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USES OF THE LEGAL SYSTEM THAT ATTENUATE PATIENT SAFETY

*Ross Koppel, Ph.D., FACMI**

INTRODUCTION

Electronic Health Records (EHR) vendors' contracts with hospitals and doctors exist within the framework of the U.S. legal system. This constraint offers neither comfort nor safety—often enhancing vulnerabilities to patients, clinicians, and healthcare organizations via the EHR industry's regulatory capture.¹ First, by the appointment of policy leaders with conflicted commitments, and second, by the acceptance of clauses in EHR vendors' contracts that are deemed unethical by leading medical organizations but nevertheless remain in force.²

I. CONTEXT

Medical errors are the third largest killer of Americans, only exceeded by cancer and heart disease.³ EHRs were deemed the solution to medical errors because of their abilities, including: to convey clear medication orders to pharmacies; to display all lab reports and medical notes; to be accessible from anywhere in the hospital or, indeed, anywhere in the country; and to easily share patient information

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1. RAND CORP., AHRQ PUB. NO. 11-0105-EF, GUIDE TO REDUCING UNINTENDED CONSEQUENCES OF ELECTRONIC HEALTH RECORDS (2011).

2. Ross Koppel, *Forward to HIT OR MISS: LESSONS LEARNED FROM HEALTH INFORMATION TECHNOLOGY IMPLEMENTATIONS* (Jonathan Leviss et al. eds., 2d ed. 2013); Ross Koppel, *Great Promises of Healthcare Information Technology Deliver Less*, in HEALTHCARE INFORMATION MANAGEMENT SYSTEMS: CASES, STRATEGIES, AND SOLUTIONS 101–25 (Charlotte A. Weaver et al. eds., 2016) [hereinafter Koppel, *Great Promises of Healthcare Information Technology Deliver Less*]; Kenneth W. Goodman et al., *Challenges in Ethics, Safety, Best Practices, and Oversight Regarding HIT Vendors, Their Customers, and Patients: A Report of an AMIA Special Task Force*, 18 J. AM. MED. INFORMATICS ASS'N 77, 77–78 (2010).

3. Martin A. Makary & Michael Daniel, *Medical Error—The Third Leading Cause of Death in the US*, 353 BMJ i2139 (2016).

amongst all healthcare providers, thus reducing redundant tests and speeding time to diagnoses. With those promises and context, we begin our discussion with the 1997 agreement between the U.S. Food and Drug Administration (FDA) and the EHR industry, including the industry's supporters.⁴ That agreement reflected the successful efforts by the EHR industry to convince the FDA that EHRs were so safe they need not be effectively regulated. There were two easily-met exceptions to this valuable accommodation: (1) EHR vendors should adopt "a code of good business practices," and (2) EHR vendors should submit voluntary reports of harms if known.⁵ In effect, the EHRs in the United States have had a regulatory-free zone since that 1997 agreement with the FDA and EHRs' supporters and vendors. As recently as 2009, the legislation that created incentives worth \$27 billion for hospitals and doctors to buy EHRs still excluded safety and quality standards for EHR systems in the release of the final rule for the meaningful use of EHRs.⁶ Moreover, when Dr. Jeffrey Shuren—head of the FDA's medical devices division—called for mandatory reporting of adverse events, and required pre-marketing approval of EHR devices, the Office of the National Coordinator for Health Information Technology (ONC) dismissed Shuren's findings as "anecdotal and fragmentary."⁷

A review of the supporting arguments and terms of that 1997 agreement illustrates how advantageous it was and remains for EHR vendors. The EHR vendors and supporters: (1) claimed that regulation would impede innovation of this new industry; and (2) "charitably" offered to relieve the FDA of the burden of regulating them because

4. Randolph R. Miller & Reed M. Gardner, *Recommendations for Responsible Monitoring and Regulation of Clinical Software Systems*, 4 J. AM. MED. INFORMATICS ASS'N 442, 442–45 (1997).

5. *Id.* at 447.

6. 42 U.S.C. § 300jj (Supp. V 2018); Fred Schulte & Emma Schwartz, *FDA Asks Hospitals to Report Safety Glitches in Digital Health Systems*, HUFFINGTON POST (May 11, 2010, 5:12 AM), https://www.huffingtonpost.com/entry/fda-asks-hospitals-to-rep_n_495691.html. "Meaningful use" refers to the Medicare and Medicaid EHR Incentive Programs that provide financial incentives to "eligible professionals" (e.g., physicians and hospitals that have bought and installed EHRs). In the words of CMS, these users have to "demonstrate 'meaningful use' of certified EHR technology through improved quality, safety, and efficiency of patient care." *The Medicare and Medicaid EHR Incentive Programs—Meaningful Use*, AM. C. PHYSICIANS, <https://www.acp.org/practice-resources/business-resources/health-information-technology/the-medicare-and-medicare-ehr-incentive-programs-meaningful-use> (last visited Dec. 8, 2018). In reality, "meaningful use" refers to the obligation to buy and use some EHR functions to gain subsidies for the purchase of the software and to avoid penalties via CMS reimbursement deductions for failure or refusal to use the EHRs.

