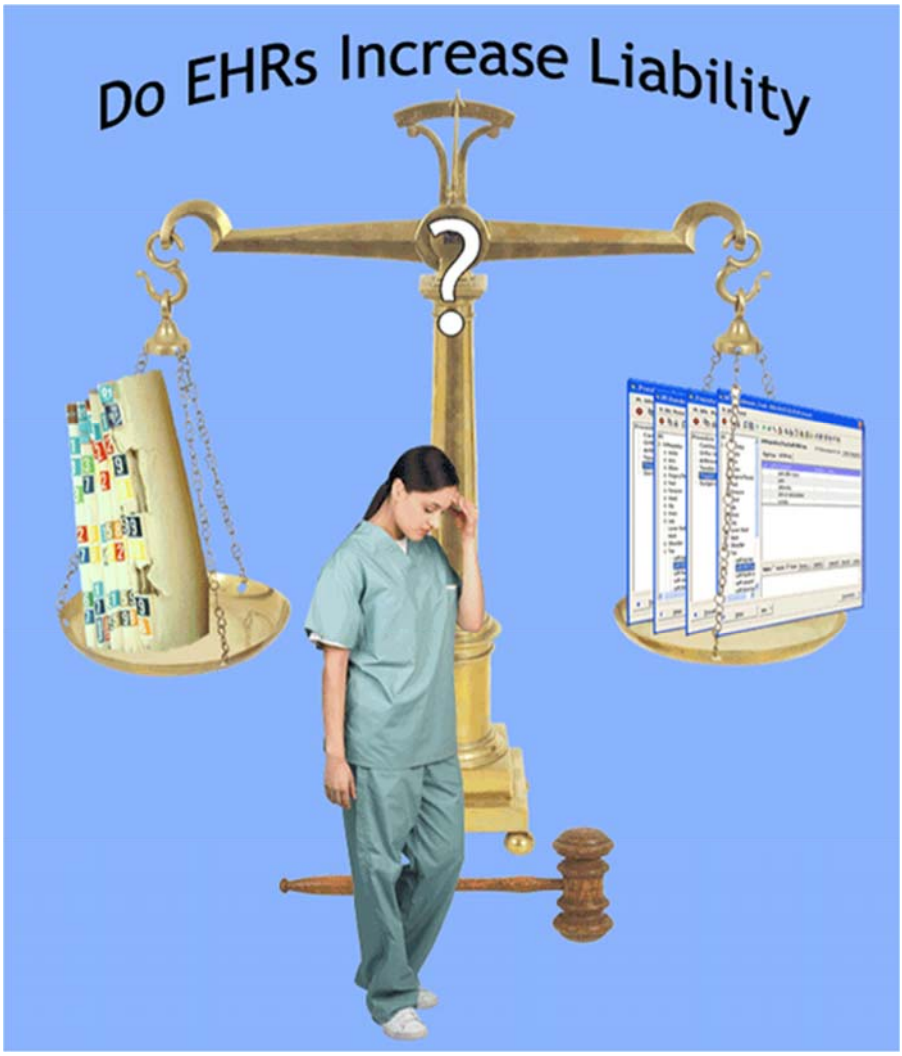
Do EHRs Increase Liability
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Do EHRs Increase Liability?

Executive Summary

In the past 18 months, there has been an uptick in the number of malpractice claims filed against providers that are using established Electronic Health Record (EHR) products. In fact, the problem has led a few Medical Liability Carriers to consider **raising** the cost of medical malpractice insurance for physicians using an EHR. Just a few years ago, these same Medical Liability Carriers were offering physicians a discount for implementing an EHR. So why have EHR products transformed from being the beloved darlings of Medical Liability Carriers to scary stepchildren?

This white paper explores some of the leading factors. Let's begin to explore this issue by looking back at the history of EHR products.

President George Bush announced to the world in 2004 that Health Information Technology (HIT) had become a national priority. After much applause and interest, little was done to promote this priority until the 2009 ARRA "stimulus" legislation provided up to $36 billion for HIT. With the sudden influx of potentially billions of dollars, short time tables, and an insufficient work force for the task, many individuals with limited expertise have entered the industry. The lackluster economy has increased the individual motivation to "follow the money".

HIT implementations have suffered high levels of failure. As many as 70% of implementations will suffer a significant cost overrun, a major delay, a failure to achieve a significant goal or objective, or an abandonment of the entire project. In this post-incentive environment with constrained timelines, the number of HIT projects expected to fail is very large. Regrettably, it is likely that patients will be harmed in the process. The likelihood of legal action in many venues and on an unprecedented scale is comparably likely. This paper describes several legal risks, suggests the expertise that will be required to mitigate those risks, and proposes methods to support at-risk organizations.

As more providers adopt new EHR technology, software design flaws will be identified as the systems are tested. Data coding errors, implementation challenges, and operation failures will occur as the systems are utilized. These errors should decrease over the long term as insurers, providers, and vendors monitor the new systems and develop process improvements, but there will be early challenges that will also serve to develop case law through legal action. Medical liability claims may also increase as patients gain easier access to their electronic data and discover that their provider may not have followed one or more treatment protocols that are embedded therein. The authors expect that the cost of defending against these claims will increase as more attorneys use electronic legal discovery for both the data and the metadata. These factors are likely to drive up the cost of medical liability insurance until:

1) the software vendors effectively resolve numerous medico-legal flaws and limitations in their EHR technology and

2) best practices in selection, implementation and operation become wide spread.

