



## Transitional Chaos or Enduring Harm? The EHR and the Disruption of Medicine

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A decade ago, a primary care physician I admired seemed to come undone. His efficiency had derived not from rushing between patients but from knowing them so well that his charting was effort-

less and fast. But suddenly he became distracted, losing his grip on the details of his patients' lives. He slumped around, shirt half-untucked, perpetually pulling a yellowed handkerchief from his pocket to wipe his perspiring forehead. Everyone worried he was sick. His problem, however, turned out to be the electronic health record (EHR).

Ten years and nearly \$30 billion of government stimulus later, the mandate to implement EHRs has spawned many similar stories, some of which Robert Wachter catalogues in *The Digital Doctor: Hope, Hype, and Harm at the Dawn of Medicine's Computer Age*, which explores the tension between the

push to digitize medicine and the sanctity of the doctor–patient relationship.<sup>1</sup> Wachter centers his EHR analysis around the story of an 18-year-old given a 39-fold overdose of Bactrim (sulfamethoxazole–trimethoprim) — a near-fatal error partially caused by an EHR. Investigating the root causes, Wachter discovers design flaws, such as defaulting to certain units for medication dosing and alerts rendered meaningless by their sheer number. But he concludes that the mistake stemmed less from the EHR itself than from its effects on our collective psychology. “I realized,” he writes, “that my beloved profession was being turned upside down by technology.”

For inhabitants of this upside-down world, Wachter's “House of Horrors” tour is vindicating. There's the critical care doctor who, unable to identify new information in daily notes, has begun printing them out and holding two superimposed pages up to the light to see what's changed. There's the cardiologist who says, “It could be worse . . . I could be younger.” To these tales of EHR fallout, most of us could add our own. Physicians retiring early. Small practices bankrupted by up-front expenses or locked into ineffective systems by the prohibitive cost of switching. Hours consumed by onerous data entry unrelated to patient care. Workflow disruptions. And above all, massive intrusions on our patient relationships.

These complaints might be dismissed as growing pains, born of resistance to change. But tran-

sitional chaos must be distinguished from enduring harm. According to sociologist Ross Koppel, who has studied the EHR's limitations and why they've been largely ignored, one key barrier is that physicians who voice reservations are labeled "technophobic, resistant, and uncooperative."<sup>2</sup> But in fact a recent RAND study showed that most physicians recognize the potential of EHRs and appreciate such features as the ability to view data remotely. Nevertheless, the researchers found remarkable EHR-induced distress. They conclude, "No other industry, to our knowledge, has been under a universal mandate to adopt a new technology before its effects are fully understood, and before the technology has reached a level of usability that is acceptable to its core users."<sup>3</sup>

Perhaps medicine finds itself in this position in part because it isn't exactly, or entirely, an industry. "Medicine," Wachter explains, "is at once an enormous business and an exquisitely human endeavor; it requires the ruthless efficiency of the modern manufacturing plant and the gentle hand-holding of the parish priest; . . . it is eminently quantifiable and yet stubbornly not."

Recognizing this duality, Wachter offers a certain balance: he feels our pain but is well versed in the exigencies of safe, efficient care delivery. The purpose of widespread EHR adoption, as envisioned by the Obama administration in 2008, was to permit a transition from volume-based to value-based payments: a digital infrastructure was essential for measuring quality.

At the time, however, less than 17% of physician practices were using EHRs, and their systems often lacked necessary data-cap-

ture capabilities. Given the high up-front costs and uncertainty regarding future returns, financial and cultural hurdles to adoption were formidable. Indeed, Robert Kocher, then an Obama advisor who'd overseen a failed EHR adoption in which physicians had actually been given computers, noted, "Free isn't cheap enough." So in 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act earmarked nearly \$30 billion in incentive payments for EHR adoption and "meaningful use."

Beyond such prods, the government's role was unclear. Wachter interviewed three former national coordinators for health information technology (IT): the libertarian-inclined David Brailer, who has such faith in market-driven innovation that he barely believed in the organization he was leading; David Blumenthal, the consummate diplomat, whose \$30 billion budget was 71,000% greater than Brailer's and who, in precipitating widespread adoption, was arguably the most successful leader; and Farzad Mostashari, perhaps the most controversial, whose hard-line insistence on the importance of Meaningful Use 2 (MU2) has been widely criticized.