7. *FDA, ONC Clash Over Need for Regulation, Oversight of EHRs*, MEDSPHERE, <http://www.medsphere.com/resources/news/health-it-news/3241-fda-onc-clash-over-need-for-regulation-oversight-of-ehrs> (last visited Apr. 15, 2018).

the FDA had such limited resources it should best focus on devices that pose real risks to patient safety.⁸ EHRs, the vendors argued, were too safe to bother to regulate.

The first argument about impeding infant industry is remarkable because EHRs were already over thirty-five years old in 1997.⁹ Perhaps more relevant, if you ask any physician to pick a word—even now—to describe EHRs, “innovative” would almost certainly not be among their choices. Additionally, the second argument—the idea that EHRs are low risks for patient safety—is clearly absurd, perhaps paradoxical.¹⁰ Last year, for example, the Emergency Care Research Institute (ECRI Institute)¹¹ listed EHRs and EHR guidance as the most dangerous of all the patient safety hazards of their top ten risks.¹² EHRs were more hazardous than wrong patient errors, opioids, mismanagement of anticoagulants and antibiotics, missing critical test results, and failures to recognize when patients are dying.¹³ And, as detailed below, there are thousands of examples where EHRs were associated with patient harm.

II. “HOLD HARMLESS” AND NON-DISCLOSURE CLAUSES

Putting aside (temporarily) the concern about regulatory capture, we focus on two clauses in EHR contracts that powerfully and deleteriously affect patient safety. They are the “hold harmless” and non-disclosure clauses.¹⁴

The “hold harmless” clause in EHR contracts functions to prevent vendors from being held responsible for errors in their software even if the vendor has been repeatedly informed of the problem and even if

8. Miller & Gardner, *supra* note 4, at 447 (“We recommend that the FDA focus its regulatory efforts on those systems posing highest clinical risk . . .”).

9. As a thought experiment, what if commercial passenger jets in 1997 claimed that regulation was premature because it would impede innovation?

10. See, e.g., Mary G. Amato et al., *Computerized Prescriber Order Entry-Related Patient Safety Reports: Analysis of 2522 Medication Errors*, 24 J. AM. MED. INFORMATICS ASS’N 316 (2017); Ross Koppel, *The Health Information Technology Safety Framework: Building Great Structures on Vast Voids*, 0 BMJ QUALITY SAFETY 1 (2015); G. D. Schiff et al., *Computerized Physician Order Entry-Related Medication Errors: Analysis of Reported Errors and Vulnerability Testing of Current Systems*, 24 BMJ QUALITY SAFETY 264 (2015).

11. The ECRI Institute is a non-profit organization that evaluates patient safety risks.

12. Mike Miliard, *Top 10 Patient Safety Concerns for 2017, According to ECRI*, HEALTHCARE IT NEWS (Mar. 14, 2017, 1:10 PM), <http://www.healthcareitnews.com/news/top-10-patient-safety-concerns-2017-according-ecri>. EHR guidance is comprised of alerts that warn of allergies and drug-drug interactions, among other things. EHR guidance is known as Computer Decision Support (CDS).

13. *Id.*

14. Ross Koppel & David Kreda, *Health Care Information Technology Vendors’ “Hold Harmless” Clause: Implications for Patients and Clinicians*, 301 JAMA 1276, 1276–78 (2009).

the problem causes harm or death to patients. The clause relies on the doctrine of a “learned intermediary,” that the doctor, pharmacist, nurse or other clinician has unique, esoteric medical knowledge and unique bedside knowledge which makes them entirely responsible for the patient’s care.¹⁵ Vendors claim they simply supply a “tool” used by medical professionals. Vendors are held harmless for any and all errors, even if they are unambiguously at fault, and, as noted, even if they’ve been repeatedly informed of the risks.¹⁶ When I testified at Congressional and other hearings, every vendor’s spokesperson began with, *inter alia*: “We create tools used by learned intermediaries—clinicians, in the practice of their profession.”

