# IS THERE AN APP FOR THAT? ELECTRONIC HEALTH RECORDS (EHRS) AND A NEW ENVIRONMENT OF CONFLICT PREVENTION AND RESOLUTION

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Information is the lifeblood of modern medicine. Health information technology (HIT) is destined to be its circulatory system.<sup>1</sup>

# I

#### INTRODUCTION

In January 2007, Dave deBronkart was diagnosed with stage IV kidney cancer, a condition which at the time, had a median survival rate of twenty-four

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<sup>1.</sup> David Blumenthal, Launching HITECH, 362 NEW ENG. J. MED. 382, 385 (2010).

weeks.<sup>2</sup> He immediately underwent surgery and became a participant in a clinical drug trial. deBronkart, who was employed in the computer industry, also became a determined "e-patient,"<sup>3</sup> using any and all online resources that might help his treatment and aid him in coping with his condition. All of this was successful, and deBronkart became a technology-focused cancer survivor, an active blogger on an e-patient website,<sup>4</sup> and a year later, co-chair of the Society for Participatory Medicine.<sup>5</sup>

The hospital that provided his medical care, Beth Israel Deaconess Medical Center in Boston, had been a pioneer in providing patients with online access to their medical records,<sup>6</sup> and in early 2009, deBronkart took advantage of a new feature that allowed him to download his medical data into an electronic health-record system called Google Health.<sup>7</sup> The Beth Israel system was not linked electronically to other hospital systems. Therefore, the primary benefit of Google Health was that it would allow deBronkart to keep all his medical data, from any system or physician, in one place, accessible from anywhere.

Shortly after Beth Israel copied deBronkart's data into the Google Health system, the Google site reported to him that his cancer had spread to his spine and that he had chronic lung disease and many other illnesses and conditions.<sup>8</sup> He was informed via a "Medication Alert" that his blood-pressure medication required "immediate attention." Given the news he was receiving, deBronkart probably did need a much higher dosage of blood-pressure medication at that point, but he eventually figured out that he did not have any of the problems Google Health told him he had. What he learned was that in downloading his file to Google Health, Beth Israel Deaconess sent billing codes instead of clinical diagnoses.<sup>9</sup> Google, however, accepted the codes as medical diagnoses and then informed deBronkart that he was quite ill.

<sup>2.</sup> *About Dave*, E-PATIENTDAVE.COM, http://epatientdave.com/about-dave (last visited Feb. 11, 2011).

<sup>3.</sup> TOM FERGUSON, E-PATIENTS: HOW THEY CAN HELP US SAVE HEALTH CARE 11 (2007).

<sup>4.</sup> See Author Archive, E-PATIENTS.NET, http://e-patients.net/archives/author/Dave%20 deBronkart (last visited Jan. 28, 2011).

<sup>5.</sup> See Founders Circle, SOCIETY FOR PARTICIPATORY MEDICINE, http://participatorymedicine .org/about/founders-circle (last visited Feb. 5, 2011).

<sup>6.</sup> See BETH ISRAEL DEACONESS MED. CTR. PATIENTSITE, http://www.patientsite.org (last visited Jan. 11, 2011).

<sup>7.</sup> See GOOGLE HEALTH, http://www.google.com/health (last visited Jan. 11, 2011).

<sup>8.</sup> Dave deBronkart, *Imagine Someone Had Been Managing Your Data, and Then You Looked*, E-PATIENTS.NET (Apr. 1, 2009), http://e-patients.net/archives/2009/04/imagine-if-someone-had-been-managing-your-data-and-then-you-looked.html.

<sup>9.</sup> Essentially, Beth Israel provided what they billed for rather than for what they treated. This is largely due to the billing codes not mapping well to all the medical procedures. The current system, called ICD-9, will be replaced by 2013 with ICD-10. The old system had a total of 3,838 procedure codes, while ICD-10 will have 71,957 procedure codes. *About ICD-10 CM and PCS Codes: A Review of ICD-10 History, Pros and Cons for Providers and Plans for Implementation*, ICD10CMCODE.COM (2010), http://www.icd10cmcode.com/abouticd10.php. A less complex system being replaced by a more complex system, as will be explained later in this article, opens up increasing opportunities for errors

deBronkart's problem was novel and his response unusual. Instead of consulting a lawyer and threatening to litigate, he recounted his experience on his blog.<sup>10</sup> That led, eventually, to a front-page story in the *Boston Globe*<sup>11</sup> and prompt attention by the hospital to correcting the problem. In the long term, deBronkart used the publicity he received to focus attention on the role of the patient in healthcare, and his credibility in this regard enabled him to turn his avocation into a vocation.<sup>12</sup>

This article is about new problems and the need for new solutions. The new problems are a consequence of a new technological environment in healthcare, one that has an array of elements that makes the emergence of disputes likely. This novel environment, for example, will generate large numbers of transactions; innovative entrepreneurial efforts; and the appearance of new roles, responsibilities, and relationships; all generating large amounts of data being used in novel ways and supported by an extraordinarily complex technological infrastructure. If, as noted earlier, "information is the lifeblood of modern medicine," it is also true that high-quality information is the lifeblood of high-quality medicine and, conversely, that low-quality information is the lifeblood of how-quality medicine. The manner in which information is currently employed in healthcare is highly inefficient, which slows down communication and can, as a result, reduce the emergence and discovery of problems. Accelerating communication and the use of information creates new

Will the Increased Number of Codes Make ICD-10-CM More Difficult to Use?, HEALTH AND HUMAN SERVS. (May 18, 2010, 9:33 AM), https://questions.cms.hhs.gov/app/answers/detail/a\_id/10023/~/will-the-increased-number-of-codes-make-icd-10-cm-more-difficult-to-use%3F.

10. See deBronkart, supra note 8:

Imagine that for all your life, and your parents' lives, your money had been managed by other people who had extensive training and licensing. Imagine that all your records were in their possession, and you could occasionally see parts of them, but you just figured the pros had it under control.

Imagine that you knew you weren't a financial planner but you wanted to take as much responsibility as you could—to participate. Imagine that some money managers (not all, but many) attacked people who wanted to make their own decisions, saying "Who's the financial planner here?"

Then imagine that one day you were allowed to see the records, and you found out there were a whole lot of errors, and the people carefully guarding your data were not as on top of things as everyone thought.

12. Dave deBronkart, *Should Patient Engagement Be Regulated*?, BETTER HEALTH (Oct. 11, 2010), http://getbetterhealth.com/should-patient-engagement-be-regulated/2010.10.11.

and disputes. A contrary view has been presented by the Centers for Medicare and Medicaid Services, which, in answer to the question, stated the following:

Will the increased number of codes make ICD-10-CM more difficult to use?", responded, "No, a higher number of codes do[es] not necessarily increase the complexity of the coding system[;] in fact[,] it makes it easier to find the right code. . . . It is anticipated that the improved structure and specificity of ICD-10-CM will facilitate the development of increasingly sophisticated electronic coding tools that will assist in faster code selection.

<sup>11.</sup> Lisa Wangsness, *Electronic Health Records Raise Doubt*, BOSTON GLOBE, Apr. 13, 2009, *available at* http://www.boston.com/news/nation/washington/articles/2009/04/13/electronic\_health\_records\_raise\_doubt/.

opportunities to improve healthcare, but also new opportunities for problems to occur.

The problems that surface "when the digital world merges with the physical world"<sup>13</sup> need to be addressed with tools made possible by the digital world. These tools should be employed not only to address disputes but to prevent them. Novel uses of technology have already addressed both the problem and its source in other contexts, such as e-commerce, where large numbers of transactions have generated large numbers of disputes.<sup>14</sup> If technology-supported healthcare is to improve the field of medicine, a similar effort at dispute prevention and resolution will be necessary.

