

Health Information Technology: The End of Medicine as We Know It?

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The health information technology (HIT) juggernaut is promising—or threatening—to ram medicine into the 21st century, leaving behind hapless private physicians who aren't wired in.

Practices with insufficient revenue to afford the expensive systems—or practices that can't or won't attract HIT subsidies from hospitals or other behemoths—are expected to wither and die.

The Bush Administration and members of Congress from both parties believe that HIT, of the “interoperable kind,” is the answer to medical errors and overwhelming costs. The interest groups that dominated the Clinton Task Force on Health Care Reform now appear to own the government.

Cluster Group III of the Interdepartmental Working Group headed by Ira Magaziner concerned “New System Infrastructure” and included Working Groups on Quality Measurement and Information Systems. It appears that the briefing books prepared by these chosen experts are the basis for existing and proposed policy. The archives from the Clinton Task Force, which include the lists of known players as well as a large number of documents, are available online as a result of the AAPS lawsuit challenging the legality of the Task Force.¹

Present trends, which predict that “healthcare” will soon devour both federal and state treasuries, cannot continue. Therefore, they will not. Wrenching change, or revolution, appears inevitable. But what form will it take, and what will be the role of HIT?

Strengths and Weaknesses of HIT

Computer technology and the Internet have certainly revolutionized much of the American economy—including the field of diagnostic imaging. Computers, however, are not the appropriate tool for every job. Two features of the medical record—the need for confidentiality and for reliability—make the Internet and centralized data bases a highly problematic repository.

The paper medical record offers inherent protection against data mining or other misuse: inaccessibility. It is an expensive and labor-intensive operation to seize and process thousands of paper charts in an effort to find incriminating data—as for blackmail, discrimination, or prosecution. Unless copies have been made and released, the record can be destroyed. Yet if left undisturbed, it can endure for many centuries. And alterations can be easily detected. Paper and ink also remain readable for centuries, whereas computer media deteriorate with time or become obsolete with rapid changes in technology.²

Digital records kept on an isolated computer within a private medical office are also relatively secure. Physical access to the facility is required to obtain records, and the media can be physically destroyed. But once data are entered into a networked computer, they are out of the owner's control. Various security

measures are possible, such as password protection and encryption, but accessibility and security are mutually exclusive objectives. Then there's the question of the integrity of the records. How could we be certain that a record has not been altered by a method that does not leave a trace?

Hurricane Katrina destroyed many paper medical records and has been used as an argument for keeping records of Louisiana patients in, say, Bethesda. The possibility of a volcanic eruption destroying a child's immunization records was actually cited by a public health official as a rationale for a state vaccine registry. Such events, however, are rare and local in scope. Moreover, they also make it impossible to access electronic records. Paper records can be read by candlelight. For computerized records, electricity is required—in large enough capacity to run air conditioning systems in large facilities—as are connections to the remote computers.

Disruptions in the electric power grid affecting large areas of the country are not unknown. In an instant a paperless facility could become one without records. In the age of proliferation of nuclear weapons and escalating hostility against the United States, the prospect of an electromagnetic pulse (EMP) cannot be ruled out. National security experts believe it is one of the few threats that put our society at risk of catastrophic consequences.³ A single high-altitude nuclear detonation could instantly shut down the power grid while permanently destroying computers and other unprotected electronic devices.

Assuming that normal electronic commerce is never disrupted, is the potential benefit of HIT exaggerated? Financial expert Andy Kessler, who made nearly a billion dollars riding the technology wave of the late 1990s, immediately dismisses the idea that the electronic medical record (EMR) could revolutionize medicine.

“Nothing EDS and Ross Perot did could save the beast at General Motors. It had bigger problems that a digitized back office couldn't solve.”^{4,p59}

“I just didn't see how electronic medical records were going to change the fact that we spend \$1.8 trillion on health care and are quickly headed toward \$3 trillion,” Kessler continued.^{4,p61}

This is not to say computerized technology will not continue to revolutionize medicine, in applications that handle billions of data points that the human brain cannot grasp, as in computerized tomographic scans. But what is in the highly touted interoperable EMR, designed to feed everyone's information into the National Health Information Network (NHIN)? Medication lists. Hemoglobin A1c measurements, a few times a year. Serum lipid levels. Periodic blood pressure readings. Lots of demographic data. Increasingly, data of interest to social engineers and law enforcement such as gun ownership, child-rearing practices, and family relationships. And claims data.

There are researchers who apparently hope that access to millions of patient histories and examinations, often performed perfunctorily by persons with minimal training, combined with unverified diagnoses and treatment data, will enable them to

determine “what works.” Implausible on its face, this has never been subjected to the rigors that are supposed to characterize “evidence-based medicine.”

The driving force behind HIT is third-party payers and government, and the motivation is to save money.