Since the publication of the Koppel & Kreda article in the Journal of the American Medical Association (JAMA), two Institute of Medicine (IOM) reports and the American Medical Informatics Association (AMIA) task force on vendor relations have urged the removal of the hold harmless clause, calling it “unethical” and counter to the improvement of patient safety.¹⁷

A. *Has That Clause Been Removed? Unlikely*

There is some confusion about the persistence of that clause. Several vendors claimed that they did not intentionally insert them in their contracts; that they just sort of appeared—a form of spontaneous emergence or a vestigial from previous sales agreements. That said, few vendors deny their existence, although they claim that the clause is less onerous than it looks because of the possibility that it might be challenged in court. Some vendors also claim they have removed them. However, to date, no vendor to my knowledge has certified that their contracts are free of that clause. Moreover, vendors refuse to provide their contracts for public review on the grounds that the contracts are protected intellectual property (IP). Of note here, neither the ONC or the Centers for Medicare and Medicaid (CMS)—theoretically the regulators of EHRs—have ever demanded its removal.¹⁸

III. NON-DISCLOSURE

The second clause discussed in the Koppel & Kreda piece is the non-disclosure clause. It is a more direct threat to patient safety because it prohibits doctors from openly making pejorative statements

15. *Id.* at 1278.

16. *Id.*

17. Koppel, *Great Promises of Healthcare Information Technology Deliver Less*, *supra* note 2, at 111.

18. *Id.*

about the EHR software; and far worse, it prevents them from posting screenshots of EHR interfaces that they find dangerous to patients. Thus, for example, a clinician cannot post a screenshot of a vendor's software that she finds misleading, disorganized, confusing, or downright lethal. A physician can complain about it in the vendor's electronic forum (which is controlled by the vendor), she can show it to the colleague at her shoulder, but she cannot make a pejorative comment at a public meeting, on a public listserv, or at a public forum. Most critical, she cannot post a dangerous screenshot to fellow clinicians or to the general medical community even if she accompanied that image with evidence of harm, with an explanation of why it is a danger to patient safety, and with a discussion of the role of, say, her hospital's IT department in exacerbating or facilitating the problem.

The results of this non-disclosure clause are that other clinicians and medical informaticists are prevented from learning of the problem or problems, they may harm more patients, and they are thwarted in efforts to improve safety or improve clinical efficiencies. I argue that patient safety is directly imperiled by this non-disclosure clause.

As to the existence of non-disclosure clauses in vendor contracts and the efficacy of their power: Everything noted above about hold harmless clauses applies exactly the same as the non-disclosure clauses. These clauses can be hidden in a sea of contract pages and they can be argued about, but we cannot get a public presentation or an assertion of their total removal.

IV. LONG AND COMPLEX VENDOR CONTRACTS

Part of the difficulty of determining the prevalence and power of those clauses is the complexity of the vendor contracts. I have a copy of the EpicCare Inpatient Clinical Systems (Epic)¹⁹ contract with the Dallas hospital that misdiagnosed and failed to correctly treat Thomas Eric Duncan, the first American to die of Ebola. The hospital's EHR vendor contract is over 3,000 pages long. It was only obtained via the Freedom of Information Act (FOIA) because the hospital received public funding. It has hundreds of subparts and linked references. I have been told only a healthcare attorney familiar with health information technology (HIT) contracts could discern the many interrelated parts. I have also been told that because of the "joint and several

19. Epic is the name of a large EHR company. EpicCare is one of the many local brand names hospitals adopt to refer to their Epic EHRs.

clause,” it is hard to easily identify the hold harmless or non-disclosure provisions.²⁰

V. WHY SCREENSHOTS ARE NEEDED

This following example illustrates the implications of the screenshot prohibition. It involves Dr. Robert Wachter’s best-selling 2015 book: *The Digital Doctor: Hope, Hype, and Harm at the Dawn of Medicine’s Computer Age*.²¹ The first chapter of that book—which parallels our topic here—is about a young doctor who entered an order for a child needing an antibiotic. Almost all children’s dosages are created in weight-based dosages, e.g., so many milligrams per kilograms of the child’s weight. However, when the patient grows to be about 110 pounds (50 kilograms) the dosage usually shifts from weight-based to those of an adult, which are specified as the number of pills for each time of administration, e.g., one pill three times a day.

Unfortunately, this young patient was just at that point where the dosage ceased to be weight-based, but rather shifted to a standard adult dosage. There was a very subtle shift in the EHR ordering screen that imperceptibly switched from weight-based dosage to simply the number of pills to be administered. The two screens were almost identical. Tragically, because of the almost imperceptible screen change, the doctor meant to order the appropriate weight-based dosage, but instead accidentally ordered a full adult dosage multiplied by the child’s weight. This accidental order equaled about thirty-eight adult-size pills—a dose that could have been lethal was given to the child. There’s a long explanation of how the several alarms and efforts to intervene failed to stop the massive overdose, but the result was awful, with the child suffering grand mal seizures and requiring weeks in the ICU. Fortunately, the young boy survived.