The transition from paper to digital in the healthcare field is still in an early stage and occurring gradually. It is, as will be described below, an extremely complex transition involving patients, doctors, and a variety of old and new stakeholders. What has been learned from other contexts over the last two decades is that the introduction of new applications and the transition from paper to digital are never frictionless, and the problems that occur are rarely anticipated. The Internet and viruses, email and spam, peer-to-peer file sharing and copyright violations, e-commerce and identity theft, domain names and trademark infringement, and social networks and cyberbullying are only some of the more prominent examples of technological developments and their unanticipated and undesired consequences as use of the new technology has grown.<sup>15</sup>

Some of these cases involved malicious behavior. In others, although the behavior was not intended to cause harm, the newly available capabilities were employed, often creatively, with problematic consequences. In many if not most instances, however, these problems and conflicts were simply inevitable byproducts of a powerful and complex system that facilitated interactions and transactions on an unprecedented scale and in a novel manner. If deBronkart had been part of a different hospital system and had only a medical file in a manila folder, there would be no story about him. While the exact nature of all the disputes or problems that surface may be difficult to plan for, appropriate processes can still be put in place to assist those, like e-Patient Dave, who find themselves in the midst of a set of events that can be extremely troubling but not well understood. Even more importantly, a serious effort needs to be made to anticipate potential problems, understand why existing approaches and solutions oriented toward errors in paper files are inappropriate for the electronic environment, and explore possible preventive efforts.

<sup>13.</sup> NEIL GERSHENFELD, WHEN THINGS START TO THINK 10 (1999).

<sup>14.</sup> Ethan Katsh, Janet Riifkin & Alan Gaitenby, *E-Commerce, E-Disputes, and E-Dispute Resolution: In the Shadow of "eBay Law"*, 15 OHIO ST. J. ON DISP. RESOL. 705, 709 (2000).

<sup>15.</sup> See generally EDWARD TENNER, WHY THINGS BITE BACK: TECHNOLOGY AND THE REVENGE OF UNINTENDED CONSEQUENCES (1996).

This article is not an argument to stop the movement towards greater use of electronic health records (EHRs). The potential benefits to individual health, public health, and to the healthcare system are huge. Rather, it is an argument about the importance of trying to anticipate what disputes and problems are likely to arise as the transition proceeds over the next several years, why they are occurring, and what might be done to prevent or respond to them. As will be explained below, innovations such as EHRs need to be trusted to function effectively or else the new capability will not be used. Anticipating problems and preparing responses to them is one of the ways to build trust among users.

# Π

## HEALTH INFORMATION TECHNOLOGIES: AN OVERVIEW

In 2010, when the healthcare reform legislation was enacted, the White House expressed its hope that the legislation would "make health care more affordable, make health insurers more accountable, expand health coverage to all Americans, and make the health system sustainable, stabilizing family budgets, the Federal budget, and the economy."<sup>16</sup> It also made clear that these ambitious and challenging goals would require not only changes in regulatory policies and financing, but also equally ambitious and challenging uses of technology. For healthcare reform to be successful, in other words, the current system would not only need to be more efficient and work better, it would also need to be innovative and work differently. New uses of technology, particularly EHRs, would be at the center of this transformation.

The medical technologies that most patients experience, such as machines that provide internal imaging, deliver medications through the skin, enable complex surgeries, or function in a variety of ways to assist or carry out directives from doctors, can be expected to improve, grow in use, and be of critical importance. However, improved healthcare is not relying upon these technological breakthroughs, but on something else: health information technologies (HIT).

HIT, according to the Department of Health and Human Services, involves the

comprehensive management of medical information and its secure exchange between health care consumers and providers. Broad use of HIT has the potential to improve health care quality, prevent medical errors, increase the efficiency of care provision and reduce unnecessary health care costs, increase administrative efficiencies, decrease paperwork, expand access to affordable care, and improve population health.<sup>17</sup>

<sup>16.</sup> Health Reform Puts American Families and Small Business Owners in Control of Their Own Health Care, WHITEHOUSE.GOV, http://www.whitehouse.gov/health-care-meeting/proposal (last visited Dec. 27, 2010).

<sup>17.</sup> Catalyze Breakthroughs for National Priorities: Health IT, WHITEHOUSE.GOV, http://www.whitehouse.gov/issues/economy/innovation/breakthroughs (last visited Feb. 13, 2011); see

Interoperable health IT can improve individual patient care in numerous ways, including:

- Complete, accurate, and searchable health information, available at the point of diagnosis and care, allowing for more informed decision making to enhance the quality and reliability of health care delivery.
- More efficient and convenient delivery of care, without having to wait for the exchange of records or paperwork and without requiring unnecessary or repetitive tests or procedures.
- Earlier diagnosis and characterization of disease, with the potential to thereby improve outcomes and reduce costs.
- Reductions in adverse events through an improved understanding of each patient's particular medical history, potential for drug-drug interactions, or (eventually) enhanced understanding of a patient's metabolism or even genetic profile and likelihood of a positive or potentially harmful response to a course of treatment.
- Increased efficiencies related to administrative tasks, allowing for more interaction with and transfer of information to patients, caregivers, and clinical care coordinators, and monitoring of patient care.<sup>18</sup>

This list reveals how extensively the goal of quality healthcare is dependent upon high-quality information and efficient communication.<sup>19</sup> Improvements in healthcare depend on a large and extraordinarily complex transition from a medical-record environment traditionally oriented around paper to one shaped by information and communication in digital form. If the "broad use of HIT has the *potential* [to improve healthcare]" in the ways stated above, this potential will only be reached if careful attention is paid to the processes employed to generate, use, and communicate information in new ways.

A year before healthcare reform was passed, and shortly before deBronkart's story became known, the American Recovery and Reinvestment Act (ARRA), frequently called the "stimulus bill," was enacted.<sup>20</sup> Title XIII of ARRA was given a subtitle: Health Information Technology for Economic and Clinical Health Act (HITECH), and it authorized \$19.2 billion for HIT.<sup>21</sup> Most of the funding was to be used as incentives for physicians and hospitals to adopt and use EHRs, but the ultimate purpose of the legislation was to improve the

*also* THE OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., http://healthit.hhs.gov/portal/server.pt?open=512&objID=1204&parentname=CommunityPage&parent id=1&mode=2&in\_hi\_userid=10741&cached=true (last visited Feb. 13, 2011).

<sup>18.</sup> Health Information Technology General Information, NEV. DEP'T OF HEALTH AND HUMAN SERVS.: OFFICE OF HEALTH INFO. TECH. (HIT), http://dhhs.nv.gov/Hit\_GenInfo.htm (last visited Feb. 13, 2011).

<sup>19.</sup> Without HIT, "neither individual physicians nor health care institutions can perform at their best or deliver the highest-quality care, any more than an Olympian could excel with a failing heart.... The provisions of the HITECH Act are best understood not as investments in technology per se but as efforts to improve the health of Americans and the performance of their health care system." Blumenthal, *supra* note 1, at 382.

<sup>20.</sup> American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).

<sup>21.</sup> *Health Care Reform and Health IT Stimulus: ARRA and HITECH*, AM. HEALTH INFO. MGMT. ASS'N, http://www.ahima.org/advocacy/arrahitech.aspx#difference (last visited Jan. 11, 2011).

healthcare of patients. Dr. David Blumenthal, President Obama's chief advisor on healthcare, stated the following:

One of HITECH's most important features is its clarity of purpose. Congress apparently sees HIT—computers, software, Internet connection, telemedicine—not as an end in itself but as a means of improving the quality of health care, the health of populations, and the efficiency of health care systems. Under the pressure to show results, it will be tempting to measure HITECH's payoff from the \$787 billion stimulus package in narrow terms—for example, the numbers of computers newly deployed in doctors' offices and hospital nursing stations. But that does not seem to be Congress's intent. It wants improvements in health and health care through the use of HIT.<sup>27</sup>

EHRs often receive attention because of their novelty for doctors, but they are even more novel for patients. Three pioneers in the EHR field wrote the following several years ago:

Traditionally, clinical records have been sequestered in hospitals and provider's offices. Although HIPAA mandates that patients can access their medical records, it does not specify the manner in which this access is given, so most patients must visit the medical records departments of caregivers to obtain paper copies of their charts. As more clinicians adopt EHRs and a nationwide health information network (NHIN) is implemented, more and more patients will demand access to records online. Such access raises many questions. What information should be shared? How should patients be authenticated? How should privacy be protected?<sup>23</sup>

While protecting patient privacy is already an issue of concern and will be an ongoing challenge, the focus of attention here is the most common consequence arising out of patients looking at their records: questions and disputes about the accuracy, meaning, and content of the record. For example, e-Patient Dave, among all his other problems, found that he was listed in his original Beth Israel medical record as a fifty-three-year-old female.<sup>24</sup> One of the authors of this article looked at his own EHR and found X-ray reports that had been mistakenly filed. These examples illustrate why, when patients move from having a right of access to actually looking at their records, it is likely that many questions will be raised about the quality of the data they find. There is, however, no effective approach currently in place to respond to such concerns.

