Remember “six sigma?” In the 2000-2002 period, it was health care’s Next Big Idea, preoccupying its restless technocracy as the Health Insurance Portability and Accountability Act (HIPAA)-generated anxiety was waning and “consumer-driven health care” had yet to reach its current frenzy. Six sigma was and still is an important industrial engineering methodology developed by General Electric over several decades of practice and experimentation. As year-2000 (Y2K) and HIPAA conversions came and went, with great effort but none of the devastations predicted by the technocrats, six sigma filled an important void for the health care consulting industry in its eternal quest to generate billable hours.

The goal of six sigma in its original context was to reduce the incidence of manufacturing production errors to 6 per 100,000 production units. It was never clear, when applied to health care, what a six sigma “production unit” might represent. Was it the care of one patient with a chronic illness over a period of time? An isolated episode of care experienced by that patient at one medical facility? Or any one of the hundreds of products and services that might be administered to that patient during that one episode?

When asked about this at a public event, the leader of a major health care consulting practice—after singing the praises of six sigma methodology—was not sure. Not that it mattered. The consultant and those in the audience never had to go through the obvious methodological difficulties inherent in translating a manufacturing accounting exercise to medical care. The idea of measuring and managing the medical treatment of human beings with complex illnesses as though they were light bulbs moving along an assembly line was absurd enough for the health care technocrats to abandon six sigma as quickly as they adopted it, en masse, and move along to the Next Big Idea.

As of this writing, health care’s Next Big Idea is “evidence-based medicine (EBM).” Exactly like six sigma, EBM is a legitimate, quantitative discipline that was invented and honed over decades for a very specific purpose—and has since been co-opted for a completely different purpose. Since health care’s current folk wisdom is focused almost obsessively on the erroneous twin beliefs that drugs are (1) overused in the United States and (2) singularly responsible for rising health care costs, EBM—as applied to pharmaceutical use—has been seized upon as the next messiah coming to save the U.S. health care system from itself. Its champions view EBM as a way to rein in what they perceive as the overuse of drugs.

Because the EBM “fix” and the problems themselves are all steeped in folk wisdom rather than actual empirical reality about drug use and health care costs, this mindless rush to sham EBM is merely the latest expression of American society’s resentment of the pharmaceutical industry for its success and a deeper frustration with the chronic cost, inefficiency, and equity problems in health care.
Evidence-Based Medicine 101

Before analyzing the soundness of applying EBM methods to pharmaceutical use, it is important to review the origins and conclusions of those methods. In its original incarnation, EBM involved the use of longitudinal empirical outcomes analyses to measure, in retrospect, the usefulness of diagnostic and surgical procedures. It is important for society to measure the outcomes associated with such procedures specifically because they do not undergo the same clinical testing, prior to their introduction into mainstream medical care, that drugs undergo prior to their approval by the U.S. Food and Drug Administration (FDA).

One needs to look no further than at the continuing struggle, after nearly 15 years of study, over whether or not Pap smears and mammograms actually reduce, respectively, long-term cervical and breast cancer mortality rates. The answers, according to EBM studies still in progress, vary greatly by age group (e.g., 40+ years versus 50+ years), periodicity (e.g., annual versus biannual), and myriad other risk factors for the disease. Judging by the literature, it seems that no two researchers can agree on any conclusion, at least not over time. This lack of agreement about the usefulness of clinical interventions, endemic to all of medicine, provides the crucial entry point for EBM’s newest champions, who argue that any intervention is guilty of uselessness until proven innocent (i.e., useful 5 years after the fact.)

The EBM movement emerged in Canada in the late 1980s and early 1990s with the work of the McMaskes Group. It was imported into the United States by a number of health services researchers working under grants from the federal government’s Agency for Health Care Policy Research (now AHRQ) and for the Kaiser Health Plan. The methods of EBM were codified by David Eddy in a series of fascinating articles in the Journal of the American Medical Association in the early 1990s.

The EBM movement was presaged in John Wennberg’s groundbreaking work on variations in surgical procedures in the late 1980s. Within adjacent counties in Vermont, Wennberg discovered 4-, 5-, and 6-fold differences in the utilization of common surgical procedures like tonsillectomy and prostatectomy. Although it was technically not EBM because of its absence of outcomes data, Wennberg’s work on “small-area variations” unleashed a cottage industry of research on variation analysis, enlivening the careers of several dozen physician-researchers. At first, the identification of such variations implied overuse; these phenomena were decoupled by Lucian Leape and colleagues in a landmark study of small-area variations of surgical procedures in 1990, during the cresting of the variations analysis wave unleashed by Wennberg and the wave of EBM to follow.

One of the core assumptions of those who would apply EBM to drug use is that drug utilization patterns, when finally studied, would surely mirror the sloppy, uneven, and occasionally bizarre utilization patterns of diagnostic and surgical procedures uncovered by the EBM movement. EBM methods would show physicians how and how often their knee-jerk prescribing habits were inappropriate, the same way those methods have shown surgeons how and how often their propensity to operate has been inappropriate.

The goal of all EBM has been to add rationality to the clinical decision making of a medical community that, despite all its training and technology, engages in what often looks like folk art. Objective measures of medical practice, in a political vacuum, frequently reflect this notion. Such a vacuum does not account for things like defensive medicine, which is practiced to avoid frivolous medical malpractice lawsuits and thus compels the overuse of diagnostic testing, nor does it account for the dysfunctional economics of fee-for-service medicine, which compels the overuse of surgical procedures. This has led to the conclusion of EBM advocates that physician prescribing must be subject to the same tendency toward overuse.