I present this example because even the world-famous Dr. Robert Wachter struggled for many months with the vendor to be allowed to show the screenshot of the EHR ordering screen change that led to the event. This is the non-disclosure agreement in practice. Moreover, it illustrates how screenshots can enable others to learn from problems and then repair dangers. One can imagine how long it would take the average MD or IT staffer to get permission to display rele-

20. Koppel, *Great Promises of Healthcare Information Technology Deliver Less*, *supra* note 2, at 111.

21. ROBERT M. WACHTER, *THE DIGITAL DOCTOR: HOPE, HYPE, AND HARM AT THE DAWN OF MEDICINE’S COMPUTER AGE* (2015). Professor Wachter is one of the most famous doctors in the world; he is the founder of the “hospitalist” doctor movement, and he recently wrote the evaluation and plan for the English National Health Service’s system and technology use.

vant screens and inform the profession and the patient safety community. She would probably never receive permission.

VI. SCREENSHOTS AND THE FDA STUDY OF EHRs

This next Section, which discusses the nation-wide implications of non-disclosure clauses, provides a more comprehensive perspective that includes most major EHR vendors and several leading healthcare systems. Two years ago, I co-authored an analysis of EHR medication ordering screens. The study was commissioned by the FDA²² and coordinated at Brigham and Women's Hospital at Harvard Medical School (BWH) and Harvard Vanguard Medical Associates. It reflected the participation of the hospital systems from the University of Pennsylvania (where I was the site leader and co-Principal Investigator), Montefiore Medical System in New York City, Kaiser Permanente Northwest, and the University of Illinois at Chicago.²³

The FDA wanted this study of EHR medication ordering screens to examine if drug name truncations might facilitate or generate medication errors. For example, if drug names were artificially truncated, the clinician might not be able to see if the dose was a different formulation, or in fact a very different medication with a longer name. We convinced the FDA to allow us to also examine the entire ordering screen to explore dangers caused by pop-ups (warning screens) that obscure the patient's full medication list (which could cause double-dosing) or hide the problem list (which is used for understanding the reasons for medications). Inconsistent listings might also defeat alerts for overdosing, under-dosing, double-dosing, or drug-drug interactions. To resolve this concern, we studied many EHRs screens and found over 50 examples that could lead to errors, some of which were serious. For one instance, we found an EHR that listed the medication "Coumadin" (brand name) and also listed the exact same drug as "warfarin" (generic). Critically here, if a patient were prescribed both of these identical drugs the EHRs alert system could not catch it and would not give a double-dose warning, thus endangering the patient with an anticoagulant overdose leading to hemorrhage and perhaps death.

We asked several local physicians in each of the five participating hospital systems with a different EHR to order a predetermined list of medications and to conduct a series of actions (e.g., change a dose

22. U.S. FOOD & DRUG ADMIN., UCM477419, COMPUTERIZED PRESCRIBER ORDER ENTRY MEDICATION SAFETY: UNCOVERING AND LEARNING FROM ISSUES AND ERRORS, <https://www.fda.gov/downloads/Drugs/DrugSafety/MedicationErrors/UCM477419.pdf>.

23. *Id.*

from 4 milligrams to 5 milligrams). We then observed each screen as the process occurred. Obviously, to document the screens used for ordering medications we had to have images of the screens. At first, the vendors refused to allow us to record the screens on their usual grounds that screenshots are not permitted because of the non-disclosure clauses in their contracts. They additionally claimed that the screens are protected intellectual property (IP). We countered, first with the question: “Why do you want to protect the IP of screens that lead to patient harm?” That brought no response. Second, we emphasized that by refusing us, the vendors were refusing the FDA. That argument had a salutatory influence, and after much discussion, we received permission to tape the sessions with the caveat that only the FDA would see the resulting screenshots. While disappointed that others would not learn from the graphic examples, we accepted the limitation and conducted the research.

The results were remarkable and remarkably distressing. We identified and took screenshots of over fifty different dangers, including:

- inability to see what medications the user or other clinicians have ordered;
- inability to see the patient’s other medications (thus leading to possible double-dosing or drug-drug interaction errors);
- items in drop-down lists not visible on the screen;
- ambiguity or inability to see the form of the drug (e.g., liquid, pill, patch, or suppository);
- drug names with added confusing text;
- inconsistent suffixes and modifiers (e.g., child dose, extended release, or “only for use on patients with renal monitoring”);
- failure to transmit medication discontinuation orders;
- inability to put orders “on hold” (which is usually placed before a surgery and many examinations); and
- use of inconsistent taxonomies and dosage systems.

After a year or two of additional discussions with the vendors, all but one vendor allowed us to share the screenshots publicly. However, that one vendor—with more than a lion’s share of the market—prevented us from displaying the screenshots, some of which are clearly dangerous or deadly. We worked around this limitation by substituting the one vendor’s screens with parallel screens taken from Harvard’s homegrown, but by then superannuated, EHR. These images and screenshots illustrated over fifty EHR risks caused by dangerous and confusing EHR interfaces. The resulting publication, now available from the FDA as a free PDF, is titled “Computerized Pre-

scriber Order Entry Medication Safety: Uncovering and Learning from Issues.”²⁴

But wouldn’t that document have been more helpful if we were able to present the findings when first available, rather than haggle for a year or two? Wouldn’t it be more helpful if the document included all of the full images from each system we studied?