#### III

#### WHAT IS AN EHR?

The banking industry is more advanced in information technology than health care. I can take money out of my bank account anywhere in the world, but my hometown doctor can't tell me results from the lab across the street.<sup>25</sup>

<sup>22.</sup> David Blumenthal, *Stimulating the Adoption of Health Information Technology*, 360 NEW ENG. J MED. 1477, 1477–78 (2009).

<sup>23.</sup> John D. Halamka, Kenneth D. Mandl & Paul C. Tang, *Early Experiences with Personal Health Records*, AM. MED. INFO. ASS'N, Jan.–Feb. 2008, at 1, 1.

<sup>24.</sup> deBronkart, supra note 8.

<sup>25.</sup> AGENCY FOR HEALTHCARE RESEARCH & QUALITY, ADVANCING PATIENT SAFETY: A DECADE OF EVIDENCE, DESIGN, AND IMPLEMENTATION 5 (Nov. 2009), *available at* http://www.ahrq.gov/qual/advptsafety.htm.

The function of the paper medical record was to serve as a container and storage device, occasionally being opened to add or reveal information while, at the same time, preserving an authoritative record of treatment. EHRs, however, "do much more than keep records."<sup>26</sup> Although paper records have a very limited set of information- and communication-based functions, EHRs have a wide range of information and communications technology (ICT) capabilities. EHRs do not simply provide the user with a larger and more convenient record; they provide a record that is continuously linked to other sources. EHRs receive and transmit information while bypassing those persons previously in charge of various aspects of paper records, and they organize and process information in ways not possible with paper and manila folders. If not now, then in the future, EHRs will assist and even collaborate with physicians rather than merely provide them with information. At the same time, and perhaps more importantly, EHRs should increase patient contributions to their own healthcare.

In terms of functionalities provided, a more useful frame of reference for understanding EHRs than the paper medical file are websites, such as online banking sites, that provide "services" in addition to information. Online banking began with the relatively straightforward goal of providing balance information to account holders in a convenient manner. Over time, more data and capabilities for using data have been added, from paying bills to tracking expenses to providing suggestions about financial matters that might be relevant to the customer, all done wirelessly by phone or laptop. Online banking, in other words, began with an attempt to provide convenient access to information that had been previously available only from the passbook of decades ago and the original automated teller machine (ATM).<sup>27</sup> Gradually, however, as banks acquired information that earlier generations were unlikely to have had, and that could be collected from sources to which they were never before connected, it became possible and profitable to turn that information into something quite different from the static container of information. Indeed, online banking became a means not only to benefit its users but to gather data that could bring revenue to the bank. When aggregated with existing data, this new information would contribute to the vast array of statistics that informs us about the health of the economy. Over the next five to ten years, a similar development is likely to occur with medical information, in that expanded use of EHRs will evolve into increasingly complex, multifaceted, and dynamic records that are not only oriented toward providing data to the individual patient, but also toward collecting data with the goal of providing the

<sup>26.</sup> Sharona Hoffman & Andy Podgurski, Finding a Cure: The Case for Regulation and Oversight of Electronic Health Record Systems, 22 HARV. J.L. & TECH. 103, 108 (2008).

<sup>27.</sup> Ellen Florian, The Money Machines: The Humble ATM Revolutionized the Way We Deal with Money and Turned Global Commerce into a 24/7 Affair, FORTUNE, July 26, 2004, available at http://money.cnn.com/magazines/fortune/fortune\_archive/2004/07/26/377172/index.htm.

government and others with a better understanding of the country's healthcare system.

Another similarity between EHRs and online banking is that neither provides anything but a minimal amount of information as to what the system does. "Online banking" can refer to a system that merely provides bank balances at a distance, or it can refer to a website from which users can accomplish many tasks, such as paying bills, checking credit-card balances, purchasing stocks, and receiving retirement advice. Discussions about EHRs are often confusing because medical records in electronic form are frequently referred to using other acronyms, such as EMRs (electronic medical records) and PHRs (personal health records). Given the growing range of functionalities appearing in EHRs, however, distinctions among the different approaches represented by these acronyms are likely to become less and less meaningful. A common experience online is that boundaries that were clear in the paper environment often erode in the electronic environment, as the screen connects entities that in the physical world had been quite separate.

Whether the transition from paper to electronic is viewed from a patientcentered perspective, or one with a doctor, other stakeholder, or no one at the center, change on many levels is taking place. There are, for example, more stakeholders, increased amounts of data flowing more quickly among the stakeholders, and, much less visibly, an array of side effects. These side effects will include not only privacy issues but other clashes of interests and concerns that will only gradually emerge.

#### IV

## CURRENT USE AND "MEANINGFUL USE" OF EHRS

As EHRs began to be adopted a decade or so ago, the varied array of functions performed by different EHR software products made it difficult to compare rates of adoption and purposes for which different medical entities were using EHRs. In 2003, therefore, the Institute of Medicine identified eight core functionalities for EHRs: (1) health information and data, (2) results management, (3) order entry and management, (4) decision support, (5) electronic communication and connectivity, (6) patient support, (7) administrative processes, and (8) reporting and population health management.<sup>28</sup>

Specific components and capabilities of an EHR system were then placed in these broad categories. In 2006, the Robert Wood Johnson Foundation convened an expert group to define what constitutes "basic" and "fully

<sup>28.</sup> INST. OF MED., COMM. ON DATA STANDARDS FOR PATIENT SAFETY, KEY CAPABILITIES OF AN ELECTRONIC HEALTH RECORD SYSTEM: LETTER REPORT 7 (July 31, 2003).

functional" EHR systems.<sup>29</sup> Basic systems were defined to include patient demographics, problem lists, medication lists, clinical notes, prescription orders, laboratory results, and imaging results. Fully functional systems require all of the capabilities of a basic system with the following additions: medical history and follow-up, orders for laboratory and radiology tests, electronic transmission of prescriptions and orders, electronic images returned, warnings of drug interactions and contraindications, highlighting of out-of-range test levels, and reminders of guideline-based interventions and screening.

Current usage of EHRs, however they are defined, is limited. The National Ambulatory Medical Care Survey (NAMCS), conducted by the National Center for Health Statistics, has been asking providers about EHR usage for a decade.<sup>30</sup> In addition to providers' self-reported rates of EHR usage, NAMCS asks about specific system capabilities. The survey then applies the Robert Wood Johnson distinction between "basic" and "fully functional" systems. The 2009 NAMCS found 20.5% of respondents reported using a basic system.<sup>31</sup> This follows both the 2008 NAMCS estimate of 16.7%<sup>32</sup> and a late 2007 and early 2008 nationwide survey of practicing physicians, which was conducted by the Institute for Health Policy using the same system criteria, which found a rate of 13% usage of basic EHRs.<sup>33</sup> Adoption of a fully functional system is lower still. The 2009 NAMCS found 6.3% of physicians reporting use of a fully functional system, following its 2008 figure of 4.4%<sup>34</sup> and the Institute for Health Policy's rate of 4%.<sup>35</sup>

Various explanations account for the low rates of adoption. Providers are discouraged from adoption both by the high initial cost of system implementation and the difficulty in recouping the costs.<sup>36</sup> Many of the benefits of EHRs fall to insurance companies and patients while the costs fall to the physicians. Thus, the return of the initial investment may be prohibitively slow, particularly for smaller practices that might rely on credit to finance the project. A study commissioned by the California HealthCare Foundation to survey the barriers faced by hospitals noted that financial concerns were not limited to the initial implementation cost; other costs cited included system maintenance,

<sup>29.</sup> ROBERT WOOD JOHNSON FOUND., HEALTH INFORMATION TECHNOLOGY IN THE UNITED STATES: THE INFORMATION BASE FOR PROGRESS 2:6 (2006).

<sup>30.</sup> About the Ambulatory Health Care Surveys, CTR. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/nchs/ahcd/about\_ahcd.htm (last visited Mar. 17, 2011).

