSSs such as VisualDx, MyDermPath, YouDermoscopy are currently in use.(226) It is important to note that, in the realm of prediction, images are the easier to predict (identify) than outcomes because they possess spatiotemporal

Table 1. In terms of data acquisition, there are two main types of CDSS.

Autonomous systems: they operate independently of the EHR. They require that an individual manually input the data and receive the results. Historically, autonomous systems have been used for diagnosis.
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 (discussed below), laboratory and radiographic test results and, (b) clinician alerts, reminders, and checklists. Integrated systems allow for the automated detection of safety issues in order to prevent their occurrence and to ameliorate their effects. An integrated system can operate in one of two modes: (i) in batch mode, where it periodically accesses, analyzes and reports its results or (ii) in real-time mode, where it continuously accesses, analyzes, and reports its results.

contiguity – which means that adjacent information can be used to assist in image identification.

Although there are some autonomous CDSSs today most are integrated into EHRs. They operate on structured fields and check boxes, and on laboratory, radiology, and pathology data. Furthermore, these CDSSs can be running in the background in real time during the patient encounter – assessing and responding to information entered into the EHR. It is the CDSSs real-time monitoring and response system capability that make it a potentially very powerful safety and quality tool. Examples of integrated systems are medication computerized provider order entry systems (CPOE) and alerts, reminders, and check lists.

Medication errors are a tremendous safety problem. Published in 2007, the Institute of Medicine's *Preventing Medication Errors,* presented information regarding the incidence and cost of medication mistakes.(227) 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 to which the patient was allergic.(228-229) A recent study examined some of the factors related to physician medication errors.(230) It found that of 1,652,896 medical orders prescribed by 1066 physicians, 3738 (0.23%) prescriptions as erroneous. Physicians were 8.2 times more likely to make an error during high rather than normal-low workload shifts and they were more likely to make an error for medication they lacked experience with. Elliott estimated that in England 237 million medication errors occur at some point in the medication process annually, 38.4% occurring in primary care; 72% have little/no potential for harm and 66 million are potentially clinically significant.(231) Avoidable adverse drug events (ADEs) avoidable ADEs [adverse drug events] are estimated to cost the NHS £98 462 582 per year, consuming 181 626 bed-days, and causing/contributing to 1708 deaths. A recent study estimated that, annually in England, using UK National Health Service data found that there are 627 deaths in primary care due to ADEs and 1081 deaths in hospitalized patient and secondary care were due to ADEs.(231)

Medication Computerized Physician Order Entry (CPOE) systems are electronic systems that are integrated into the EHR and allow physicians to electronically order medications. They usually contain expert systems that evaluate the safety of the order using rules and information from the patient's EHR and that transmit alerts to the clinician when a potentially unsafe action (medication order) is occurring. CPOE systems have been shown to reduce duplicate medications, drug overdoses, adverse drug-drug interactions, and the prescribing medications that patients are allergic to.(232-237) A recent meta-analysis of CPOE systems in the intensive care unit found an 85% reduction in medication errors by clinicians and a 12% reduction in mortality associated with the computerized provider order entry system.(238) A CPOE system has been shown to improve medication documentation.(239) Furthermore, Colombini found that that when hospital discharge medication orders, after having been reviewed by a pharmacist, where edited by a CPOE, there were fewer prescription errors.(240) Finally, a recent study of 10,535 pre-CPOE medication orders and 13,841 post-CPOE medication orders found that CPOE reduced the proportion of orders with one or more errors by 30.1%, which included a 20.1% reduction in dosing errors, a 18.9% reduction in procedural/administrative errors, but only a 2.6% reduction in therapeutic errors.(241)

But computer-based systems are not perfect, they can make mistakes.(87,116) CPOEs can be the source of two types of errors: "(1) errors in the process of entering and retrieving information (e.g., interfaces that are not suitable for a highly interruptive use context, that produce cognitive overload by requiring structured information entry, that fragment information onto different screens, and that overemphasize information about a patient that is not useful), and (2) errors that come from a mismatch between the structured communication and coordination processes embedded in digital systems relative to the highly flexible and fluid ways in which clinical work happens in reality."(242) Furthermore, CPOEs can create duplicate prescriptions, miss wrong dose and wrong drug, generate mistakes related to drop down menus,(228,243-245) and alerts can malfunction.(228, ,243-246) It had been thought that adding additional CDSS capabilities to a CPOE systems would offer additional safety and quality benefits, but CDSSs did not provide any additional benefit.(247-250) 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.(236) Simple measures, such as checking the prescription with the patient at the point of sale, can reduce these mistakes by 56%.(251)