A physician confronting a diagnostic dilemma needs the capacity to distinguish the important from the irrelevant (a capacity utterly lacking in a computer), and to keep in his mind the pertinent set of facts. Computerized diagnostic devices and the capacity to do rapid searches of the medical literature are great assets. But does the EMR help—or hinder? There is no evidence-based answer to that question. Purveyors of HIT apparently assume that it will help. Real clinicians tend to be skeptical; some keep dual records—one to satisfy the insurer, and one for convenient access to relevant clinical data.

Most American schoolchildren have in their hands more computing capacity than scientists in university laboratories did when I was in college. Has this increased their mathematical ability? I have observed good students reach for their calculator when asked to divide a number by 10, even though it is much faster to simply give the answer—if you understand the simplest mathematical concepts. Inappropriate use of technology can create more problems than it solves, including atrophy of intellectual skills.

For doing millions of Fourier transforms, as for computerized tomography a computer is, of course, essential. Ronald N. Bracewell invented the algorithm now used for CT, in the context of mapping the surface of the sun.

“After computers arrived, I kept my slide rule and six-figure logarithms in a drawer in my desk, in case the power went out. They’re still there today,” Bracewell told Kessler.^{4,p78}

Two Possible Directions for Medicine

The prevailing political response to the burden of medical expenditures is more centralization, more intrusive monitoring of physicians and patients, and rationing based on population-based, utilitarian ethics. There is, however, a countervailing pressure to put control back in the hands of patients. “Consumer-directed health care” is generally understood to mean insurance reform that puts money and power back in the hands of patients rather than insurers. The reform of insurance, along lines outlined in the AAPS white paper on medical financing,⁵ is necessary, but concerns only part of the picture.

Instead of formalizing current expert-approved “best practices” into “practice guidelines” that soon become “standard of care,” the alternate path is to free medical practice itself, not just medical purchasing, from top-down direction. This possibility has also been opened by the digital revolution—and poses a serious threat to vested interests.

Two very different approaches were recently outlined at the 2006 Gilder Telecosm conference. One is that of Kessler, presented in his book *The End of Medicine: How Silicon Valley (and Naked Mice) Will Reboot Your Doctor*.⁴ The other is outlined by Arthur Robinson in this issue of the journal.⁶

Motivated by concerns about his own health, Kessler undertook an odyssey through catheterization labs, imaging centers, and pharmaceutical research facilities, seeking a way to “scale” something in medicine, Silicon Valley style. This would offer enormous profit potential, of course, but also savings, both financial and in terms of relief of human suffering and disability. To find a way to revolutionize medicine in some meaningful way, he

decided he needed to focus on the Big Three: heart disease, stroke, and cancer.

Kessler didn’t think too much of the primitive surrogate endpoints that were of interest to his doctor. Why take an expensive drug all his life to lower his cholesterol, when the real issue was the status of his coronary arteries? After reviewing the literature, he concluded that he still didn’t know whether statins prevent heart attacks or not. Better to use the \$25 billion now spent on statin drugs for “something useful.” But for what?

He is fascinated by rapidly evolving technology that can see plaques in the coronary arteries and remove them by minimally invasive means. Focused ultrasound, perhaps? At \$111 per scan, detection could become a mass-market item.

Kessler tells of trying to get a blood test to determine whether he had a genetic predisposition to colon cancer. But the only way he could order the test without a doctor’s signature, which he thought would triple or quadruple the cost, was to say the blood was from a cat or a dog. He ran into an enormous hurdle—trying to get two tubes of blood drawn—and never reveals how he finally overcame it.

While Kessler was trying to find out whether he had a gene that increased his risk for colon cancer, he was surprised to learn that it is already a “post-genomics world.” There are fewer than 30,000 genes, but more than one million proteins in the human body.

His friend Will Kruka told him: “DNA is just a blueprint for a house, for example. You might have a bad blueprint, which would be an important problem. But did the construction company properly execute against the blueprint? And what about the tenants—are they destroying the place, or taking care of it?”^{4,p148}

Cancer detection of the future might use a radioactive tracer attached to a substance that attaches to tumor cells and then lights them up for sophisticated imaging, say positron emission tomography.

There’s also the question of what you do about the cancer once you find it. Naturally one would prefer early detection, as with a specific protein marker. And then one could theoretically launch a search-and-destroy operation, as with a monoclonal antibody. We certainly need something better than the “throwing spaghetti at the wall” approach in current pharmaceutical research, where companies may spend as much as \$1 billion on a single Phase III trial. It can then all be lost in a Vioxx-type event.

Kessler, who’s not even a biochemist, has a very profound insight: “Hmm, the human body is really a complex system. Push down somewhere and something else pops up to bite you.”^{4,p226}

He has decided that the trick is to be specific enough in the treatment. The answer, he believes, is in the proteome. For cancer, what we need is to identify the biomarkers, the proteins specific for a cancer. Then we need a chip with an antibody against each of those thousands of markers, which will send a signal when a patient’s blood contains one of them. Then, we deploy millions of nude mice to manufacture the curative monoclonal antibodies.

Kessler doesn’t have a very high opinion of doctors. He thinks that medical personnel are the reason for the high costs of medicine, and that they have priced themselves out of existence.