<sup>31.</sup> C.J. HSIAO ET AL., CTRS. FOR DISEASE CONTROL & PREVENTION, NAT'L CTR. FOR HEALTH STATISTICS, ELECTRONIC MEDICAL RECORD/ELECTRONIC HEALTH RECORD USE BY OFFICE-BASED PHYSICIANS: UNITED STATES, 2008 AND PRELIMINARY 2009, at 1 (Dec. 2009).

<sup>32.</sup> Id.

<sup>33.</sup> Catherine M. DesRoches et al., *Electronic Health Records in Ambulatory Care—A National Survey of Physicians*, 359 NEW ENG. J. MED. 50, 54 (2008).

<sup>34.</sup> HSIAO ET AL., supra note 31, at 1.

<sup>35.</sup> DesRoches et al., supra note 33, at 54.

<sup>36.</sup> CONG. BUDGET OFFICE, EVIDENCE ON THE COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY 17–18 (2008).

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adding qualified staff, and integrating the EHRs with existing practicemanagement systems.<sup>37</sup> Concerns about workflows and provider buy-in are also present.<sup>38</sup>

The HITECH Act,<sup>39</sup> which was part of the 2009 stimulus legislation, authorized payments of \$44,000 (for Medicare Eligible Professionals)<sup>40</sup> and \$63,750 (for Medicaid Eligible Professionals)<sup>41</sup> to overcome physician resistance and accelerate adoption and use of EHRs. The payments would be made over three or four years to those qualified who purchased an EHR system that was certified to provide an array of specific functionalities. In addition, these systems would actually have to be used in a manner meeting the statutory definition of "meaningful." A draft of these "meaningful use" requirements was released for public comment in January 2010, and the final regulations were announced on July 13, 2010.<sup>42</sup>

The requirements that must be satisfied in order to receive the initial payments are summarized in the following charts. Figure 1 contains a list of fifteen specific uses of EHRs that must be met during the first year. Figure 2 shows a list of ten additional criteria, from which physicians must select and meet five.

<sup>37.</sup> CAL. HEALTHCARE FOUND., SNAPSHOT: THE STATE OF HEALTH TECHNOLOGY IN CALIFORNIA: USE AMONG HOSPITALS AND LONG TERM CARE FACILITIES 15 (2008).

<sup>38.</sup> Id.

<sup>39.</sup> Health Information Technology for Economic and Clinical Health Act (HITECH Act), Pub. L. No. 111-5, Div. A, Title XIII, Div. B, Title IV, 123 Stat. 226, 467 (codified as amended at 42 U.S.C. §§ 201 et seq. (2009)).

<sup>40.</sup> CMS Finalizes Requirements for the Medicare Electronic Health Records (EHR) Incentive Program, CTRS. FOR MEDICARE & MEDICAID SERVS. (July 16, 2010), http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3792&intNumPerPage=10&checkDate=&checkKey=&srchType=1&num Days=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pY ear=&year=&desc=&cboOrder=date.

<sup>41.</sup> *EHR Incentive Programs*, CTRS. FOR MEDICARE & MEDICAID SERVS. (last modified Jan. 11, 2011), https://www.cms.gov/ehrincentiveprograms/.

<sup>42.</sup> Fact Sheet: Meaningful Use Final Rule Overview, CTRS. FOR MEDICARE & MEDICAID SERVS. (July 16, 2010), https://www.cms.gov/apps/media/press/factsheet.asp?Counter=3794&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date.

# Figure 1: Summary Overview of Meaningful-Use Criteria<sup>43</sup>

Summary Overview of Meaningful Use Objectives.*	
Objective	Measure
Core set of objectives to be achieved by all eligible professionals, ho	spitals, and critical access hospitals to qualify for incentive payments
Record patient demographics (sex, race, ethnicity, date of birth, preferred language, and in the case of hospitals, date and preliminary cause in the event of death)	Over 50% of patients' demographic data recorded as structured data
Record vital signs and chart changes (height, weight, blood pres- sure, body-mass index, growth charts for children)	Over 50% of patients 2 years of age or older have height, weight, and blood pressure recorded as structured data
Maintain up-to-date problem list of current and active diagnoses	Over 80% of patients have at least one entry recorded as structured data
Maintain active medication list	Over 80% of patients have at least one entry recorded as structured data
Maintain active medication allergy list	Over 80% of patients have at least one entry recorded as structured data
Record smoking status for patients 13 years of age or older	Over 50% of patients 13 years of age or older have smoking status recorded as structured data
For individual professionals, provide patients with clinical sum- maries for each office visit; for hospitals, provide an electronic copy of hospital discharge instructions on request	Clinical summaries provided to patients for over 50% of all office vis- its within 3 business days; over 50% of all patients who are discharged from the inpatient department or emergency department of an eligible hospital or critical access hospital and who request an electronic copy of their discharge instructions are provided with it
On request, provide patients with an electronic copy of their health information (including diagnostic-test results, problem list, medi- cation lists, medication allergies, and for hospitals, discharge summary and procedures)	Over 50% of requesting patients receive electronic copy within 3 business days
Generate and transmit permissible prescriptions electronically (does not apply to hospitals)	Over 40% are transmitted electronically using certified EHR technology
Computer provider order entry (CPOE) for medication orders	Over 30% of patients with at least one medication in their medica- tion list have at least one medication ordered through CPOE
Implement drug-drug and drug-allergy interaction checks	Functionality is enabled for these checks for the entire reporting period
Implement capability to electronically exchange key clinical infor- mation among providers and patient-authorized entities	Perform at least one test of EHR's capacity to electronically ex- change information
Implement one clinical decision support rule and ability to track compliance with the rule	One clinical decision support rule implemented
Implement systems to protect privacy and security of patient data in the EHR	Conduct or review a security risk analysis, implement security up- dates as necessary, and correct identified security deficiencies
Report clinical quality measures to CMS or states	For 2011, provide aggregate numerator and denominator through attestation; for 2012, electronically submit measures

43. David Blumenthal & Marilyn Tavenner, *The "Meaningful Use" Regulation for Electronic Health Records*, 363 NEW ENG. J. MED. 501, 502 (2010).

# Figure 2: Summary Overview of Meaningful-Use Criteria (Continued.)44

Summary Overview of Meaningful Use Objectives (Continued.)		
Objective	Measure	
Eligible professionals, hospitals, and critical access hospitals may select any five choices from the menu set		
Implement drug formulary checks	Drug formulary check system is implemented and has access to at least one internal or external drug formulary for the entire reporting period	
Incorporate clinical laboratory test results into EHRs as structured data	Over 40% of clinical laboratory test results whose results are in positive/ negative or numerical format are incorporated into EHRs as struc- tured data	
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate at least one listing of patients with a specific condition	
Use EHR technology to identify patient-specific education re- sources and provide those to the patient as appropriate	Over 10% of patients are provided patient-specific education re- sources	
Perform medication reconciliation between care settings	Medication reconciliation is performed for over 50% of transitions of care	
Provide summary of care record for patients referred or transi- tioned to another provider or setting	Summary of care record is provided for over 50% of patient transi- tions or referrals	
Submit electronic immunization data to immunization registries or immunization information systems	Perform at least one test of data submission and follow-up submis- sion (where registries can accept electronic submissions)	
Submit electronic syndromic surveillance data to public health agencies	Perform at least one test of data submission and follow-up submission (where public health agencies can accept electronic data)	
Additional choices for hospitals and critical access hospitals		
Record advance directives for patients 65 years of age or older	Over 50% of patients 65 years of age or older have an indication of an advance-directive status recorded	
Submit electronic data on reportable laboratory results to public health agencies	Perform at least one test of data submission and follow-up submis- sion (where public health agencies can accept electronic data)	
Additional choices for eligible professionals		
Send reminders to patients (per patient preference) for preventive and follow-up care	Over 20% of patients 65 years of age or older or 5 years of age or younger are sent appropriate reminders	
Provide patients with timely electronic access to their health information (including laboratory results, problem list, medication lists, medication allergies)	Over 10% of patients are provided electronic access to information within 4 days of its being updated in the EHR	