Until these challenges are addressed, medical liability insurance costs are likely to increase even faster than historical controls in order to compensate the liability carriers for **their** increased professional liability payouts.

This white paper identifies several medico-legal issues posed by EHR adoption that should be addressed by those who wish to minimize the risks to vendors, physicians and the medical liability industry. The authors encourage each at-risk organization to perform a liability assessment within the next 12 months so that they do not become the losing party in new case law.

Do EHRs Increase Liability?

Introduction

Health Information Technology (HIT) has a history dating back almost 50 years to its origins in bioinformatics. The earliest HIT pioneers considered how best to encode and store information about patient treatment, but were limited primarily to basic science research projects or managing patients in their own institutions. Only in the last 30 years have there been an increasing number of larger corporate interests, developing products intended to reach a broader industry audience. Despite several decades of development, marketing, and sales, penetration into both the hospital and medical practice environments has been limited and fairly stable.

There are many reasons attributed to the challenge of selling a commercially viable HIT solution into healthcare organizations:

- inadequate involvement of end users in development (see NIST usability study)
- high software cost
- high cost infrastructure needed to support HIT
- increased personnel costs during the selection and implementation stages coupled with revenue reduction due to lowered productivity during those stages
- change management challenges coupled with limited education and training of stakeholders
- poor clinician training because trainers are often not clinicians

These factors, and many other factors not noted, have limited the broad adoption of HIT in the healthcare industry. Ultimately, technology that benefits organizations is adopted widely when it makes the process that it is replacing **cheaper, faster, better,** or **easier**. Regrettably, few HIT software products have demonstrated more than one of these benefits and none has demonstrated all of them simultaneously. The benefits of Electronic Health Records (EHRs) have frequently been touted, but have not been reliably reproduced in settings different from the original studies. For example, studies in academic medical centers have not yet been reproduced in tiny; resource limited critical access hospitals or small provider offices. It is likely that the resources of each environment have an impact on the ability of the organization to benefit from the potential of the technology. Patient harm induced by technology also has been seen, such as when critical pediatric patients had medication delayed. It is likely as HIT becomes more widespread that more complications will be seen. In this environment, sharing information about problems and challenges would both inform others of their possibility and potential solutions, thus improving all implementations and reducing systemic risks.

In this environment of change, the 2009 ARRA stimulus legislation included billions of dollars to support the implementation and meaningful use of EHRs. ARRA also offered limited support for integration of patient health data through Health Information Exchange (HIE). This huge potential influx of capital has created an environment of businesses desperate to capture these dollars, regardless of the skills at hand. It has been estimated that the nation needs about 50,000 trained HIT workers, which some of the stimulus money has been dedicated to train. Effective selection and implementation processes to support HIT are not rapid. The timelines required in the ARRA legislation to obtain the stimulus dollars are unreasonably short and are likely to induce errors in the selection and implementation process of many healthcare organizations as they look for ways to cut corners to meet the deadlines with the limitation of resources at their disposal, especially as they move to stages 2 and 3 of meaningful use.

Do EHRs Increase Liability?

The fairly limited adoption of HIT has been due primarily to the limitations of the technology itself. Now there are financial incentives to adopt technology, regardless of its potential negative impacts. In this environment, promoting technology that may not be quite ready, in the face of inadequate personnel, limited funds, and shortened timelines for selection and implementation, it would be surprising if mistakes were not made.

Historically, 70% of HIT implementations fail due to cost overruns (negatively impacting spending in other areas), delays (negatively impacting revenues and use of personnel and other resources), missing critical functionality, or project abandonment. In this current environment, the failure percentage is likely to be higher than usual due to the rush to meet the short timelines.

A secondary impact of this rush is likely to be policies or design decisions that inadequately account for the risks of patient harm. Certainly this will not occur in every institution, but if these failures occur in only 1% of organizations, the negative results could impact thousands of patients every year. Equally concerning is the limited number of healthcare institutions that are openly discussing their risks in a proactive manner so that they can address their limitations in a timely fashion.

As in other situations where inadequate time, money or resources are available to accomplish the task at hand in the safest manner, it is often left to the legal system to sort out who was responsible for the harm that occurred. There will be a need for experts to assist the legal system in teasing out responsibility on the one hand and identifying when best practices were employed on the other hand, even though a bad outcome occurred.

In 20150, a report by Conning Research and Consulting[1] found that the increased adoption of EHRs by hospitals and medical practices may indeed drive up the cost of medical liability insurance, at least in the early EHR adoption phase. The researchers at Conning believed that documentation errors and the EHR software design will drive up medical liability claims and the cost of defending them, thus driving up the cost of medical liability insurance. According to the 20150 report, even though more than 50% of the medical practices had purchased an EHR, 90% of both hospitals and medical practices had not yet implemented EHRs that meet federal meaningful use standards.

As more providers migrate to new EHR technology that meets the meaningful use requirements, errors will be made, design flaws will be identified, and operational failures will occur. Over the long term, vendors, providers, and insurers will improve their processes and products. Until then, early challenges will become the basis of new case law through legal action.