VII. THE PROBLEM WITH REPORTING PROBLEM

Another consequence of non-disclosure and lack of sharing information, in the already complicated process of EHR implementation and optimization, is that clinicians are often uncertain why things don’t work and who is at fault.²⁵ Their uncertainty is understandable because EHRs are affected by a number of factors: tens of thousands of moving parts; constant updates and modifications by the provider’s local IT department and by the vendor; frequent changes to the medication formulations (e.g., the pharmaceutical company changes the 40 milligram pill to a 35 milligram sustained release capsule); the inventory decisions of internal pharmacies, called “formularies;” the actions of outside pharmacies; and computer decision support algorithms which often differ from ward to ward and from facility to facility.²⁶ In addition, because the EHR digitally interacts with hundreds of other IT systems—e.g., inventory, local pharmacy IT, thousands of smart pumps and monitors, outside labs, inside labs, medical devices, and outside pharmacies—the user often does not know the reason she is encountering a problem.²⁷ The user always wonders: Is it me? Is it a recent update? Is it a missed memo? Is it a recent training session I forgot to attend? Is it a new drug formulation? Is it a new treatment protocol? Is it new order-sets? Thus, users’ uncertainties often result in few problems being reported because of their unknown causes, fear of looking foolish, and, of course, lack of time when they are trying to order medications for patients.²⁸ Bad user interfaces therefore continue unreported and unaddressed. The implications to patient safety and clinician frustration are obvious.²⁹

24. *Id.*

25. See Christine A. Sinsky et al., *Comparative User Experiences of Health IT Products: How User Experiences Would Be Reported and Used*, INST. MED. NAT’L ACADS. 8 (Sept. 2012), <https://nam.edu/wp-content/uploads/2015/06/comparative-user-experiences.pdf>.

26. See *id.* See generally ROSS KOPPEL & SUZANNE GORDON, FIRST, DO LESS HARM: CONFRONTING THE INCONVENIENT PROBLEMS OF PATIENT SAFETY (2012).

27. Sinsky et al., *supra* note 25, at 8. See generally KOPPEL & GORDON, *supra* note 26.

28. Sinsky et al., *supra* note 25, at 8.

29. *Id.* See generally KOPPEL & GORDON, *supra* note 26.

VIII. LACK OF DATA STANDARDS AND LIMITED
INTEROPERABILITY

Without unified data standards and data formats, achieving interoperability across systems—and indeed sometimes across the hallway—is impossible. Proprietary interests, legacy systems, and previous capital investments make agreement on standards difficult. But without unified data standards and data formats, we create Towers of Babel within each medical facility and across the nation. Worse, we severely attenuate the utility of HIT, which was based on the essential idea that patients' data were available anywhere for both routine care and emergencies. Without unified data standards we cannot share information across systems, and we fail to achieve real interoperability. These Towers of Babel become isolated from each other—a noisy but deaf city.

A. Missing Data Standards and the Loss to Medical Progress

In addition to the loss of information for individual patients, data standards would enable far greater patient safety and medical knowledge advancement. This would allow research to move medical science ahead by decades via access to the oceans of available data to be combined and analyzed. Yet, despite enthusiastic agreement on their need and value, EHR data standards are still not set. I suggest six reasons:

1. Speed Available Products to Market

Legislators and regulators did not insist on data standards in part because of the government's expectation that EHRs would bring massive improvements in safety and money savings just by use of the technology itself.³⁰ With this belief, regulators allowed the EHR vendors to sell whatever systems were then available with whatever separate data standards existed in their systems. This benefitted the vendors by not delaying their products' passage to the market and also by encouraging market share capture with their existing or nascent products—a powerful lock because of the vast costs and lengthy implementation process. In the words of many physicians, “the industry rushed their not-ready-for-prime-time software to market.”

30. See Koppel, *Great Promises of Healthcare Information Technology Deliver Less*, *supra* note 2, at 106.

2. *Network Effects and Lumpy Capital Investments*

Vendors also benefit from sales of integrated collections of proprietary systems that communicate primarily with their own brands. This requires the purchase of the vendor's entire suite of products and discourages the purchase of "best of breed" systems or of maintaining some legacy systems. Probably more important here, however, is that large HIT systems are so costly and take so many years to implement, there is little room for buyer's remorse. Once an organization buys an EHR, it is generally wed to that system for many years. Organizations do not easily junk a system that costs five hundred million dollars in direct cost and four or five times that figure in personnel costs and other costs for implementation, linkages, retrofitting, and training. The vendors thus sought to capture market share as soon as possible. They were incentivized to rush their HIT products to market before the products were sufficiently tested and before the vendors could be pressured to harmonize or set data standards.

