The Syndrome of Inappropriate Overconfidence in Computing: An Invasion of Medicine by the Information Technology Industry?

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I have written that the rigor of medical science is almost completely lacking in the very field that ironically is touted as revolutionizing medicine: health information technology (HIT).[1]

I arrived at this conclusion a decade ago, after observing harmful, ad hoc, and capricious decision-making by HIT leaders and vendors. Years of further observations have not changed my opinion.

Problems created by lack of scientific rigor in a cross-disciplinary, exploratory field such as HIT, which should be guided by the most rigorous scientific principles, are increasing in scope and severity. In fact, I believe medicine is suffering an unhelpful "cross-occupational invasion" by the IT industry, with the IT industry's best interests as the primary driver, not medicine's.

We've recently been informed that physicians and patients have been test subjects without consent in a mass vendor-driven experiment to develop future HIT software versions. In the style reminiscent of the Tuskegee Experiment, these computer experiments have been conducted with full approval of healthcare organization executives, while all of the legal burdens have been shifted to the test subjects in an environment of contractual secrecy about HIT defects.[2]

The rationale for this "hold harmless" environment and censorship regarding HIT defects has itself been unscientific and lacking in the critical thinking imperative in biomedicine. The assumption that HIT vendors should be held harmless for IT-related morbidity and mortality (the rates of which are not known, thanks in part to the secrecy clauses), because clinicians are "learned intermediaries" between silicon chips and human flesh, is faulty.

This assumption arises, at best, from the assumption that HIT is an innocuous technology, capable only of good, and that any minor glitches should be recoverable through infallible cognitive skills of "learned" clinicians.

The belief that HIT errors can be caught with 100 percent reliability by physicians and other clinicians, learned as they might be, is in fact dangerous and risible. It reflects an ill-informed layperson's understanding of the complex, poorly bounded, unpredictable, often improvisation-driven environment of medicine.[3]

It is an assumption based on a view of HIT as an "inventory system" of medical data, not an overseer of all aspects of medical care. It is a view devoid of knowledge of medicine or of informatics, which inform us that technology malfunctions interact with other local and/or systemic issues. These include such factors as the hectic workday of clinicians, the role of trainees in patient care, cognitive overload caused by HIT's all too common "mission-hostile user experience," and so forth. These unpredictable interactions can cause medical error.

The possibilities for causing error are in fact endless, and the assumptions of the industry about HIT's unmitigated beneficence were certainly not arrived at scientifically. Wishful thinking, profit motive, hope, faith, anything but scientific rigor, were in play.

Beyond the risk of medical error, the phenomenon of "cybernetic mysticism," the belief that computers are almost magical devices, is creating worse problems. Have we suffered a complete breakdown in scientific thinking with regard to the electronic health record (EHR) and other features of HIT? I believe we are approaching that point in our current irrational exuberance over HIT, evidenced by a plan to invest tens of billions of dollars and impose economic "incentives" and "penalties" (a.k.a. government force) in a push for universal HIT by 2014.

The goal of 2014 is itself overly optimistic, based on projections in a study of HIT diffusion[4] as well as the common sense of those who've worked in HIT in real world settings. I read announcements like this one with trepidation:

> "The goal," Sebelius said, "is to provide every American with a safe, secure electronic health record by 2014." The nominee also endorsed efforts to use data gleaned from electronic medical records to conduct "comparative effectiveness research to provide information on the relative strengths and weaknesses of alternative medical interventions to health providers and consumers."[5]

The use of EHR data to reliably detect uncommon (but strong and discrete) signals from a single drug or treatment is itself a medical informatics "grand challenge." A grand challenge is a fundamental scientific or technologic problem whose solution requires significant increases in current levels of scientific knowledge and/or technical capabilities. Solutions should improve the health of the population and be achievable within a decade.[6] An example would be finding the association of rofecoxib (Vioxx) with myocardial infarction earlier than we did, via an EHR-based automated postmarketing surveillance process.

Performing this type of postmarketing surveillance is in fact a "grand challenge" because of the uncontrolled nature of aggregated EHR data. The statistical methods needed to reliably pull warning signals out of such data for even a single drug are experimental.