Underwriters for medical liability insurance are concerned that software failures and medical coding errors may occur more frequently during the early stages of EHR implementation, which could lead to an increase in medical liability claims. The authors predict that the frequency of such errors will decrease over time.

[1] For more on the increased costs of medical liability insurance to be potentially caused by EHRs, check out "20150: Medical Professional Liability in a Changing Health Care Environment - The New Story Unfolds," a new report from Conning, and "e-Records Make Insurers Jittery," a recent article on the report from Nextgov.

Do EHRs Increase Liability?

Analysis

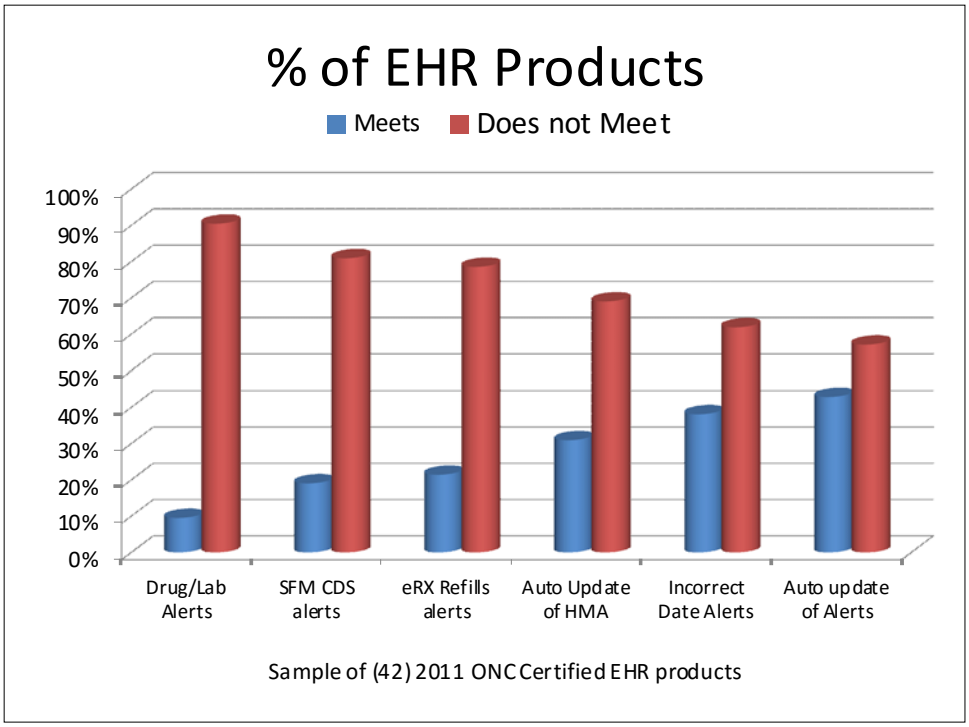
EHRs offer considerable opportunities to improve outcomes and reduce costs, but they also raise new medico-legal issues that must be considered. As is often the case, technology is advancing more rapidly than our ability to identify and address the medico-legal issues. The result of this uneven progression is that physicians and other stakeholders may be unknowingly exposed to medical liability risk.

Some EHRs may be office-based and accessible by only one physician and their office staff. However, where the EHR is more complex, the medico-legal risks of the EHR may be broader than for paper. When an EHR is used as the medical record for a large interdisciplinary clinic, the EHR of one physician or clinic may be linked to one or more other physician or clinic EHRs, or a core data set of information from the EHR may be automatically uploaded to an EHR. This is similarly true in a functioning Health Information Exchange (HIE). The privacy risks expand for EHRs relative to paper because they can exist virtually in multiple physical locations simultaneously. Physicians adopting EHRs face several areas of uncertainty that need to be addressed by the professional medical associations, EHR vendors, IT support structures (internal departments or hired consultants), risk managers, and the medical liability industry:

- Who is responsible for entering, managing, and monitoring the data in the EHR?
- What are the patient's rights and what expectations can they reasonably hold with respect to the privacy of their personal health information in an EHR? Do patient's rights vary by state?
- What are the physician's obligations to obtain patient consent for the use and disclosure of information in the EHR to local and regional HIEs or to other providers? For what purposes?
- Can a physician rely on information in the EHR contributed by other health care providers? What is the consequence of relying (or not relying) on medical information that was provided by another care provider or the patient electronically?
- If information in the EHR is used in patient care and found to be inaccurate, what is the provider's legal liability? How does that change if the information came from another provider, either directly or via HIE? How does the liability change if harm is a consequence versus when no harm occurs?
- If information in the EHR from another provider is presumed to be inaccurate, possibly based upon prior inaccuracies, and is **not** relied upon in treatment, but a harmful outcome occurs, is either provider legally liable?
- What is a provider's liability for not relying on information in a PHR (Personal Health Record)?
- What is the medical liability issues arising from these and other questions?

As medical practice moves from traditional paper-based patient records to an electronic version of the record, physicians may also be challenged to meet patients' privacy expectations. Failure to do so may now carry HIPAA permitted civil penalties.

Do EHRs Increase Liability?



Note: The chart above shows what percentage of the evaluated 42 EHRs had the ability to provide needed alerts.