Wachter gives a sympathetic airing to each but is unsparing about the overreach of MU criteria (the proposed MU3 criteria are even more prescriptive). Shadowing Iowa primary care physician Christine Sinsky, Wachter observes several frustrating workflow disruptions by the EHR, but he's most appalled when Sinsky shows him the repository of effective patient-education handouts she used until MU2 required that 10% of patients receive handouts "prompted by the EHR." She proposed creating a spreadsheet to

document handout delivery; the Office of the National Coordinator for Health Information Technology (ONC) said no. As Sinsky explains, "That would be just documenting that you *gave* the handout, but the computer wouldn't be *prompting* you to give the handout."

Despite such failings, even Brailer argues that the government must create common standards to ensure reliability and efficiency. Common standards are necessary but not sufficient for interoperability — the as-yet-unrealized dream of caring for a patient with chest pain in New York and pressing a button to receive the results of a stress test performed in Florida last week. So why focus on meaningful use rather than interoperability?

Some generous explanations: As Blumenthal notes, there can be no interoperability without operability. Patient privacy is another salient concern, especially given the increasing frequency of cyberattacks. Finally, the technical complexity of establishing standards is daunting. As Koppel explains, even something ostensibly simple, such as blood-pressure measurement, can get lost in translation because of the modifiers accompanying the numbers: standing, sitting, preinjection, labile, non-compliant. So imagine a common language for MRI reports or operative notes.

More cynical explanations suggest that the ONC is beholden to vendors and hospitals, which profit from "closed" systems. Although industry influence is indisputable, such an explanation conflicts with the impression I got from Judy Faulkner, chief executive officer of EHR maker Epic Systems, who advocates for government-created standards. Epic

has strived to make its own systems interoperable with one another since 2005, when Faulkner's husband, a pediatrician, had a patient who died in a distant emergency department — a death he thought could have been prevented had the patient's records followed her.

Whether or not other vendors are willing to make their products interoperable, government often overrides industry's financial interests to achieve a greater public good. But as Wachter notes, the MU requirements respond less to the "corporate leviathan types" than to special interest groups of "the *don't forget us variety*." MU2, for example, requires that people with vision problems be able to transmit their health information. As John Halamka, an IT leader at Boston's Beth Israel Deaconess Medical Center, told Wachter, "I've got glaucoma. I'm all for people with vision problems. But now I have to put my most talented staff on this problem even before sorting out the basics of transmitting information." Current systems thus reflect the fact that vendors have "spent the last three years creating EHRs for blind people and making sure patients can download their smoking status in the appropriate computer language and transmit it to nowhere."

Though the ONC's recent emphasis on prioritizing interoperability is encouraging, the question remains: If vendors are liberated to compete, can the market solve our EHR challenges? In our iPhone-reverent age, the dismissal of EHR critics as Luddites is supported by the recognition that technologies we once couldn't imagine we now can't live without. Steve Jobs's oft-repeated claim that "the customers don't know

what they want" has fostered a belief that technological progress is inevitable and depends not on input from the masses but on its absence. But the assumption that EHR evolution will mirror the cell phone's trajectory has three notable flaws.

First, such aspirational narratives beget complacency — and a tendency to dismiss contradictory evidence. The EHR is touted as a cost-saving, quality-promoting tool, though cost-saving projections have been debunked and data on quality are mixed.<sup>4,5</sup> Koppel notes that "a seldom voiced barrier" to health IT's achievement of its promise is our refusal to acknowledge its problems and learn from them: "Researchers and data that do not support the syllogism of *health IT equals patient safety*, and *more health IT equals more patient safety*" are ruthlessly attacked.<sup>2</sup> Although we've made progress in patient safety only by carefully examining our errors, somehow the dangers posed by technology are expected to right themselves.

Second, letting the market shape usability assumes that clinicians are the target users. But EHRs were designed to optimize not workflow or communication but billing — which is increasingly predicated on an ability to document quality. So EHRs will be only as good as the quality metrics they're designed to capture; technology can't overcome fundamental measurement challenges. We measure many things that have no value to patients, while much of what patients do value, including our attention, remains unmeasurable. If "value" is our currency, the market will select for systems that capture it, giving customers what they want — but these customers are often

administrators rather than practicing clinicians.