These figures reveal that the goal of the meaningful use requirements is not simply to put more information in a more useable form in front of the doctor. Instead, new roles and new uses of information are anticipated, the most significant of which concerns patients. The paper record was something that assisted doctors in managing patient healthcare. The EHR is intended to provide even more assistance to physicians in managing the healthcare of patients, and it is also intended to assist patients in monitoring and managing their own healthcare. The means to improved health is not simply to provide the physician with more information more quickly, but to establish a new relationship between doctors and patients in which responsibility for the patients' healthcare and well-being is truly a shared responsibility. What is envisioned is a more consistent and effective flow of information among patients, physicians, and other healthcare providers with the EHRs managing much of this communication process.<sup>45</sup>

Rendering patient medical records in electronic form and allowing patients to share access with physicians is considered an important element in achieving all the goals desired from HIT. The goal of what has been labeled "patient engagement," however, is not simply to have the patient monitor his or her own health, but to monitor the health record and contribute to its value by identifying errors and other problems. One of the Health and Human Services working groups on EHRs stated the following:

Patient Engagement plays a major role in identifying errors and preventing problems. For example, in ambulatory settings, in nearly every encounter when it is possible for patients to observe and discuss information as it is entered during the health care encounter, potential errors can be avoided. Through a personal health record (PHR) or patient portal, patients obtain the ability to review some of the data in their EHR, and, as a result, PHRs and/or patient portals should continue to be encouraged. Access by family members to inpatient medication lists should also be encouraged (assuming appropriate authorization from the patient). Mechanisms that make it easier for patients to report inaccurate or questionable data need to be encouraged as "best practices." Examples include (a) the use of a "feedback button" that makes it easy for a patient to communicate with and receive feedback about system problems, and (b) a secure communication link, perhaps through a PHR, that permits patients to link back to the provider to report data corrections and omissions.<sup>46</sup>

EHRs will continue to be a resource for doctors but a new role is being created for the patient, and new uses are intended for the information being

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... If employed more broadly, it has the added benefits of enhancing communication among all providers of care and engaging patients and families/caregivers more consistently and meaningfully in their overall care.

Jeffrey L. Greenwald et al., *Transforming Healthcare: Making Inpatient Medication Reconciliation Patient Centered, Clinically Relevant and Implementable: A Consensus Statement on Key Principles and Necessary First Steps*, 5 J. HOSP. MED. 477, 481–85 (2010).

<sup>45.</sup> One example of this is the medication list part of the EHR and the process of medication reconciliation. Having a complete, up to date, and accurate medication list is a challenge and requires ongoing exchanges between patients and their doctors. It has been noted that

In order to implement successful medication reconciliation processes, one must build the steps with the patient and family/caregiver as the focus and demonstrate an understanding of the intent of these processes. At its roots, medication reconciliation was developed to ensure that clinicians do not inadvertently add, change, or omit medications and that changes made are communicated to all relevant caregivers ....

<sup>...</sup> Included within this strategy must be a clear and compelling message that transmits the importance of safe medication practices. Current messages such as "keep a list" while important, do not offer enough of a sense of urgency or importance. A more powerful message could involve highly publicized medication errors or close calls that would resonate with a broad audience.

<sup>46.</sup> OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., ADOPTION-CERTIFICATION WORKGROUP HIT SAFETY RECOMMENDATIONS 3 (Apr. 22, 2010), available at http://healthit.hhs.gov/portal/server.pt/community/healthit\_hhs\_gov\_policy\_recommendations/1815/A doptionCertificationLetterHITSafetyFINAL508.pdf.

collected. Those requirements in Figure 1 that involve "structured data," for example, are intended to facilitate communication of that data to public-health authorities. As the stage-one meaningful-use guidelines state, a main goal is

electronically capturing health information in a coded format; using that information to track key clinical conditions and communicating that information for care coordination purposes (whether that information is structured or unstructured, but in structured format whenever feasible); consistent with other provisions of Medicare and Medicaid law, implementing clinical decision support tools to facilitate disease and medication management; and reporting clinical quality measures and public health information.<sup>47</sup>

Placement of information in electronic form makes it possible to empower patients and increase the amount of data communicated to public-health authorities. At the same time, it increases opportunities for problems to arise, and the informal and perhaps invisible systems that prevented or resolved disputes in the paper environment are not present or play less of a role in the new system. The "meaningful use" criteria illustrate quite clearly that technology is being employed not simply to duplicate the paper record in a more efficient way, but to exploit technology now available in ways that will change roles and relationships as well as what information is available and how it is used.

# V

# CORRECTING ERRORS: PAPER MEDICAL RECORDS

A main purpose of "patient engagement" is to identify errors. Little attention seems to have been devoted, however, to the next step of what should happen once an error is discovered. At present, the meaningful-use criteria say nothing about this and, as a result, the most relevant legal regulations in force are those issued by the Department of Health and Human Services after passage of the Health Insurance Portability and Accountability Act (HIPAA). These regulations, contained in Section 164.526 of the Code of Federal Regulations, state the following:

Sec. 164.526 Amendment of protected health information.

(a) Standard: Right to amend.

(1) Right to amend. An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in the designated record set.

(2) Denial of amendment. A covered entity may deny an individual's request for amendment, if it determines that the protected health information or record that is the subject of the request:

<sup>47.</sup> Medicare and Medicaid Programs: Electronic Health Record Incentive Program, 75 Fed. Reg. 1844, 1852 (Jan. 13, 2010) (to be codified at 42 C.F.R. pt. 495).

(i) Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of protected health information is no longer available to act on the requested amendment;

- (ii) Is not part of the designated record set;
- (iii) Would not be available for inspection under Sec. 164.524; or
- (iv) Is accurate and complete.<sup>48</sup>

When these regulations were drafted in 1999, no previous standards existed concerning patient access to a medical record. The drafters, therefore, decided to borrow language from the Privacy Act of 1974.<sup>49</sup> That Act allowed an "individual to request amendment of a record pertaining to him" and within ten days, the agency that maintains the records must either "make any correction of any portion thereof which the individual believes is not accurate, relevant, timely, or complete" or "inform the individual of its refusal to amend the record."<sup>50</sup>

When the draft HIPAA regulations were published for public comment, the Privacy Act's language about amending and correcting was included and patients were given a right to "request a covered health care provider or health plan to amend or correct protected health information about the individual for as long as the covered entity maintains the information."<sup>51</sup> This language, however, turned out to be controversial, and the word "correct" was removed from the regulation. The change was explained as follows:

Many commenters strongly encouraged the Secretary to adopt "appendment" rather than "amendment and correction" procedures. They argued that the term "correction" implies a deletion of information and that the proposed rule would have allowed covered entities to remove portions of the record at their discretion. Commenters indicated that appendment rather than correction procedures will ensure the integrity of the medical record and allow subsequent health care providers access to the original information as well as the appended information. They also indicated appendment procedures will protect both individuals and covered entities since medical records are sometimes needed for litigation or other legal proceedings.

Response: We agree with commenters' concerns about the term "correction." We have revised the rule and deleted "correction" from this provision in order to clarify that covered entities are not required by this rule to delete any information from the designated record set. We do not intend to alter medical record retention laws or current practice, except to require covered entities to append information as requested to ensure that a record is accurate and complete.<sup>52</sup>

The challenge of amending without deleting, or correcting without changing, may be conceptually difficult, but it does not appear to have caused many actual problems or a need to reconsider or clarify the regulation. Stapling or affixing a

<sup>48. 45</sup> C.F.R. § 164.526.

<sup>49. 5</sup> U.S.C.A. § 552(a) (2006).

<sup>50.</sup> Id.

<sup>51.</sup> Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,558 (Dec. 28, 2000) (to be codified at 45 C.F.R. pt. 160 and 164).

<sup>52.</sup> Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,736.

note acknowledging an error in the paper record was convenient. Indeed, for most patients who never exercised their right to access the paper file, the right to amend was also largely irrelevant.

VI

## ERRORS, DISPUTES, AND EHRS

The Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information, published in December 2008 by the Office of the National Coordinator for Health Information Technology (ONC) included a section labeled "Correction."<sup>53</sup> It stated that

[i]ndividuals should be provided with a timely means to dispute the accuracy or integrity of their individually identifiable health information, and to have erroneous information corrected or to have a dispute documented if their requests are denied.