There are more than 675 vendors selling an EHR product in the US Marketplace. As of 1 October 2015~~4~~, there are 499 ONC 2014~~4~~ certified complete EHR products[2]. This certification does not mean that each vendor's product is the same. In reality, the 2014~~4~~ ONC certification includes only basic functionality, far more limited than the functionality required by the 2011 CCHIT full certification. As stated in the AC Group's 2016~~4~~ Digital Medical office of the future" book,[3] "the ONC 2014~~4~~ certification is like getting your kindergarten certificate, while the CCHIT 2011 certification was like getting your college degree". Though most EHR vendors can pass the minimal ONC 2014~~4~~ certification, only an estimated 10% of the EHR vendors would pass the 2011 CCHIT certification. It is worth remembering that the ONC 2014~~4~~ certification does not look at usability, company viability, or strength of implementation and training. No certification entity is looking at the numerous medical liability issues that have been identified, even though a direct study of 50 EHR products suggests that these issues would be found in approximately 80% of the EHR products on the market.[4]

[2] http://onc-chpl.force.com/ehrcert/EHRProductSearch

[3] http://www.acgroup.org/2016~~4~~pmsehrreports.html

Field Code Changed

[4] Source: AC Group 2016~~4~~ EHR product functionality survey.

Do EHRs Increase Liability?

Do EHRs Increase Liability?

There are many liability risks in existing EHR products. For example, when:

- clinical notes do not highlight the most important patient issues – too many "normal" indicators
- it is so easy to identify a medical condition as normal, the default setting, that some areas not evaluated and actually abnormal are incorrectly documented. Clinical notes have expanded from an average of one page to eight pages, making it harder to find relevant data, not easier – there is more data, but usable information is harder to find
- EHRs do not include an area for documenting the provider's actual thoughts, the actual "medical assessment", only an area for documenting the final diagnostic charge code(s)
- cutting and pasting clinical findings from one section of the EHR to another, or from one patient to another, results in the entry of incorrect information into the patient's record
- failing to adjust from paper-based documentation practices; physicians might document events before they actually occur
- a dictated progress note is entered for the wrong patient in an emergency – this error may not be corrected if the system does not require anyone to subsequently identify the patient once there is time to confirm their identity
- during the discovery process of a malpractice claim, the printed record shows the current information, but **not** the information that was available to the provider at the time the care was rendered
- an emergency room physician documents patient care four hours after actual treatment, but the system records the entry as occurring at the time of treatment
- time synchronization between different electronic charting systems is lacking – for example, one time sequence might indicate that a child was born before the C-section was performed

- audit trails suggest that providers are not reviewing all of the data because they accept options every 1-2 seconds – this reflects the down side risk of the vendors' claim that "it's easy"; a plaintiff's attorney can ask, "How much time did you spend looking at the results?"
- relying on the failed electronic capture of physiological data, an anesthesia care team fails to document 90 minutes worth of vital signs
- actual documented patient clinical data doesn't flow from one section to the next (e.g. to Medical History, ROS, HPI, PE, or Assessment). For example, if 2 years ago the patient had their foot amputated, but the ROS and the PE indicate that the extremities are normal, something is amiss
- data in the HPI and ROS conflict with social, family, and medical histories without generating an alert
- medical guidelines and best practices are not updated automatically, e.g. as evidence changes
- the EHR fails to alert providers to medication issues based on specific lab results, for example, failing to show a recent serum creatintine when ordering gentamicin.
- prescriptions are refilled without checking for important changes in chronic conditions, labs or other medications since the initial prescription
- social, family, and medical histories don't support alerts or Clinical Decision Support (CDS)
- providers turn off alerts because there are so many of them, causing alert fatigue / overload

Do EHRs Increase Liability?

It is no secret that there is a tendency for the average United States citizen to see only a negative outcome, without regard to how they might have contributed to that outcome. Similarly, it is no secret that there are litigators champing at the bit for their big payoff. The malpractice business is a huge one, with the cost of medical malpractice litigation increasing at nearly 12% per annum since 1975 (20150 national medical malpractice report). While medical costs have increased by 113 percent since 1987, the amount spent on medical malpractice insurance has increased by just 52 percent over that time.[5] Without national tort reform, there is every reason to believe that these costs will continue to increase at a similar rate for years into the future. In fact, in order to differentiate themselves from other litigators, some consumer attorneys may seek out new niches, like EHR liability, in which to become experts.

As EHRs become the norm, EHR metadata could present a new legal risk. Unlike a paper based medical record, an EHR leaves an electronic audit trail showing who entered the data and the time when a document was opened and modified, who deleted or edited any of the information. More importantly, the authors have found multiple reporting errors in EHR products in the final patient clinical note. For example, some audit trails only show the time stamp for the most recent change. If this information is used in a medical malpractice case, the data could force physicians to defend not just their final product, but the entire medical evaluation process.

The authors have documented multiple process and software issues:

- incorrect automated clinical order systems
- inaccurate clinical decision support (CDS)
- multiple mismatches between workflow and clinical information systems
- juxtaposition errors (e.g. mistakenly selecting an adjacent patient name or medication from a list)
- mismatched data (e.g. the ROS and Medical History conflicts with the HPI and the Physical Exam (PE))
- an "illusion of communication" (e.g. when physicians assume that medications that were ordered have been administered or that order entry implies that others will see and fulfill the order)

Ideally, the EHR should reduce risk and should be designed to minimize physician liability through proactive case intervention. However, it appears that in their current form, **most EHR systems newly expose and document existing limitations in healthcare environments, and add new ones of their own,** while most stakeholders remain unaware of the new liability risks that result.