But some of the tools of actual EBM, when applied to prescribing, do not confirm this presumption. In multiple research studies, Robert Dubois and colleagues have shown that we do not have variations in drug use approaching anything like what we have found in surgery. In one study of the medication of multiple disease states across California, the researchers found variations between highest and lowest rates of drug use of 1.3 to 1.4 times—a sharp contrast to the many times greater differences
in the rates of diagnostic and surgical procedures documented by Wennberg and others.

The reliability of these numbers is confirmed by other researchers with an obvious commercial desire to find drug use variation. Mootheral and colleagues from Express Scripts, a large, national pharmacy benefits manager that would be able to use variations as a rationale for marketing its services, found variations in medication use across regions that ranged from 1.7 to 1.9 for most medication classes.¹ So much for variations. But what about overuse? In general and with a few obvious and important exceptions like antibiotics, EBM compels an expanded rather than restricted use of pharmaceuticals for almost every studied disease state. This is confirmed in a survey of the most broadly accepted published clinical guidelines, the real-world manifestation of EBM’s methods, in an analysis published in Health Affairs in January/February 2004.⁶

Now for the more acute reality check. The core presumption of EBM—that drugs are guilty of uselessness until proven innocent—stands in direct opposition to how physicians are trained to treat patients. Bonded only by the “first do no harm” covenant of the Hippocratic Oath, physicians actively prescribe drugs that are proven in FDA-sanctioned clinical trials to work; to do so is to “treat empirically,” meaning to try an individual drug on an individual patient to see if it works or not. (This is the clinically defensible part of the much-maligned practice of drug sampling, which further explains why the EBMs “guilty until proven innocent” strategy finds such favor among antipharmaceutical industry policymakers who have co-opted EBM methods to justify their rationing mandates.)

The misapplication of EBM’s methods to restrict drug use is further emboldened, mistakenly, by the occasional drug or drug class that proves, long after FDA approval and extensive utilization experience, not to lack efficacy (as the EBM champions generally believe) but actually to be implicated in potential adverse events. The most obvious and recent examples are the major reconsideration of hormone therapy and antidepressants in teenagers, along with the withdrawal of rofecoxib (a popular COX-2 inhibitor) in 2004. Such are the vagaries of a nation of physicians treating patients empirically. For many surgical and diagnostic procedures that are adopted into practice without the rigorous testing undergone by drugs, longitudinal, data-driven EBM-type analyses are often not favorable. For drugs that do undergo such testing, the actual evidence often goes the other way—the drugs not only work, they work overtime, and often result in additional, undesirable clinical effects.

### Drug Culture Shock

It is important to note that many individuals serving as medical directors and administrators in today’s public and private health care payer organizations came of professional age during the 1980s and 1990s, when the real EBM movement itself was coming of age. Consider the coincidence of this timing with the following phenomena, which occurred during the same time period:

1. A wave of studies showing widespread overuse of antibiotics, which has since grown into a very real public health problem;
2. Rapid and sustained growth in the use of prescription drugs in general;
3. The introduction of highly visible and deeply controversial direct-to-consumer advertising of drugs in 1997;
4. The launch of new drugs to treat physiological and psychological disorders never before addressed medically;
5. A doubling in the size of the pharmaceutical industry between 1990 and 2000; and finally
6. Maintenance of the profitability of that industry throughout the same decade, while the rest of the health care system is suffering from nearly identical economic crises at the beginning and end of the period.

The aggregate result of this confluence of factors seems obvious and inevitable—a collective presumption about the overuse of pharmaceuticals, never challenged by any data, that has coalesced into folklore: because we Americans are using so many drugs all of a sudden, we must be using too many. Contrary to what today’s champions of applying EBM to drug use would have us believe—and consistent with deep resentments of Americans about being forced to subsidize the drug care of the rest of the developed world—this presumption is pure fairy tale. According to an analysis of drug care by the RAND Corporation, only 68.6% of Americans with chronic illness are adequately medicated.⁷

This is why a few years from now the EBM movement, as misapplied to drug use, will have passed through health care with the permanence and profundity of six sigma reengineering. It is an intellectually bankrupt idea that will implode for the same reasons it has emerged—the current misapplication of EBM reflects an obsessive determination to manage money, not outcomes, not evidence, and certainly not disease. As has been demonstrated during numerous other attempts to reduce health spending by limiting access to expensive drugs, which actually are our best tool during numerous other attempts to reduce health spending by limiting access to expensive drugs, which actually are our best tool for managing overall health care costs, the use of EBM is certain to backfire.

The flow of almost all medical research—basic and applied, prospective and retrospective, privately and publicly funded—moves us in one direction: more medicine is better. That should be obvious to anyone who has actually read a medical journal or any newspaper account over the last decade about breakthroughs in biomedical science, the rise of protein engineering, continual improvements in diagnostic technologies, and the decoding of the human genome. All of these scientific moving parts go toward building an ever more vivid understanding of the human machine and, thereby, ever greater opportunities for manipulating and preserving that machine with biochemistry. EBM, while ably pointing out that too many patients receive diagnostic and surgical procedures they did not need, will prove only what we already know from numerous research endeavors—too few patients receive drug care, not too many.
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REFERENCES