3. *Government Subsidies and Penalties for Laggards*

In 2009, the government obliged doctors and hospitals to install the systems with a combination of carrots and sticks.³¹ The carrots were government subsidies paid to hospitals and to doctors to buy the systems. Hospitals and physicians received millions to help purchase the systems. The sticks were in the form of penalties to hospitals and doctor's offices that failed to quickly buy and use the EHRs. Healthcare providers suffered crippling penalties in Medicare and Medicaid reimbursements if they remained wallflowers at the HIT digital dance party, i.e., if they didn't buy the EHRs and use them for a prescribed set of minimal functions.

4. *Ideology, Orthodoxy, and Public Relations*

The HIT industry, its true believers, and government agencies actively promoted EHRs with a constant public relations effort to convince clinicians and patients that EHRs were safer—by definition. The ideology was constantly reinforced: more HIT = safer care. To help the campaign, government funders refused research grants to many of those who wished to conduct studies that might cast doubts about the claims of the technology's extravagant successes. HIT agnostics were seen as retrograde and dangerous to patient safety. Those with any reluctance to overlook EHR-caused problems, inefficiencies, and medical errors were seen as technophobes, incompetents, and non-

31. See 42 U.S.C. § 300jj (Supp. V 2018).

team players. This form of us-versus-them ideology ultimately deteriorated the very technology it was intended to protect by ignoring or explaining away weaknesses, and by always assuming the next version or patch will solve all problems.

5. *Publication Amenability*

The HIT bandwagon was facilitated by medical and informatics journals' usual publication bias favoring positive findings (e.g., EHRs save lives and money), and by editors and reviewers who became champions of the technology as necessary to save medicine from its problems. Major journals published papers showing EHRs could eliminate errors by up to 86% compared to paper systems—even though many of the errors “eliminated” were inherent in the digital process itself and had no relevance to actual patient safety.³² For example, with EHRs, all medication orders are automatically electronically signed, whereas with paper a physician might not sign an order that she dictated to the ward secretary. Or with EHRs, one must specify the route of the medication, whereas with paper it is possible to put in an order for a suppository or skin patch without specifically saying how it was to be administered to the patient. As the leading patient safety and HIT scholar David W. Bates noted as long ago as 1998, many of the errors “eliminated” by EHRs were inconsequential, would never have reached the patient, or both.³³ Nevertheless, U.S. professional publications overwhelmingly highlighted the strings of success and seldom devoted ink to the problems.

6. *Career Implications*

The vast funds involved, and the consequential career implications of those participating in HIT purchases also encouraged intimidation of critics and those who reported problems with the technology. That is, a Chief Information Officer (CIO) or Chief Medical Information Officer (CMIO) who advocated spending millions or billions on im-

32. See generally Joan S. Ash, et al., *Computerized Physician Order Entry in U.S. Hospitals: Results of a 2002 Survey*, 11 J. AM. MED. INFORMATICS ASS'N 95 (2004); Joan S. Ash, et al., *Some Unintended Consequences of Information Technology in Health Care: The Nature of Patient Care Information System-Related Errors*, 11 J. AM. MED. INFORMATICS ASS'N 104 (2004); David W. Bates et al., *Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors*, 280 JAMA 1311 (1998) [hereinafter Bates et al., *Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors*]; David W. Bates, et al., *Effects of Computerized Physician Order Entry and Clinical Decision Support Systems on Medication Safety: A Systematic Review*, 163 ARCHIVES INTERNAL MED. 1409 (2003).

33. Bates et al., *Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors*, *supra* note 32, at 1314.

plementing an EHR is less likely to describe that purchase and installation as a failure. Those raising doubts or demanding independent evaluations or return on investment (ROI) analyses are not appreciated. One is reminded of the Sicilian proverb that “one does not examine the bride as carefully if the dowry is very large.” On the other hand, history does not suggest that products are improved by ignoring their faults.

B. Lack of Standards and Interoperability Produce a Workaround

Because all agreed that industry-wide data standards and interoperability could and should be a key benefit of EHRs—and indeed, a major underlying function—there was increasing pressure to find a solution to the lack of interoperability. Absent regulations or self-regulation by the industry, the proposed solution now focuses on a workaround called “application programming interfaces” (APIs).³⁴ APIs are intended to create the digital equivalent of a “Rosetta stone” for different systems with different data standards. It is hoped EHRs will be able to communicate across systems via the API as a crosswalk or translation service that will make the information intelligible to different systems using differing data standards.³⁵ However, as John D’Amore et al. have demonstrated, APIs and related workarounds can fail to accurately convey the needed information across systems.³⁶ There are just so many variations on how the information is entered and stored in EHRs that overcoming the resulting cacophony with digital workarounds is not always assured. APIs are improving and work much of the time, but given the life-critical needs for correct patient data, a workaround remains a second-best solution.