The authors believe that there still is time to address these EHR issues, as studies continue to confirm low rates of adoption of EHR systems. According to a 20150 report[6], 7411% of physicians use a fully functional certified system~~, while 13% have implemented a basic system.~~ Rates are significantly higher in some categories: larger practices and primary care practices are more likely than average to have EHR applications.

Given the high and ~~low but~~ growing rates of adoption, it is time for EHR developers to seek greater input from medical liability experts, clinicians, health information managers, and risk managers when designing medical software. Until they do, all other stakeholders should acquire a better understanding of how the legal system regards electronic data in order to reduce their liability exposure. The authors are prepared to help EHR vendors and other stakeholders understand the numerous medico-legal issues impacting software design, selection and implementation today in order to improve processes and systems that would mitigate those risks.

[5] http://www.medicalmalpractice.com/National-Medical-Malpractice-Facts.cfm

[6] http://www.cdc.gov/nchs/data/ahcd/nehrs/2015_web_tables.pdf~~The 2010 CDC/NCHS national Ambulatory Care Survey~~

Do EHRs Increase Liability?

Reports and Expert Commentary

According to a recent NEJM article:[7]

> The implementation of EHRs could open users up to malpractice liability. The implementation phase of these complex systems may result in multiple errors. This is especially true in the physician practice setting. With untrained and inexperienced end users, critical information may not be communicated properly, resulting in medication errors, labs and x-rays not being completed properly, etc. There is a legal precedent requiring that procedures be in place to anticipate and mitigate these challenges.
>
> There is a potential danger that access to more data may have on evaluating patients. The ready availability of previous work-ups provides a temptation to *"cut and paste"* items from a Patient Medical History (PMH) or perhaps an inaccurate medication list. The theory is that if the records contain an inaccuracy, with this technology, the potential for that information to "go viral" is increased.
>
> Finally, the integration of clinical guidelines into the EHR may represent a double-edged sword. On the one hand, adhering to the guidelines may reduce the voracity with which an expert might question clinical decision making. On the other hand, the presence of sound reasons for overriding the guideline-recommended action may still raise the burden of proof for the clinician to convince judges and juries that those reasons represented appropriate clinical behavior.
>
> In the brave new world of EHRs and HIE, there are sure to be new medical and legal standards that evolve with the new technology. It is likely that many physicians will be subject to adverse decisions in the legal arena as case law is developed.

According to Sharona Hoffman[8], professor of law and bioethics and co-director of Case Western Reserve's Law-Medicine:

> "Electronic health record systems could give rise to increased liability for healthcare providers. Medical mistakes that are associated with EHR system use can lead to litigation and liability. Risks to patient safety can arise from software bugs, computer shutdowns and user errors," says Hoffman, who along with her husband, Andy Podgurski, professor of computer science at the university's School of Engineering, wrote a comprehensive analysis of the liability risks associated with the use of EHRs. They recently published in the Berkeley Technology Law Journal.
>
> "I don't want to discourage providers from purchasing and using EHR systems," says Hoffman. "Doctors make errors and face liability with paper records. The errors that arise from implementation of electronic records are just different, so providers need to be aware of them."
>
> "Whether or not there is a software bug, in the sense of a clear error that causes a wrong output, the usability of the system may be lacking, and that may lead a user to make mistakes that have safety implications," says Podgurski.

[7] HYPERLINK "http://www.nejm.org/doi/full/10.1056/NEJMhle1005210

[8] Sharona Hoffman, professor of law and bioethics and co-director of Case Western Reserve's Law-Medicine Center, and her husband, Andy Podgurski, professor of computer science at the university's School of Engineering, have written *"E-Health Hazards: Provider Liability and Electronic Health Record Systems,"* which offers a comprehensive analysis of the liability risks associated with use of this complex and important technology.

Do EHRs Increase Liability?

Hoffman and Podgurski's article also draws attention to the issue that vendors are not required to disclose product flaws, with some contracts even prohibiting it. At a minimum, federal regulations should require adverse event reporting when products have defects, Hoffman says. This has only recently begun, so the information is currently limited.

> "I would also hope that the government would have the power to require specific fixes if there is a serious problem and to impose fines or take other actions against vendors who engage in significant misconduct," says Hoffman

According to Scot Silverstein, MD, a senior Medical Informatics specialist at Drexel University

> "The unregulated free-for-all that has been the health IT marketplace, with dangerous and even outrageous practices I noted starting a decade ago, must come to an end as the market matures and as diffusion of this technology massively increases per the government mandates now in effect."

According to Edward F. Shay, partner at Post and Schell:

> There is a mixed environment, at best, on the legal advice in how courts look at these cases, says Shay, partner at Post and Schell, a health law and health information technology practice, in Philadelphia. "Current case law tends to illustrate that in many instances, the standard of care does not require a physician to obtain or consult a patient's prior medical records, whether in paper format or electronic," Shay wrote in a 2005 paper on EHRs and liability. The extent that EHRs will come up in malpractice litigation is going to be secondary, says Shay.