The problems are formidable if one is to perform such investigations in a scientifically sound manner. For example, to accomplish postmarketing surveillance of a single drug, innovative statistical models and methods for analysis of extremely large datasets (large number of observations or large number of dimensions), an active area of research, will be necessary to supplement and replace more simplistic methodologies such as adverse event frequency comparisons. Research in computational statistics, for example, involves experimental development of visualization and computationally intensive methods for mining large, nonhomo-geneous, multidimensional datasets so as to discover knowledge in the data.[7,8]

Experimental efforts are now underway to attempt postmarketing surveillance of drugs using EHR data. For example, the Food and Drug Administration Amendments Act of 2007 (FDAAA) calls for active postmarketing safety surveillance. FDA is launching the "Sentinel Initiative," with the ultimate goal of creating and implementing a national, integrated, electronic system for monitoring medical product safety. Specifically, Section 905 of FDAAA calls for the HHS Secretary to develop methods to obtain access to disparate data sources and to establish a postmarketing risk identification and analysis system to link and analyze medical data from multiple sources. The law also requires FDA to work closely with partners from public, academic, and private entities.[9]

In 2009, however, we have had what appears to be a leap of faith and logic from this experimental possibility to a goal of irrationally

exuberant proportions. The government has announced an enthusiasm for EHR data-based comparative effectiveness research (CER) to cut costs through elimination of more costly drugs and treatments deemed less effective, or at effectiveness parity, compared to less expensive choices.

This increasing confidence in EHR data to perform far more complex tasks than postmarketing surveillance of a single drug is of great concern. Prompt detection of adverse drug events (ADEs) from single drugs, using aggregated EHR data, is within the realm of possibility. Detection of relatively more nebulous (i.e., compared to major ADE) "outcomes differences" between two or more drugs or treatments via EHR data—such as, did treatment A lower blood pressure more than drug B, or did drug C lessen depression more than drug D—rises to the level of "grand overconfidence in computing" and perhaps "grand folly."

To accomplish this task with reasonable scientific certainty from aggregated EHR data originating from different vendor systems, input by myriad people of different backgrounds, with differing interpretations of terminologies (students/residents/attending MDs/RNs etc), under different pressures and motivators (time limits, cognitive overload from poor HIT user interfaces, reimbursement maximization, and so forth), seems improbable.

What levels of statistical validity could arise from such studies? Could they even approach the level deemed "acceptable" in good science? We do not know, although I suspect a "garbage in, garbage out" (GIGO) phenomenon, leading to studies whose results are more likely related to chance than to solid reality.

Ironically, the gold standard in medical science is the randomized controlled clinical trial, yet EHR-based CER itself as a research methodology, now touted by our government, seems to have gotten a pass on this. Where are the rigorous studies that compare EHR-based CER of drugs and treatments to controlled clinical trials-based CER?

In other words, where are the "meta-clinical trials" that compare an EHR-based CER methodology with the traditional gold standard methodology of controlled clinical trials to compare drugs and treatments? How do we know EHR-based CER studies will not produce "garbage in, garbage out" that will cause harm through elimination or de-funding of actually useful treatment options?

Ominously, there is a lot of advantage to be had with terabytes of uncontrolled data and a political agenda. I fear that what may come from CER that draws upon uncontrolled EHR data will be politics masquerading as science. Under such conditions, private practitioners, medical innovators, the pharmaceutical industry, and patients are all in jeopardy.

In medieval times, alchemists believed lead could be turned into gold. This modern cybernetic alchemy, or more precisely "EHR uncontrolled data alchemy," represents a further deviation from medical science toward an irrationality that might be described as a "syndrome of inappropriate overconfidence in computing."

In summary, the scientific approach to HIT seems to have been made obsolete by the IT industry, an industry that has increasingly invaded medicine. We see this anti-science phenomenon in HIT vendors who contractually demand suppression of release of information on defects and operational problems, and push liability onto end-users. The remarkably uncritical rush to EHRs-by-2014, now involving force of government—despite a growing body of literature advising caution[10,11]—is also anti-scientific. The pressures are only financial at present, but future punitive licensure actions and other measures are not unimaginable.