IX. USABILITY

The last issue we discuss is how usability is affected by regulatory capture and by the non-disclosure and hold harmless clauses. Usability is defined as the design and functionality of the software that allows users to accomplish their goals without undue struggles. A well-designed EHR (or any software interface) is understandable, predict-

34. Alexa T. McCray et al., *Health IT Vendors and the Academic Community: The 2014 ACMI Debate*, 60 J. BIOMEDICAL INFORMATICS 365, 366 (2016). An application program interface (API) is a piece of software that contains routines, protocols, and tools that specifies how other software components should interact.

35. *Id.* at 366.

36. John D. D’Amore et al., *Are Meaningful Use Stage 2 Certified EHRs Ready for Interoperability? Findings from the SMART C-CDA Collaborative*, 21 J. AM. MED. INFORMATICS ASS’N 1060, 1066 (2014); see also McCray et al., *supra* note 34, at 366.

able, and learnable. Additionally, EHR should allow users to understand where they are in the program (navigation) and provide useful visualizations and data displays. A usable EHR interface is less likely to generate errors than a user-hostile one and does not cause unnecessary frustration. However, many clinicians' usability problems are far less likely to be addressed without transparency, screenshots, and ongoing reporting of usability issues. Those views can be fairly characterized as user-hostile, time-consuming, frustrating, and error-prone.³⁷

Common examples of EHR usability problems include:

- the need to click 27 times and scroll for 45 seconds to find two items that should be contiguous (the clickarrhea epidemic);³⁸
- scales that are chronological on part of the screen and reverse chronological on another;
- logos that have different meanings, sometimes on the same screen;
- medical test names that differ from screen to screen;
- inability to find needed information where it should be;
- drop-down lists that continue to the next screen but don't warn the user;
- fonts that are illegible to adults of any age;
- color combinations that obscure findings; and
- failure to clearly differentiate critical findings, whether positive or out-of-range, from routine results.

Limitations imposed by the non-disclosure clause severely attenuate effective reporting of clunky, inconvenient, and even dangerous EHRs. Without free and ongoing feedback, the profession and IT leaders are less likely to be told of problems and are far less likely to receive actionable information about these problems. Underlying these problems are the motivations, beliefs, and administrative structures of the Office of the National Coordinator of Healthcare IT (ONC), which, as we shall see, may serve as an excellent example of regulatory capture. From its creation, the ONC did not focus on usability,³⁹ but rather, sought to downplay it by mirroring the vendors' views that usability was "subjective," "too theoretic for practical application," "too dependent on the implementation process," "too dependent on individual user skill," "unscientific," and "unmeasurable."

37. See Robert Wachter & Jeff Goldsmith, *To Combat Physician Burnout and Improve Care, Fix the Electronic Health Record*, HARV. BUS. REV. (Mar. 30, 2018), <https://hbr.org/2018/03/to-combat-physician-burnout-and-improve-care-fix-the-electronic-health-record>.

38. Sinsky et al., *supra* note 25, at 6–7.

39. Letter from the Adoption Certification Workgroup, Health IT Policy Comm., to David Blumenthal, Nat'l Coordinator for Health Info. Tech. (Apr. 22, 2010), <https://www.healthit.gov/sites/default/files/facas/adoptioncertificationletterhitsafetyfinal508.pdf>.

In fact, the role of EHR usability evaluation was not taken up by the ONC until recently. In the enabling legislation, the Health Information Technology for Economic and Clinical Health Act (HITECH) of 2009,⁴⁰ usability was to be overseen by the National Institute of Standards and Technology (NIST).⁴¹ However, rather than encourage NIST to actively evaluate usability, the ONC sought successfully to weaken NIST's role, and then tried—unsuccessfully—to deny any NIST function whatsoever regarding EHRs' usability analysis. In fact, the agreement with NIST succeeded in burying all of the usability evaluation research by demanding that:

1. Submission of EHRs by vendors to NIST for usability evaluations would not be required—it was entirely voluntary.
2. A vendor need not inform anyone that its product was or was not submitted.
3. The results of the findings could not be shown to anyone other than the submitting vendor.
4. The vendor need never inform anyone of the findings or of the existence of the findings.
5. No real comparisons could ever be shown or published.⁴²

When the ONC later gave funding to Dr. Jiajie Zhang at the University of Texas at Houston to test EHR usability, the ONC insisted upon the same rules of non-transparency that it obliged NIST to follow.⁴³

Of course, the ONC never discouraged improving EHRs' usability, and more recently has taken up usability's cause. However, for most of its existence, the ONC saw as its first mission to encourage and reward providers to purchase EHRs. To the extent that usability requirements might impede that mission, the ONC did not wish to impose usability metrics. Moreover, one of the leading members of the committee to create HITECH, who is also a key EHR vendor chair,

40. 42 U.S.C. § 300jj (Supp. V 2018).