Which brings us to the third problem: many clinicians know what they want — but haven't been asked. Wachter describes Boeing's engineers iteratively improving aviation safety: their industry, committed to "user-centered design," has pilots test any system changes. Why, Wachter asks, do we do nothing similar in health care? After noting challenges such as the diversity of practice settings and users, he observes, "In the aviation industry, there is an abiding respect, even reverence, for the wisdom of the frontline workers." Our biggest mistake lies not in adopting clunky systems but in dismissing the concerns of the people who must use them.

In a moving passage, Wachter speaks with a renowned surgeon who once spent his evenings before surgery reading his notes on the next day's patients. He might have eight hernia repairs scheduled, but one detail — the patient found the hernia bothersome when he played tennis, for instance — would distinguish one case from the next, the patient from the problem. No longer. His notes have been rendered uselessly homogeneous by the tyranny of clicks and auto-populated fields. When he shows up to operate on patients, he says, "It's like I never saw them before. I can't even picture their faces."

What this surgeon and the rest of us need are patient records that communicate meaning and foster understanding of the particular patient in question. The blanks on our screens can be filled with words, but the process of understanding cannot be auto-populated. Perhaps life without the EHR will soon be un-

imaginable. But the technology will support and improve medical care only if it evolves in ways that help, rather than hinder, us in synthesizing, analyzing, thinking critically, and telling the stories of our patients.

Disclosure forms provided by the author are available with the full text of this article at [NEJM.org](http://NEJM.org).

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## Reducing LDL with PCSK9 Inhibitors — The Clinical Benefit of Lipid Drugs

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In early June, the Endocrinologic and Metabolic Drugs Advisory Committee of the Food and Drug Administration (FDA), on which we serve, met to consider marketing applications for the new molecular entities alirocumab and evolocumab on the basis of their ability to lower low-density lipoprotein (LDL) cholesterol levels and their effects on other lipid fractions in patients at risk for cardiovascular disease. These first-in-class medications are fully humanized monoclonal antibodies that inactivate proprotein convertase subtilisin-kexin type 9 (PCSK9). That inactivation results in decreased LDL-receptor degradation, increased recirculation of the receptor to the surface of hepatocytes, and consequent lowering of LDL cholesterol levels in the bloodstream. Statins, by inhibiting 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, similarly act by increasing LDL-receptor expression. This shared LDL cholesterol-lowering mechanism, combined with data on cardiovascular events from genetic

studies of persons with PCSK9 gain- or loss-of-function mutations, has led to optimism regarding the potential — but as yet unproven — cardiovascular benefits of these agents.

Both alirocumab and evolocumab, which are given by injection, cause large reductions in LDL cholesterol levels, as compared with placebo (39 to 62% reduction for alirocumab and 47 to 56% for evolocumab). In the drugs' development programs, LDL cholesterol levels in approximately 37% of patients receiving evolocumab and 24% of patients receiving alirocumab dropped below 25 mg per deciliter on two consecutive measurements. Because such low plasma cholesterol levels can be attained with these medications, particularly when they're given in conjunction with a statin, the FDA raised concerns about possible gastrointestinal, metabolic, and neurocognitive adverse effects. The target populations considered for long-term use of either drug include adults with primary hypercholesterolemia (nonfamilial or heterozygous

familial), patients with mixed dyslipidemia (including those with type 2 diabetes mellitus), and patients unable to take statins. The evolocumab studies also included patients with homozygous familial hypercholesterolemia.

Both drugs were submitted through the traditional FDA approval pathway, with LDL cholesterol reduction as the surrogate measure of clinical benefit. No efficacy data on cardiovascular outcomes were provided to the advisory committee, except for encouraging but preliminary analyses of cardiovascular adverse events with evolocumab. During the meeting, the FDA noted that if a medication is approved through this traditional pathway on the basis of a surrogate end point, the FDA can subsequently mandate postmarketing safety studies but cannot require postmarketing studies of benefits, such as cardiovascular event reduction. Thus, the principal issue before the advisory committee was whether the observed LDL cholesterol reduction provided sufficient evidence to substitute for