According to Deborah Maliver, MD, JD, a physician who practices law in Pittsburgh, Pennsylvania, with Biancheria & Maliver PC:

> Maliver states "audit trails can be used to determine whether records and test results have been viewed in [a] timely manner or at all, and whether records have been altered in any way."
>
> Seeking access to that information, according to Maliver, is "what I do in every case now, where they have EHR records. [Physicians] swear up and down, they never looked at the chart. I can see they looked at it five times. They swear they looked at an x-ray. I can see that they never logged in and never looked at it."

According to a study available on the Federal Trade Commission's Web site:

> "EHRs increase access to information for medical professionals and the chance that malpractice lawyers will find some evidence of wrongdoing." That study also discussed the risks involved in data loss or destruction, inappropriate corrections to the medical record that would be revealed by electronic time stamps, inaccurate data entry, and unauthorized access.

According to another article in the New England Journal of Medicine:

> New information systems tend to initially increase, rather than decrease, malpractice risks for physician practices, largely because of unfamiliarity with the system and computer-related errors. The existence of metadata, such as the audit trail or email tracking systems, can provide more documentation in malpractice cases, which can be good or bad for the defense. Metadata are discoverable in civil trials, under federal law, and must be made available to plaintiff's lawyers. State laws vary on whether metadata is discoverable or usable in trials, but the trend is to move most state laws closer to the federal standards.

Stakeholder Solutions

The optimal solution to the serious challenges identified in this white paper would proactively avoid the errors in the first place. This might require slowing down the pace of change to a manageable rate, which would permit appropriate due diligence and safe implementation. ONC has indicated (but not yet committed) that it may extend the timeline for meeting Stage 1 of meaningful use to 2014, from the current 2013 deadline, but current ONC director Dr. Mostashari has indicated no interest in other extensions[9]. Beyond the shortened timelines, below we discuss how different participants in this environment may best prepare for what is likely to be coming and move forward effectively.

> Some medical malpractice claims are being re-filed after the original claims were closed without showing provider fault. These cases are being reopened to look for missing data elements in electronic records as evidence of malpractice unrelated to adverse health events. (*Vigoda and Lubarsky 2006*)

One way Congress can encourage the adoption and use of HIT is through the development of legal safe harbors that allow for the continual improvement of provider practices without limiting patients' rights to legal recourse when they are harmed by medical malpractice. This will reduce the doubt among some providers that liability risks outweigh the benefits of EHR adoption and HIE utilization, and promote increased willingness to fully integrate HIT into provider practices.

Armed with an awareness of the changing legal landscape and the areas of potential risk, healthcare organizations and individual providers can take important steps to limit their liability exposure. They can:

- Openly discuss with their medical liability carriers the advantages and risks of using an EHR
- Reach out to HIM and IT professionals within their organizations, networks, or communities for support to ensure that their EHRs meet their clinical, legal, business, and record management needs
- Ask in-depth questions of potential vendors to ensure that their vendors' products and processes address medico-legal issues

Physicians, as key users, must demand the functionality that supports both their clinical and business needs. Physicians must take an active role in raising and addressing medical liability issues if they want to achieve the benefits and minimize the risks associated with EHR implementations. These concerns are critical at several stages: system evaluation, testing, and selection; system training and implementation; and post-implementation modifications or upgrades.

HIT Vendors

Hundreds of HIT vendors have protected themselves from liability through two contractual clauses that may not survive the next few years of regulatory change. Gag clauses, which prohibit each vendor's clients from publicizing information about software errors, are already seen as antithetical to improving the care intended as part of the original ARRA stimulus legislation. Efforts by AMIA and ONC to markedly limit these clauses are already underway, so it is likely that in the next few years these clauses will not provide significant protection if a serious software flaw exists. Recent FDA rules promoting disclosure of software failures may completely invalidate these clauses. The public may report such failures at: EHRevent.org

[9] healthit.hhs.gov/.../2011-04-21_policy_ca_transcript_draft.pdf

Do EHRs Increase Liability?

Indemnification clauses that require the client to indemnify the HIT vendor against any legal action brought due to patient harm are also under attack. It is likely that some form of indemnification will remain for harm due to implementation or modification errors by the client, but it is equally likely that software vendors will become responsible for errors due to the software itself. An additional indemnification clause to protect the vendor if it breaches its Business Associate Agreement (BAA) is also unlikely to stand over time.

In this changing environment, software vendors should address key aspects of this issue: improve software quality and utilize experts to assist in a third party software review as well as to prepare for potential future defense. Rigorously adopting the recommendations of the NIST usability guide is likely to reduce liability with the defense that best practices are in place and nothing can be made error free. Ignoring the NIST usability guide and not meeting best practices in development is likely to create a hole in a vendor's defense.

Liability Carriers

Insurers of medical organizations may be asked to shoulder the payments associated with patient harm due to HIT. Carriers may want to clarify their coverage with their clients, both the circumstances and the limits of liability protection, if different from their standard liability policy. To the extent that liability carriers cover the costs of defense and payment for claims made due to HIT misadventures, there would be value in preventive measures through education and training of internal staff as well as covered clients.