“Forget the ‘God complex’ thing. I’ll forgive doctors for that. The real crime is that they don’t really know anything. Doctors use ancient tools, memorize symptoms and solutions, and a halfway decent search engine can leave them in the dust.

“But now, the days of doctors are over.”^{4,p320}

Kessler imagines that all medical knowledge can be imbedded in software and silicon. Patients can access a “spreadsheet product,” customized for their own use, which can “take a look,

equate conditions to possible outcomes, and suggest corrective action.^{254, p 321} Radiologists are replaced by computer-aided detection, ophthalmologists by LASIK, physical examinations by 256-slice scanning machines, cardiac drugs by roto-rooter procedures, and cancer specialists by antibody-laden chips.

Problems with Kessler's Vision

The problem with medical knowledge is not just that an individual doctor doesn't have all of it in his mind; it's that the knowledge doesn't even exist. Our understanding of human biochemistry and physiology is quite primitive; embedding it in a computer chip or software will only compound and fossilize the errors. And of course patients present to doctors with many problems besides the Big Three.

Kessler basically has a surgical view of medicine, though his approach is more like that of a plumber than a sophisticated surgeon, even if the tools are microsurgical or even nanosurgical in dimension. Find the plaque and cut it out. Find the cancer and extirpate it. But the processes in the human body occur at the molecular level. The body is constantly finding and repairing problems such as errant cells that could become cancerous, or defects in the endothelium that could accumulate plaque. Small changes in the biochemical milieu can have major consequences.

Do plaques grow and regress? Does any "roto-rooter," however delicate, cause damage that can lead to new, worse plaques? Are cancer "markers" produced only by malignant cells, or can healthy cells produce them in smaller quantities? Kessler doesn't raise questions like this, much less answer them.

Even if Kessler could get rid of rubber-hammer-wielding doctors, the technology would remain in the control of billion-dollar industries. There would be no end to the four-inch-thick research grants for every component. The solutions to the problems that are detected are just as complex as the diagnostic systems. Whatever its merits, the system on the whole is likely to raise spending enormously, despite saving or eliminating some costs.

Another problem Kessler overlooks is the consequence of patients' being identified as carrying a marker for an expensive disease. Would patients face discrimination in employment or financial markets? Would they become uninsurable? Would third-party payers deny or ration their care in subtle ways? The very word "marker" can have sinister overtones—especially since Robin Cook used it as the title for a best-selling medical thriller.⁷

The Metabolome

The techniques pioneered by Robinson and coworkers also utilize advanced information technology, but are different from Kessler's in several important ways. The Robinson techniques can be extremely cheap, putting ownership of the technology itself in the hands of the customer, and making very frequent testing feasible. The idea does not depend on the existence or discoverability of unique proteins for every condition. The frequent quantitative measurement of physiologic age, or of a pattern characteristic of a particular disease, makes the "N of 1" experiment possible.

The randomized, double-blind experiment is essential in drug testing because large numbers of subjects are necessary to average out the effects of biochemical individuality. The expense is prohibitive, so that only drugs or procedures with huge profit potential can be subjected to the testing. The endpoints may be

surrogate markers, or uncommon long-term events such as myocardial infarction or death. Thus, the actual effect of the treatment on the disease itself is a surmise. Also, each subject usually gets only one chance. If the treatment to which he is assigned is ineffective or harmful, even the researcher won't know this until it is too late to benefit that patient.

Many physicians, from Hippocrates onward, have believed that diet and other "lifestyle" factors are of critical importance in disease. The theories have been difficult or impossible to test because of the huge number of variables and the prolonged length of time necessary to see measurable effects. Quantitative measurement of the actual state of health or disease, as reflected in metabolic end-products, make it possible to try a large number of sequential interventions on the same individual. Mild effects, or effects that occur only in a minority of subjects, are not diluted out in the random noise of an experiment on many subjects.

If the instrument itself, or the digitized data from a scanner in a neighborhood facility or shopping mall, is in the hands of the patient, then it is possible to keep the results confidential and also to utilize the expertise of the patient's chosen consultants.

This method has the potential to bring an unprecedented golden age of scientific breakthroughs in both diagnosis and treatment, and at the same time to return control of medicine to patients.

Vigorous opposition is to be expected, from the middlemen as well as the proverbial buggy-whip manufacturers. Many surgical procedures could become obsolete; many drugs could be reclassified as poisons; and many "health" insurers and bureaucrats could be forced into productive employment.

The most important question in medicine could once again become, "How is this patient doing?" Not "Did the doctor follow the guidelines?" or, "Was the correct code assigned?" or, "Does the laboratory have an up-to-date CLIA certificate?"

Conclusions

The end of medicine as we know it could be the dawn of humane medicine based on precise measurements rather than contrived statistics. The outcome would be optimized health. The judge of effectiveness would be the patient. And the role of the doctor would once again be to teach, to counsel, or to do limited necessary surgery—rather than to churn, to certify, to comply, to document, and to keep the gate.

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