Individuals have an important stake in the accuracy and integrity of their individually identifiable health information and an important role to play in ensuring its accuracy and integrity. Electronic exchange of individually identifiable health information may improve care and reduce adverse events. However, any errors or conclusions drawn from erroneous data may be easily communicated or replicated (e.g., as a result of an administrative error as simple as a transposed digit or more complex error arising from medical identity theft). For this reason it is essential for individuals to have practical, efficient, and timely means for disputing the accuracy or integrity of their individually identifiable health information, to have this information corrected, or a dispute documented when their requests are denied, and to have the correction or dispute communicated to others with whom the underlying information has been shared. Persons and entities, that participate in a network for the purpose of electronic exchange of individually identifiable health information, should make processes available to empower individuals to exercise a role in managing their individually identifiable health information and should correct information or document disputes in a timely fashion.<sup>54</sup>

It was not surprising that ONC was concerned with errors. A landmark study in 1999 by the Institute of Medicine called *To Err Is Human* had highlighted the error problem.<sup>55</sup> It noted that

[p]reventable adverse events are a leading cause of death in the United States. When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of these two studies imply that at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of medical errors. Even when using the lower estimate, deaths in hospitals due to preventable adverse events exceed the number attributable to the 8th-leading cause of death. Deaths due to preventable adverse for eventable adverse events exceed the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516).<sup>56</sup>

<sup>53.</sup> OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., NATIONWIDE PRIVACY AND SECURITY FRAMEWORK FOR ELECTRONIC EXCHANGE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION 7 (Dec. 2008).

<sup>54.</sup> Id.

<sup>55.</sup> INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn et al. eds., 2000) [hereinafter TO ERR IS HUMAN].

<sup>56.</sup> Id. at 26.

#### More recently, a study of Medicare data found that

2.7 percent of the nearly 11.9 million records in the database, approximately 321,300 records, contained coding errors. Such errors can impact the clinician's and/or the patient's insurance reimbursement and/or cause additional time to be spent correcting the errors. The study also identified the immediate benefits of addressing the errors. According to the Medicare study, the top 10 coding errors accounted for 70 percent of the total errors. By focusing on those 10 coding errors a high percentage of the problem can be addressed instantly, saving time and money.<sup>57</sup>

As a result of these studies, the hope that data quality in EHRs would be high and generate fewer errors became a key selling point for EHRs. Reducing medical errors through EHRs was even mentioned in two State of the Union Addresses by President Bush<sup>58</sup> and in an address to a Joint Session of Congress by President Obama.<sup>59</sup>

EHRs certainly have the potential to reduce errors. Medication errors can be reduced by alerting doctors of two or more drugs whose interaction is known to produce side effects or of a drug to which the patient is known to be allergic.<sup>60</sup> Electronic reminders sent to patients and data about a patient sent wirelessly and automatically to the health provider can also lower error rates. Several of the meaningful-use requirements are explicitly aimed at reducing the particular kinds of errors identified by *To Err Is Human*, such as drug interactions and misread prescriptions.

On the other hand, the widespread use of EHRs is creating an environment in which new kinds of errors and problems can emerge, while no new processes or standards have been put in place to respond to these errors. Moving from a paper to electronic environment can influence both how disputes emerge and how they are managed. In any environment, context can affect the kinds of disputes that are likely to arise, as well as the parties who are likely to be involved. Context implicitly provides information about the extent or nature of the injury as well as how the injury or dispute is perceived by those involved.

<sup>57.</sup> MARKLE FOUND., THE CONNECTING FOR HEALTH COMMON FRAMEWORK, BACKGROUND ISSUES ON DATA QUALITY 2 (2006) (citation omitted).

<sup>58.</sup> In his 2006 State of the Union address, President Bush stated, "We will make wider use of electronic records and other health information technology, to help control costs and reduce dangerous medical errors." George W. Bush, President of the United States of America, State of the Union Address (Jan. 31, 2006). In his 2005 State of the Union address, he asked Congress "to move forward on a comprehensive health-care agenda with tax credits to help low-income workers buy insurance; a community health center in every poor county; improved information technology to prevent medical error and needless costs." George W. Bush, President of the United States of America, State of the Union Address (Feb. 2, 2005).

<sup>59.</sup> President Obama, in an Address to the Joint Session of Congress in February 2009, stated, "Our recovery plan will invest in electronic health records and new technology that will reduce errors, bring down costs, ensure privacy and save lives." Barack Obama, President of the United States of America, State of the Union Address (Feb. 24, 2009).

<sup>60.</sup> AGENCY FOR HEALTHCARE RESEARCH & QUALITY, REDUCING ERRORS IN HEALTH CARE: TRANSLATING RESEARCH INTO PRACTICE (Apr. 2000), *available at* http://www.ahrq.gov/qual/errors.htm.

Context situates a dispute in a particular time and place, and individuals react and adjust accordingly as the parameters of the environment become clear.

In other words, by creating a new context for physicians to treat and interact with patients, a new context for generating disputes and problems is being created as well—one in which "EHR systems may generate errors rather than prevent them, especially early in the adoption process."<sup>61</sup> The following factors are illustrative of some of the elements of the new environment that make this a likely scenario.

1. Level of Complexity. The new environment is more complex than the old, and its level of complexity is ever increasing. Complexity is related to the number of parts or elements in any process or system, and paper, on almost any measure, supports a less complex environment than digital. Not much can go wrong with a manila folder. It can, of course, get lost, but that in itself can remove the record as an element in a dispute. Mark Rothstein, for example, has observed that

in a largely paper-based system, individual privacy with regard to old, sensitive health information is protected because the records tend to "disappear" with age—based on patient relocation, provider retirement, storage issues, or similar factors. In an age of electronic health records, nothing will disappear, and the protections of blocking, role-based access, or other measures will not necessarily relieve the anxiety of individuals who know that embarrassing information is in their health records.<sup>62</sup>

The simplicity of the paper record is visible to us, but the complexity of EHRs is hidden by the screen. EHRs may be convenient and easy to use, but this should not be confused with simplicity. Bill Gates once remarked that "[t]he magic of software can eliminate . . . complexity."<sup>63</sup> More accurately, the magic of software is that it hides complexity, thus providing us with the illusion

<sup>61.</sup> Hoffman & Podgurski, *supra* note 26, at 120; A Canadian report has similarly pointed out that there is

evidence to suggest that EHRs may facilitate medical errors and/or generate new kinds of errors, which in turn may have direct and far-reaching negative impacts on patient safety. In survey interviews conducted by Ash and colleagues, for instance, 176 physicians from various U.S. hospitals with implemented CPOE systems reported various "new kinds of errors" associated with using CPOEs, including "entering orders for the wrong patient, errors of omission, nurses not knowing an order had been generated, desensitization to alerts, loss of information during care transitions, wrong medication dosing, and overlapping medication orders.

NICOLE GRIMM, MICAELA BROWN & NICOLA SHAW, THE RELATIONSHIP BETWEEN ELECTRONIC HEALTH RECORDS AND PATIENT SAFETY: A JOINT REPORT ON FUTURE DIRECTIONS FOR CANADA 7 (2007), *available at* http://www2.infoway-inforoute.ca/Documents/EHR-Patient%20Safety%20Report .pdf (citations omitted).

<sup>62.</sup> Mark Rothstein, *Protecting Privacy and Confidentiality in the Nationwide Health Information Network, in* PAPER KILLS: TRANSFORMING HEALTH AND HEALTHCARE WITH INFORMATION TECHNOLOGY 17, 24 (David Merritt ed., 2007).

<sup>63.</sup> Scarlet Pruitt, *Gates Touts Software Magic*, PCWORLD (Nov. 16, 2004, 10:00 AM), http://www.pcworld.com/article/118605/gates\_touts\_software\_magic.html.

of simplicity.<sup>64</sup> Successful software leads us to confuse ease of use with simplicity, and to assume that when we perform challenging tasks with a computer, what is behind the screen is as simple as what is on it. We can be empowered by the complexity of software but, as was the case with e-Patient Dave, greater levels of complex interactions and relationships also often create greater levels of errors and disputes.<sup>65</sup>

2. Why Mistakes Happen. To Err Is Human notes that "the majority of medical errors do not result from individual recklessness or the actions of a particular group—this is not a 'bad apple' problem. More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them."<sup>66</sup> In addition, many errors, problems, or mistakes occur not from faulty systems, but from systems being employed in unanticipated ways or generated as a byproduct of a novel combination of

- Data Accuracy: Data are the correct values and are valid.
- Data Accessibility: Data items should be easily obtainable and legal to collect.
- Data Comprehensiveness: All required data items are included. Ensure that the entire scope of the data is collected and document intentional limitations.
- Data Consistency: The value of the data should be reliable and the same across applications.
- Data Currency: The data should be up-to-date. A datum value is up-to-date if it is current for a specific point in time. It is outdated if it was current at some preceding time yet incorrect at a later time.
- Data Definition: Clear definitions should be provided so that current and future data users will know what the data mean. Each data element should have clear meaning and acceptable values.
- Data Granularity: The attributes and values of data should be defined at the correct level of detail.
- Data Precision: Data values should be just large enough to support the application or process.
- Data Relevancy: The data are meaningful to the performance of the process or application for which they are collected.
- Data Timeliness: Timeliness is determined by how the data are being used and their context.