Attorneys, Firms, and Legal teams

Legal teams will need a stable of HIT experts who can be reliably called upon to determine the extent to which entities (patients, vendors, healthcare organizations, and individual providers) may be liable for misadventures. These experts will need to be able to determine whether the process used to obtain the software, including its implementation, was a proximate cause of the negative outcome and to what extent. These experts will need to be able to review software logs and follow the trail of events that led to the result. Some of these experts will need to excel at forensic assessment, while others may need to have explanatory or presentation skills, and still others may need to be effective while under cross examination.

Clinical Risk Managers

Most large healthcare organizations have individuals tasked with reducing the chance that a risky event will lead to a costly expense for the organization. In this environment, risk managers may seek the advice of HIT medico-legal experts to provide strategic and educational assistance to their organizations. Strategic advice can be incorporated into the organization's strategic plan and existing policies to limit the risks associated with the adoption of HIT. Clinician training and education can improve the likelihood that clinicians will diligently watch for problems and rapidly report them for resolution. IT staff training may help to prioritize which problems must be addressed immediately and which may remain lower on their to-do list.

Do EHRs Increase Liability?

Conclusion

Whether EHRs increase overall medical liability relative to their paper-based peers is not yet known. While EHRs may reduce the medical liability for certain errors, it appears that EHRs both create new forms of medical liability and expose existing liability issues in the healthcare environment that might otherwise remain unknown.

It is critical that medico-legal issues and risks be identified and discussed openly as healthcare organizations and individual physician practices invest in and adopt EHRs. The legal landscape related to EHRs is still fluid and evolving, but important progress is being made – research is being conducted, case law is emerging, and standards are being established. The full value of EHR systems will be realized when design and implementation support physician workflow and clinical needs as well as each entity's medico-legal needs.

A review of 65 EHRs showed that more than 90% of them did not provide adequate medico-legal training and 95% of them had specific medico-legal issues. Either could increase the potential risk of a liability claim and would hamper its defense. The EHR vendor community should strongly consider external reviews of their software for potential medico-legal issues that may have been missed by internal reviews due to employee familiarity with the process and the product.

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- Sharona Hoffman, professor of law and bioethics and co-director of Case Western Reserve's Law-Medicine Center, and her husband, Andy Podgurski, professor of computer science at the university's School of Engineering, have written *"E-Health Hazards: Provider Liability and Electronic Health Record Systems,"* which offers a comprehensive analysis of the liability risks associated with use of this complex and important technology.
- Hoffman and Podgurski are well known for their research and findings documenting a national need for effective EHR regulation. They analyzed the need for federal regulation of electronic health record systems in the scholarly article *"Finding a Cure: The Case for Regulation and Oversight of Electronic Health Record Systems"* (Harvard Journal of Law and Technology, 2009). That paper came after two previous publications by the two on security and privacy issues of electronic health records.
- For more on the increased costs of medical liability insurance to be potentially caused by EHRs, check out "2010: Medical Professional Liability in a Changing Health Care Environment - The New Story Unfolds," a new report from Conning, and "e-Records Make Insurers Jittery," a recent article on the report from Nextgov.
- An article in the November 18, 2010 issue of the *New England Journal of Medicine* (NEJM) explores "Medical Malpractice Liability in the Age of Electronic Health Records."

Do EHRs Increase Liability?

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Acronyms

AMIA – American Medical Informat*ics Association*

***ARRA – American Recovery and Reinvestment* Act (of 2009)**

CCHIT – Certification Commission for Health Information Technology

CDS – Clinical Decision Support

CIS – Clinical Information System

EHR – Electronic Health Record

EMR – Electronic Medical Record

HIM – Health Information Management

HIMSS – Health Information Management Systems Society

NIST – National Institute for Science and Technology

ONC – Office of the National Coordinator

ONCHIT – Office of the National Coordinator for Health Information Technology

PHR – Personal Health Record

Glossary

Bioinformatics - The science of collecting and analyzing complex biological data (e.g. genetic sequences)

Clinical Decision Support – software feature that collects patient information and known practice guidelines to present reminders or suggestions at the time that care is provided

Clinical Informatics - the study of information systems (computers and software) used in the clinical practice of medicine.

Clinical Information Systems – computer systems which support clinical process and care delivery

End user – the persons using the software (doctors, nurses, therapists, administrators, etc.)

Health Informatics - the study of information systems (computers and software) used in the clinical, administrative, and policy components of managing health, including population health.

Health Information Management – the department in a healthcare organization that manages health information, formerly called medical records in most institutions

Health Information Technology – hardware, software, networking, processes, policies and procedures which support the collection, manipulation, sharing and display of data supporting the provision of healthcare to patients.

Metadata – information that describes data (e.g. a time stamp for when vitals were collected)

Personal Health Record – an electronic copy of patient health information that may be collected from the patient's treatment records, insurance company billing records, or entered by the patient directly. There are two primary types of PHRs: tethered (attached to the healthcare organization's EHR) and untethered (which the patient maintains separate from any of the patient's health care provider EHRs).