Another form of CPOE is the system related to the ordering of laboratory and radiology tests. Whereas,

ordering medications dealt with safety, laboratory test ordering systems usually deal with quality and costs; reducing unnecessary testing in order to reduce the volume of tests patients undergo and the cost of testing. A recent study used a CDSS to detect tests with a high repetition probability, or great complexity, or which were mutually incompatible within the same order.(252) 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.(253) 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 or they would invent a workaround. In order to improve the functioning of test ordering alerts, Bellodi et al. developed machine learning models that automatically predicted whether the clinician would accept the CDSS's advice.(252) They found that their predictive models, which targeted CDSS alerts, could substantially reduce clinician alert burden while maintaining most or all the CDSS benefit.

There are many kinds of alerts, including interruptive, facilitative interruptive, non-interruptive, and graded or tiered alerts.(255) Unfortunately, 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.(256-262) Cerqueira assessed the effectiveness of interruptive medication-prescriber alerts in changing prescriber behavior using a CPOE system.(263) They found that alerts were effective in changing prescriber behavior but it was not clear whether the interruptions themselves led to errors or whether they even improved outcomes. Furthermore, there is a tradeoff between safety and alert fatigue.(264) Alert fatigue has significantly reduced clinician enthusiasm for medication alerts.(256,262,265)

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.(266) 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.(267) 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. (268) 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.(269) Checklists sequentially focus clinicians' attention on specific tasks. 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. They have been used in surgery,(269) in rounding in intensive care units,(270) and for cross-checking in emergency departments.(271)

Surgical checklists can reduce preventable medical mistakes.(269,272-275) When they are used, patients have better postoperative outcomes.(276) They reduce the rate of complications, reoperations, and readmission. They have a positive impact on the clinician outcomes of communication, case understanding and safety, and on the patient outcomes of complications and mortality.

Recently, computer-based interactive, dynamic, adaptive safety checklists have been developed, many of which are linked to the EHR.(277-281) 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 that: (1) it can tell if an action was done or not done but it cannot tell if what was done was what was supposed to be done and it cannot tell whether it was done correctly, (2) checklists are time consuming, and (3) checklists can disrupt an established workflow.(282-283) Some have found that some checklists are not relevant to the medical activity, that they are too long, and that they are not integrated with the daily work flow.(270)

Checklist compliance is many times reported as high but these reports of success are rarely accompanied by empirical support. Empirical evidence has been adduced

to assess checklist compliance. In an audio-recorded assessment of their use, Salgado found that, although the reported compliance rate was 97.5%, the actual compliance rate was only 73.6%.(284) Furthermore, using video recordings, Kulp identified three non-compliant checklist use behaviors: failure to check items for completed tasks, falsely checking items when tasks were not performed, and inaccurately checking items for incomplete tasks.(285) A recent observational study in 11 hospitals and consisting of 715 valid observations, found that only 71% of the checklist items were read off from the checklist, the rest were recalled from memory.(286) Two of the items were only readout 74% and 60% of the time. Visual checks with another source, for example the patient wristband, occurred only 41% of the time and verbal confirmation of the items on the checklist by someone other than the checklist coordinator occurred, on average, 76% of the time. The surgical teams' reaction to the peer feedback was only 64% positive. 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.(282)

How well the CDDSs are implemented can have a profound effect on their acceptance and use.(111,287-289) For example, in an odd twist of fate, the CPOE prescription system used at a major teaching hospital in France crashed and they had to return to a paper-based order system.(290) 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.(111,291) Finally, because clinical decision support systems 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)

Molecular biomarkers (including proteogenomics which are constitutive of many disease processes) have the potential to allow us to better understand, predict, and treat disease. Currently, there is limited collection and reporting of molecular biomarkers. The use of molecular biomarkers is accelerating and will soon be routinely collected and entered into patients' medical records. This molecular biomarker use will allow CDSSs to become more powerful and more clinically useful.(292)

Real-Time Systems

Although medication alert and reminder systems operate in real time, they are just the initial steps in the development and implementation of real time CDSSs. We would like to have the following:

1. Clinician-patient clinical encounter: This system takes as its input the real time natural language information added to the EHR by the physician during the physician-patient interaction.(241) 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 physician while the interaction is in progress so a safety event can be prevented.
2. Medical procedure: This system takes as its input audiovisual information produced in real time during the procedure and adds it to the EHR. The CDSS continuously monitors the participant's activities input in real time in order to detect unsafe actions and conditions and to report unsafe actions and conditions to the physician while the procedure is in progress so that a safety event can be prevented.