AHIMA's e-HIM Workgroup on Health Info. Mgmt. in Health Info. Exch., *HIM Principles in Health Information Exchange: Data Quality Attributes Grid (Appendix), in HIM Principles in Health Information Exchange (AHIMA Practice Brief), J. AHIMA, Sept. 2007, at 69, available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1\_035071.pdf.* 

65. Ray Ozzie, until recently the Chief Software Architect at Microsoft, has written that "*Complexity kills*. Complexity sucks the life out of users, developers and IT. Complexity makes products difficult to plan, build, test and use. Complexity introduces security challenges. Complexity causes administrator frustration. And as time goes on and as software products mature—even with the best of intent—complexity is inescapable." Ray Ozzie, *Dawn of a New Day*, RAY OZZIE'S BLOG (Oct. 28, 2010), http://ozzie.net/docs/dawn-of-a-new-day/.

66. INST. OF MED., REPORT BRIEF: TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 2 (2009), *available at* http://iom.edu/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err %20is%20Human%201999%20%20report%20brief.pdf.

<sup>64.</sup> Among the data-quality elements that make the content of the EHR complex are the following from the "HIM Principles in Health Information Exchange: Data Quality Attributes Grid" (appendix), developed by the American Health Information Management Association.

factors. A system, for example, that may work correctly when used by a few may encounter problems when employed on a large scale.

The most frequently cited example regarding the emergence and resolution of disputes in cyberspace is eBay. eBay handled over sixty-million disputes between buyers and sellers in 2009.<sup>67</sup> While some involved fraud, most involved accidental damage, miscommunication, or misunderstandings of the kind that may affect a certain percentage of any kind of transaction in any context when the overall number of transactions is extremely large.

3. *Disruptive Technology*. EHRs are a "disruptive technology."<sup>68</sup> They are disruptive not in a negative sense, but in that new roles and relationships will be generated if patient engagement succeeds. The end result may be positive for most, but not for those who benefit from the manner in which the old system functioned. The former Director of the Agency for Healthcare Research and Quality has stated that

[h]ealth IT promises to be transforming. But transformation means fundamental change. When we talk about 're-engineering' health care settings that were never really 'engineered' to begin with, we're talking about a lot of learning: valuable learning, but lots of it. One of our grantees has figured that, for the provider, transition to health IT is 'one part technology, and two parts culture and work process change.<sup>69</sup>

Roles, responsibilities, assumptions, and expectations were all clear in the old environment. Both patients and physicians' offices will be facing not only a complex environment but an unfamiliar one, one previously managed face-to-face and now managed at least in part by software. Rapid change of this kind also challenges informal dispute-resolution models that had evolved over time and had been sufficient in the past.

4. *Meaningful Use.* "Meaningful use" is creating a new and valuable market not only for existing EHR vendors but for a variety of entrepreneurial activities that do not yet exist, and will be built on the new technological infrastructure that is being put in place. If meaningful use is successful in accelerating adoption of EHRs, a new kind of technology-related health marketplace is likely to develop. Meaningful use, after all, is traceable back to the economic benefits hoped for in the stimulus-package legislation of 2009, not the health-reform legislation of 2010. In general, a decision to pursue a claim or complaint also requires a decision concerning whether something is valuable

<sup>67.</sup> Interview with Colin Rule, Dir. of Online Dispute Resolution, eBay and PayPal (June 4, 2010).

<sup>68.</sup> See generally Joseph L. Bower & Clayton M. Christensen, *Disruptive Technologies: Catching the Wave*, HARV. BUS. REV., Jan.–Feb. 1995, at 43; CLAYTON M. CHRISTENSEN, THE INNOVATOR'S DILEMMA: WHEN NEW TECHNOLOGIES CAUSE GREAT FIRMS TO FAIL (1997).

<sup>69.</sup> Carolyn Clancy, M.D., Dir. of the Agency for Healthcare Research & Quality, Remarks at the American Medical Informatics Association Annual Symposium: Health Information Technology, Quality of Care, and Evidence-based Medicine: An Interlinked Triad (Oct. 25, 2005).

enough to justify engaging in a dispute-resolution process.<sup>70</sup> Parties only engage in dispute resolution or problem solving over items of value to them, and errors connected to EHRs are valuable not only because personal health is valuable but because the data may have an impact on something, for example insurance, that is not directly connected to health. The same data may be more worth fighting over when it appears in an EHR than when it was in a paper record.

5. *Patient Engagement*. If patient engagement or empowerment actually occurs, patients will access files and discover problems that existed before but were unknown to them. Errors, in the past, were likely to be discovered either when patients were admitted to a hospital or as part of discovery in a malpractice suit. The more patients are engaged, the more errors they will discover, which is just what they are expected to do. However, lack of processes to resolve disputes or respond to problems will also likely lead to even more disputes.

6. *More Useful and Usable Information.* The new context is not simply one of more accessible data for the doctor and patient to see. As noted earlier, the meaningful-use requirement of having certain information in a structured format is designed to make that information more useful and usable. There are some existing reporting responsibilities for public-health purposes, but stage one of meaningful use may be the beginning of a larger, lucrative activity of using data in a de-identified state for a variety of purposes that will inevitably generate new relationships, commercial enterprises, and disputes. Clear benefits can be obtained "by aggregating our data into large, anonymized databanks that smart software can analyze to look for patterns. Early detection means early intervention means fewer crises."<sup>71</sup> At the same time, this not only has privacy and security implications, but it also presents significant opportunities for disputes and other unanticipated problems.

7. *Trust.* The least visible but perhaps most important challenge in moving from an established environment to a novel one is maintaining a level of trust. The reshaping of roles and responsibilities by the Internet can lead to ambiguity, uncertainty, and higher levels of risk. Mistrust can affect both the emergence of disputes and how difficult they are to resolve. Signs of trust that had been understood implicitly, or that had been fashioned over time as a result of experience, now need to be created, or recreated, out of code. Relying on

<sup>70.</sup> For example, the domain-name system existed for almost fifteen years before a process was established to resolve disputes between domain-name holders and trademark owners. For most of that time, until 1992, domain names were essentially worthless because commercial activity was banned from the Internet until 1992. For several years after that, domain names remained of little value because relatively few companies established websites during that period. *See generally* Jay P. Kesan & Rajiv C. Shah, *Fool Us Once Shame on You—Fool Us Twice Shame on Us: What We Can Learn From the Privatizations of the Internet Backbone Network and the Domain Name System*, 79 WASH. U. L.Q. 89 (2001).

<sup>71.</sup> Dave deBronkart, *I'm Putting My Data in Google and HealthVault*, THE NEW LIFE OF E-PATIENT DAVE (Feb. 22, 2009), http://patientdave.blogspot.com/search/label/Google%20Health.

prior trusting relationships to resolve problems will not be successful. Patient engagement will require trust on the part of patients or patients will not be willing to "engage." On the other hand, innovations that make old standards less relevant also create uncertainty and can be "costly in terms of loss of trust in the system by patients and diminished satisfaction by both patients and health professionals."<sup>72</sup>

One lesson of the e-commerce experience was that when mistrust and fear of loss were present, convenience and cost savings were generally not sufficient to entice users to experiment with, and participate in, novel online activities. The most successful online ventures have understood this. For example, eBay recognized the importance of trust, and put in place a feedback rating system that allowed buyers to gauge the trustworthiness of a seller prior to bidding on an item. Amazon simply promised to take back any book in which a reader had expressed dissatisfaction. Government regulation in the United States limited risk of loss to fifty dollars for a stolen credit card and banks promised no liability for both credit cards and debit cards. In a more recent example, anyone purchasing and downloading an "app" for their phone from the Android Marketplace can cancel the sale within twenty-four hours if they are dissatisfied with it. Those designing and implementing EHRs need to understand the importance of trust and build trust-enhancing processes into EHRs.