We see this in a medical spin-off industry of HIT that, unlike the rest of medicine, remains unregulated, with well-reasoned calls for regulation largely ignored.[12] We see it in calls for dubious cost-control projects using uncontrolled EHR data. We see it in a consortium of big business, payers, vendors, and secondary feeder organizations gunning full blast for this unregulated, exploratory technology without consideration of the downsides.

Biomedical informatics, a scientific discipline (at least in those parts not yet compromised by conflicts of interest) whose pioneers created HIT, is unfortunately very much a minority player in today's environment. Recent contributions from experts and pioneers in the field of biomedical informatics, such as the January 2009 National Research Council's report,[13] have not slowed the stampede.

If the medical profession allows further cross-disciplinary invasion and hijacking of our profession's science-based values by the IT industry and uncritical IT pundits, the results could be disastrous—and we will only have ourselves to blame.

Uncontrolled cross-occupational invasion of medicine by the IT industry must be stopped at the hospital and office gates. Physicians should actively educate themselves on these issues and become advocates for a rational, scientific approach to HIT through their professional societies, governmental representatives, news media, and patients.

HIT can improve medical practice, and may be able to achieve some of the benefits claimed, but not if the approach to HIT is based primarily on secrecy, uncritical overconfidence in computers, politics, and myths, rather than on science.

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REFERENCES

1. Silverstein SM. Contemporary issues in medical informatics: common examples of healthcare IT failure. Drexel University Website. Available at: http://www.ischool.drexel.edu/faculty/ssilverstein/medinfo.htm. Accessed Apr 9, 2009.
2. Koppel R, Kreda D. Health care information technology vendors' "hold harmless" clause—implications for patients and clinicians. *JAMA* 2009;301:1276-1278.
3. Nemeth C, Cook R. Hiding in plain sight: what Koppel et al. tell us about healthcare IT. *J Biomed Inform* 2005;38:262-263.
4. Ford E, Menachemi N, Phillips TM. Predicting the adoption of electronic health records by physicians: when will health care be paperless? *J Am Med Inform Assoc* 2006;13:106-112.
5. Buxbaum P. Sebelius champions national health IT system. *Government Health IT*, Mar 31, 2009. Available at: http://govhealthit.com/articles/2009/03/31/sebelius-confirmation.aspx. Accessed Apr 30, 2009.
6. Sittig D. Grand challenges in medical informatics. *J Am Med Inform Assoc* 1994;1:412-413.
7. Computational statistics in the data sciences. George Mason University Website. Available at: www.scs.gmu.edu/~jgentle/compstat/index.html. Accessed Apr 9, 2009.
8. Silverstein S. A medical informatics grand challenge: the EMR and postmarketing drug surveillance. Scribd Website. Presented at: Merck Research Laboratories, Dept. of Clinical Risk management & Safety Surveillance, November 2006. Available at: http://www.scribd.com/doc/12392184/A-Medical-Informatics-Grand-Challenge-the-EMR-and-Postmarketinging-Drug-Surveillance. Accessed Apr 30, 2009.
9. Food and Drug Administration. The Sentinel Initiative: A National Strategy for Monitoring Medical Product Safety. Available at: www.fda.gov/oc/initiatives/advance/reports/report0508.html. Accessed Apr 9, 2009.
10. Silverstein S. Common examples of healthcare IT failure. Drexel University Website. Available at: www.ischool.drexel.edu/faculty/ssilverstein/failurecases/?loc=other. Accessed Apr 9, 2009.
11. Silverstein S. A primer on why we have busywork generators masquerading as EMR's. Healthcare Renewal blog. Available at: http://hcrenewal.blogspot.com/2009/03/reader-on-why-we-have-busywork.html. Accessed Apr 9, 2009.
12. Hoffman S, Podgurski A. Finding a cure: the case for regulation and oversight of electronic health records systems. *Harv J Law Technol* 2008;22(1):103.
13. Stead W, Lin H, eds. *Computational Technology for Effective Health Care: Immediate Steps and Strategic Directions*. Committee on Engaging the Computer Science Research Community in Health Care Informatics, National Research Council; January 2009.