Decision Aids for Shared Decision Making

Patients need information in order for them to participate in the shared decision-making process. This information can be provided by decision aids. The World Health Organization has created the International Patients Decision Aid Standards process(293), which may be customized by disease and other factors.(294) Esmaeili assessed 16 mammography decision aids and found that they improved knowledge and informed choice, they decreased decisional conflicts and increased decisional confidence, but they did not affect attitudes towards mammography, mammography participation rates, psychological issues, anticipated regret, or perceived risk of breast cancer.(295) In terms of womens' motivation for screening, decision aids only an effect in rare cases. Furthermore, a recent study provided moderate-quality evidence that decision aids, compared with usual care, are associated with only a small decrease in decisional conflict and low-quality evidence that they are associated with an increase in knowledge but they did not help with whether physicians and patients discussed prostate cancer screening or with screening choice.(296) Keikes successfully implemented a decision aid that consisted of a consultation sheet and web-based tailored information for metastatic colorectal cancer treatment options.(297) They implemented it at 11 Dutch hospitals. They achieved adequate patient participation and patient and medical

oncologist satisfaction but the oncologists and patient login rates varied widely between hospitals.

A recent evidence review of 71 patient decision aids found that "the evidence identified for our decision aids was indeed a "scattered landscape" and often poor quality.(298) Facing a high prevalence of low-quality, non-directly comparative evidence for treatment alternatives doesn't mean it is not necessary to choose an evidence-based approach to inform patients. While there is an urgent need for high quality comparative trials, best available evidence nevertheless has to be appraised and transparently communicated to patients."(298) Decision aids have been used to decide whether the patient should undergo an elective joint replacement.(299) The use of decision aids has been shown to reduce the rate of hip and knee surgery, thus reducing medical utilization and costs.(300-301)

One way to improve decision aids is to make them part of a CDSS. In other words, instead of the CDSS just providing the physician with the decision-related information, have it also provide the patient with the relevant decision-related information. For example, the CDSS can 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.

U.S. Food and Drug Administration

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 medical hardware and software. The Food and Drug Administration has been interested in medical software, including clinical decision support systems, for many years. It held hearings and provided guidance in 1998, 1999, and 2002.(302-304)

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*."

Shortly after the 21st Century Cures Act, the FDA released three guidance documents, including "Draft Guidance for Industry and Food and Drug Administration Staff."(305) It accepted the Act language and went on to state that software that analyzes medical images or laboratory or medical tests would remain under FDA oversight. The FDA agency has proposed changes to previously published regulatory guidelines covering general wellness and mobile medical apps that pose a low risk for patients. They have also established a common framework for regulators to evaluate software as a medical device based on the overall risk of the product. The FDA plans to provide its final guidance in 2022. The Act not only made many medical software products legal, but it also opened the field to tremendous innovation.

FUTURE TRENDS

Health informatics will at some time in the future develop an accurate NLP program. This advance will allow for the automatic detection of meaning in free text, which will drive the redesign and improvement of the EHR – hopefully making it more clinician-friendly. It will also advance safety and quality because programs can be developed that ingrate free text detection and reporting systems into the EHR. Furthermore, predictive modeling and machine learning, through their integration into CDSSs, will become part of the everyday practice of medicine. These CDSSs will improve risk (including prevention), diagnosis, and prognosis (including treatment) predictions. Furthermore, they will operate in real time and alert clinicians to actions that may place patients at risk.

CONCLUSIONS

We have shown that health informatics is a vital and necessary part of safety and quality. Furthermore, that EHRs and CDSSs can provide physicians with real time information that can improve the safety and quality of their medical care. But there are problems that must be addressed. For example, 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 centralized 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."(306) Indeed, health infor¬matics must move beyond measuring selected clinical activities and being administrative tools designed to increase revenue and reduce costs. It must be accepted by physicians which means that it must make life easier for the physician while, at the same time, helping them improving their medical care and, as a consequence, improving safety, quality, and value.

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