## VII

# ONLINE DISPUTE RESOLUTION AND PREVENTION

Online dispute resolution (ODR) is an approach to resolving disputes that relies on the communications and information-processing capabilities of digital machines. In some instances, such as with eBay, the technology is used to help parties in a dispute negotiate a solution to their problem. Blind bidding software<sup>73</sup> that is used in monetary disputes is another. In other contexts, software assists a third party in interacting with the disputants, facilitating some stages of mediation such as brainstorming and identifying options and interests, facilitating participation from a distance, and, in general, providing the third party with capabilities for communicating and using information in ways that help and support the mediator. This role for software has been described as a "fourth party."<sup>74</sup>

Not surprisingly, computers are more frequently used to directly assist parties in less complex disputes than in highly complex ones. Monetary disputes meet this criterion even if a large sum is involved because the dispute involves a

<sup>72.</sup> TO ERR IS HUMAN, supra note 55, at 2.

<sup>73.</sup> See, e.g., Web Assisted Claim Settlement, CYBERSETTLE.COM, http://www.cybersettle.com/pub/home/products/claimresolution.aspx (last visited Apr. 13, 2011).

<sup>74.</sup> ETHAN KATSH & JANET RIFKIN, ONLINE DISPUTE RESOLUTION: RESOLVING CONFLICTS IN CYBERSPACE 93 (2001).

single issue, which a computer's calculating capability can easily resolve. eBay disputes are in this category for another reason; namely that they are single-transaction disputes in which the range of problems that need to be dealt with are finite and predictable.

Fourth-party software can be employed in more complex multi-party disputes because the technology is working with the neutral third party. The role of technology is less focused but more flexible. There may be a complex algorithm relied on for some purpose or, more commonly, the technology supports discussion online without parties needing to be at any one place at any one time.

ODR has been successful in a variety of environments, but most of the disputes generated in these environments are less complex than those likely to arise in healthcare. For example, credit errors are fixable because the three credit bureaus contain almost everyone's credit file and these files are factual in nature. Banking and credit-card errors, under federal law, usually lead to returning money to the consumer. Domain-name disputes revolve around a small set of standards that assist an arbitrator in determining whether there was "use in bad faith."<sup>75</sup>

Disputes in the EHR environment will involve factual information at times, but at other times, there may be disagreement about what something means or what it implies. For example, when doctors' notes are made available via a patient portal, some users will question a diagnosis of "alcoholic" or a written comment that says "SOB" (that is, short of breach);<sup>76</sup> some will even challenge a characterization of "obese" not realizing the comment is based on a formula. A patient may claim that something told to and reported by an emergency-room physician was misheard, when the real reason for contesting the language has to do with a potential malpractice claim. Meaningful use should include efforts to develop software or build ODR capabilities in EHR platforms.

The drafters of the meaningful-use criteria targeted several significant errors that were documented in the past, such as medication and allergy lists, but they do not appear to have recognized that new types of errors and problems will surface. One of the oldest principles of law is that there is no right without a remedy.<sup>77</sup> In the case of EHRs, it is clear there is a right (that is, to amend) but, to date, no efficient means to obtain a meaningful remedy. The right to amend never functioned successfully in the paper environment because a precondition was the patient actually accessing his or her file. No empirical studies exist

<sup>75.</sup> INTERNET CORP. FOR ASSIGNED NAMES & NOS., UNIFORM DISPUTE RESOLUTION POLICY § 4B (Oct. 24, 1999), *available at* http://www.icann.org/en/udrp/udrp-policy-24oct99.htm.

<sup>76.</sup> Tom Delbanco et al., Open Notes: Doctors and Patients Signing On, 153 ANNALS INTERNAL MED. 121, 123 (2010).

<sup>77. &</sup>quot;It is a settled and invariable principle in the laws of England, that every right when with-held must have a remedy, and every injury it's [sic] proper redress." 1 WILLIAM BLACKSTONE, COMMENTARIES \*23.

indicating how often patients invoked the right to amend but, as noted recently, it is reasonable to assume that "[f]ew patients read their doctors' notes, despite having the legal right to do so,"<sup>78</sup> and that "the frequency with which most HIT professionals received such requests ranged from rare to never."<sup>79</sup> If meaningful use is an important goal, the need for a meaningful remedy to errors and other problems should be a priority.

If the healthcare system is to receive the benefits of engaged patients, providing rights of access or even new means of access, such as online access to a fully functioning online portal, is not enough. If there is public value in having patients as engaged in their healthcare as they are in their financial investments, merely facilitating access is necessary but not sufficient. Meaningful use at present falls far short of requiring what is needed to achieve this end. In other contexts, libraries inform borrowers when books will be due, and banks email depositors when their balances fall below a certain amount. Similarly, EHRs could notify patients whenever additions are made to their files and enable online access to the file with one click. If we want patients to alert their physicians of issues, the patients themselves need to be prompted or informed when their files change. This is easy and simple to do with technology, and anything less is unlikely to accomplish the patient-engagement goal.

The right to amend was suited to the paper environment in that the remedy provided, amendment, was clear in what it meant and easy in how it could be accomplished. Essentially, it involved stapling or affixing a note to the paper containing the error. It did not require additional staff since it happened infrequently and it involved little or no cost. The right to amend, as it is being transitioned to the EHR environment, provides a series of challenges not present in the paper environment, all of which suggest that the correction process for EHRs needs to be as oriented to the digital environment as the old amendment process was to the paper environment.

In the electronic environment, software, unlike paper, can structure the process of amendment in many ways. In doing so, however, the developer needs to understand exactly what the word "amend" does and does not mean. How the screen is presented and what functionality is provided to patients and health providers may depend on whether "amend" needs to be distinguished from editing, updating, revising, fixing, annotating, and various other words with closely related meanings and if so, how. As for "append," an on-screen visual that looks like a piece of paper affixed to another could be designed, but such a visualization will seem unnatural and unnecessary with software.

<sup>78.</sup> Delbanco et al., *supra* note 76, at 121.

<sup>79.</sup> Lydia Washington, Ethan Katsh & Norman Sondheimer, *Dispute Resolution: Planning for Disputed Information in EHRs and PHRs*, J. AHIMA, Nov.–Dec. 2009, at 25, 25–30, *available at* http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1\_045493.hcsp?dDocName=bok1\_0 45493.

In addition to the question of how to improve upon what was done with the paper system, the more fundamental question is whether the paper file is an appropriate frame of reference. The right to amend was a solution to the dilemma of achieving accuracy without deleting information in the process. Although the manner of amending a file was more cumbersome than merely crossing something out, it was necessary for a document created at a certain time to be preserved. Today, it is not as clear that the primary need is to protect against deletion or loss of a record. Indeed, we are learning frequently that the challenge of the digital age is quite different from the challenge of the print age in that everything is or can be preserved, and that it is undeleting something that may be a more significant challenge.

#### VIII

#### CONCLUSION

The late William Mitchell coined the phrase "code is the law," suggesting that the constraints and liberties we enjoy in the modern world are shaped as often by software as by law.<sup>80</sup> Looked at slightly differently, law and software share a space, and it is our task to find the optimum relationship between the use of legal codes and software code, both of which will be present and interacting with each other as public policies, such as meaningful use, are implemented. EHRs are a complex artifact, and the challenge of using law and software together to promote high-data quality and better healthcare will continue to present ongoing dispute resolution challenges.

<sup>80.</sup> WILLIAM J. MITCHELL, CITY OF BITS: SPACE, PLACE, AND THE INFOBAHN 111 (1995). See also LAWRENCE LESSIG, CODE AND OTHER LAWS OF CYBERSPACE 6 (1999); Ethan Katsh, Software Worlds and the First Amendment: Virtual Doorkeepers in Cyberspace, 1996 U. CHI. LEGAL F. 335, 338 (1996); Joel Reidenberg, Lex Informatica: The Formulation of Information Policy Rules Through Technology, 76 TEX. L. REV. 553 (1998).