Workflow – the path that a worker takes in completing the normal tasks of their job, considering physical location, resources utilized, and subtasks performed. There is usually one workflow per job function performed

Authors

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Mr. Anderson is one of the nation's premier healthcare IT futurists and a leading national speaker on healthcare at over 800 meetings since 2000. He has spent almost 40 years focusing on Healthcare issues. He specialize in the evaluation, selection, and ranking of vendors in the HIE and PMS/EHR healthcare marketplace. Twice per year, he publishes a report on vendor PMS/EHR functional, usability, and company viability. This evaluation decision tool has been used by more than 25,000 physicians since 2002. Additionally, Mr. Anderson has conducted more than 400 PMS/EHR searches, selections, and contract negotiations for physicians, IPAs and Hospitals since 2003. Mr. Anderson has advised numerous Medical malpractice companies and has been an expert witness in many cases relating to EHR products.

Prior to joining AC Group, Inc., Mr. Anderson was the worldwide head and VP of healthcare for META Group, Inc., the Chief Information Officer (CIO) with West Tennessee Healthcare, the Corporate CIO for the Sisters of Charity of Nazareth Health System, the Corporate Internal Consultant with the Sisters of Providence (SOP) Hospitals, and the Executive Director for Management Services for Denver Health and Hospitals and Harris County Hospital District. His experience includes 17 years with multi-facility Health Care organizations, 15 years Administrative Executive Team experience, 6 years as a member of the Corporate Executive Team, and 9 years in healthcare turnaround consulting. Mr. Anderson received his BS in Business, is completing his MBA in Health Care Administration, and is a Fellow with HIMSS

Larry Ozeran, MD
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Dr. Larry Ozeran has 30 years of experience with information technology and software development. He is focused on strategic development of informatics projects, including Electronic Health Records (EHRs) and Health Information Exchanges (HIEs), public policy development and interpretation, outreach and education for physicians and other clinical providers, informatics needs assessment, clinical workflow assessment, and technology evaluation for healthcare organizations.

Dr. Ozeran was employed as a software developer from 1981 to 1984 and developed an EHR in 1989. Since 1999, he has focused on minimizing Health Information Technology (HIT) failures, culminating in the book, "*H.I.T. or Miss: Lessons Learned from Health Information Technology Implementations*", published by AHIMA and AMIA in 2010. A second volume is in development.

Dr. Ozeran spent two years working with the State of California to develop their response to ARRA, for which he received an award from the State. He currently advises the California Office of Health Information Integrity (CalOHII), Cal eConnect (the governance entity for HIE for the State of California), and CalHIPSO (the largest Regional Extension Center in the nation). He is deeply involved in national informatics associations, participating in policy development in both AMIA and HIMSS.

Dr. Ozeran practiced as a general surgeon in both a medium sized multispecialty group for 13 years and a solo practice for 5 years in both urban and rural environments, giving him a broad understanding of clinical practice. He is an Associate Clinical Professor with the Health Informatics Program at UC Davis, emphasizing social and organizational issues in informatics. He received his undergraduate degree in biochemistry at Pomona College, his medical degree at the University of Chicago, and completed his surgical training at Cedars-Sinai Medical Center in Los Angeles.

Services provided by the authors:

- **System evaluation, testing, and selection.** Many organizations use multidisciplinary teams to evaluate competing EHR systems, but not all vendors have adequate resources to similarly consider the needs of all stakeholders. Without active representation by physicians and other stakeholders, the features and functions most likely to be used will be evaluated by team members who are less familiar with clinical workflows. We support the necessary physician and clinical workflow process input on the testing scenarios used to simulate actual day-to-day use to help ensure that all systems are properly evaluated. Knowledge of the criteria and functional specifications is essential. With a focus on exception analysis, we can identify clinical and process risks that might increase liability.

- **System training and implementation.** When end-user training is delivered by a small group of staff who must meet the needs of a wide variety of users, there is a tendency to approach system training in a generic way. By focusing provider training on those features and processes most important to end users, our input into training design and scheduling can result in better training results through increased clinician participation. Better provider training, in turn, can help physicians and other clinicians avoid documentation practices that pose medico-legal risks, such as indiscriminate use of "copy and paste" functions, and can ensure that providers understand the most efficient and reliable ways of retrieving needed patient information.

- **Identifying changes needed post-implementation.** We believe that workflow and training adjustments will likely be needed after the "go-live" date to support changes in work processes and in clinical decision support tools. Our systematic method of collecting, organizing, and prioritizing provider input can contribute to higher satisfaction among clinical users and minimize the need to develop unofficial "workarounds" to accommodate individual preferences and habits. Undocumented and unofficial processes to work around product or process flaws are another source of serious patient safety concern. When these undocumented "workarounds" are commonly known, new staff may not receive training about all of these unofficial processes, resulting in a serious failure. One such failure, which nearly resulted in a fatality, was documented in the book "*HIT or Miss: Lessons Learned from Health Information Technology Implementations*".

  The authors have also found that workarounds often result in inconsistent documentation practices and inconsistencies in where key patient information can be found. If, for example, 10 different physicians use 10 different methods for documenting a patient allergy to codeine, it becomes far more likely that entries will not agree, not be updated, and perhaps not even be seen. These inconsistencies pose a potential medico-legal risk by increasing the chances that key patient information could be overlooked by other users and missed by clinical decision support subsystems.

  Our organized process for considering changes also permits advance study of the medico-legal implications of those suggested changes prior to their adoption. Our program includes physicians in partnership with risk managers, legal counsel, health information managers, and compliance managers as well as other key users and maintainers of the patient record.

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