41. Margaret Rouse, *HITECH (Health Information Technology for Economic and Clinical Health) Act of 2009*, TECHTARGET, <https://searchhealthit.techtarget.com/definition/HITECH-Act> (last updated Jan. 2018); *HITECH Act Enforcement Interim Final Rule*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/special-topics/hitech-act-enforcement-interim-final-rule/index.html> (last updated June 16, 2017).

42. Interview with Dr. Svetlana Z. Lowry, Info. Access Div. Head, Nat'l Inst. Standards & Tech., Info. Tech. Lab.

43. Letter from the Adoption Certification Workgroup, *supra* note 39, at 2. For more information regarding the ONC's transparency policies, see Elise Sweeney Anthony & Steven Posnack, *Transparency Requirements for Health IT Developers Will Help Providers Know More About Their Products*, HEALTH IT BUZZ BLOG (June 1, 2016), <https://www.healthit.gov/buzz-blog/healthit-certification/transparency-requirements-health-developers-will-help-providers-know-products>.

famously stated that “usability testing will be included over my dead body.”⁴⁴

In the words of Dr. Shawn Martin, Senior Vice President of Advocacy, Practice Advancement, and Policy of the American Association of Family Practitioners, “I struggle to find an articulate and elegant way to describe what is so frustrating about electronic health records, but I think I have found a way to do so succinctly — they suck. They suck as products, and they suck the life out of everyone that uses them.”⁴⁵

CONCLUSION

The horror of medical error is so great, the cost of U.S. healthcare so outsized and troubling, the desire for technological solutions so pervasive, the societal impact of digital technologies so impressive, and the claims of EHRs so comforting that healthcare institutions sought solutions in computerization of medical records. EHRs, in fact, offer amazing and myriad advantages. They remove handwriting errors, speed orders instantly to the pharmacy, can be accessed anywhere, and provide digital audits. Additionally, they always oblige clinicians to specify exact medication routes, schedules, dosages, times, etc. They also offer order sets—collections of medications that are often used as a group. Last, via CDS, they warn of overdoses, drug-drug interactions, and drug allergies.

It is understandable, therefore, that so many in healthcare, government, and academia sought to deploy EHRs as quickly and as widely as possible. EHR vendors, not surprisingly, joined with EHR enthusiasts to reduce or eliminate regulation that might impede sales and implementation of the technology. The result was a successful effort to convince the FDA that regulation would be a hindrance to innovation and a barrier to speedy acceptance and sales. This was the setting for regulatory capture, creating what is essentially a regulatory-free zone where data standards, interoperability, and usability—the critical elements missing from EHRs—were allowed to go unaddressed. This was also the context that created compliant policy groups and regulators.

Two of the mechanisms employed by EHR vendors were the non-disclosure and hold harmless clauses. Collectively, these clauses limit clinicians’ and IT staffs’ access to information that would assist in

44. Shawn Martin, *EHR Market Needs Competition, Innovation*, IN THE TRENCHES BLOG (May 1, 2018, 8:00 AM), https://www.aafp.org/news/blogs/inthetrenches/entry/20180501ITT_ehrs.html.

45. *Id.*

avoiding harm to patients and would improve clinical efficiencies. The hold harmless clause is a “get out of jail free” card that acts as a disincentive for vendors to quickly address problems. It is telling that those clauses have not been prohibited or removed by regulators or legislators despite their known roles as barriers to patient safety and clinical efficiency.

While it is unquestionable that EHRs have improved significantly since the 1997 agreement between the FDA and the EHR industry, the FDA’s acceptance of the argument that EHRs were sufficiently risk-free so as to not require regulation remains dubious and unsubstantiated by research. Consequently, patient safety was and is compromised; clinicians were and are frustrated,⁴⁶ interoperability is still nascent, usability is primitive compared to other modern digital systems, and the innovation supposedly sought by EHR vendors in the absence of regulation remains subpar.

What is needed is a system that allows frictionless reporting of EHR hazards and inefficiencies as they are encountered by clinicians and others. These reports should be immediately available to the profession. Those hazards to patient safety should be expeditiously corrected. Vendors, of course, should be given the opportunity to counter complaints (e.g., demonstrate that the problem was entirely due to a poor implementation or user misunderstanding), but ultimately, healthcare professionals should have the final say.

EHRs offer extraordinary advantages over paper, but they will not realize their promise if contractual clauses and compliant regulators allow problems to be obscured and needed repairs to be ignored.

46. *Id.*; Wachter & Goldsmith, *supra* note 37.

