The Illusion of Evidence-Based Medicine

Description

In 1990, a paradigm shift occurred in the development of new medicines and treatments. An idea so big, that it was supposed to encompass the whole of medicine. It was to start initially at the level of pre-clinical and clinical trials and work all the way through the system to the care and management of individual patients. This new concept for how medicine would be developed and conducted is called **evidence-based medicine (EBM)**. Evidence-based medicine was to provide a more rigorous foundation for medicine, one based on science and the scientific method. Truly, this was to be a revolution in medicine – a non-biased way of conducting medical research and treating patients.

> **Evidence-based medicine**
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> Evidence-based medicine is “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.” The aim of EBM is to integrate the experience of the clinician, the values of the patient, and the best available scientific information to guide decision-making about clinical management.

So, what the hell happened?

There is a big flaw in the logic of evidence-based medicine as the basis for the practice of medicine as we know it, a practice based on science; one that determines care down to the level of the individual patient. This flaw is nestled in the heart and soul of evidence-based medicine, which (as we have seen over the last two years) is not free of politics. It is naive to think that data and the process of licensure of new drugs is free from bias and conflicts of interest. In fact, this couldn’t be any farther from the truth. The COVID-19 crisis of 2020 to 2022 has exposed for all to see how evidence based medicine has been corrupted by the governments, hospitalists, academia, big pharma, tech and social media. They have leveraged the processes and rationale of evidence-based medicine to corrupt the entire medical enterprise.

Evidence based medicine depends on data. For the most part, the data gathering and analysis process is conducted by and for the pharmaceutical industry, then reported by senior academics. The problem, as laid out in an editorial in the British Medical Journal is as follows:

> The release into the public domain of previously confidential pharmaceutical industry documents has given the medical community valuable insight into the degree to which industry sponsored clinical trials are misrepresented. Until this problem is corrected, evidence based medicine will remain an illusion.

This ideal of the integrity of data and the scientific process is corrupted as long as financial (and governments) interests trump the common good.

> Medicine is largely dominated by a small number of very large pharmaceutical companies that compete for market share, but are effectively united in their efforts to expanding that market. The short term stimulus to biomedical research because of privatization has been celebrated by free market champions, but the unintended, long term consequences for medicine have been severe. Scientific progress is thwarted by the ownership of data and knowledge because industry suppresses negative trial results, fails to report adverse events, and does not share raw data with the academic research community. Patients die because of the adverse impact of commercial interests on the research agenda, universities, and regulators.
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> The pharmaceutical industry's responsibility to its shareholders means that priority must be given to their hierarchical power structures, product loyalty, and public relations propaganda over scientific integrity. Although universities have always been elite institutions prone to influence through endowments, they have long laid claim to being guardians of truth and the moral conscience of society. But in the face of inadequate government funding, they have adopted a neo-liberal market approach, actively seeking pharmaceutical funding on commercial terms. As a result, university departments become instruments of industry: through company control of the research agenda and ghostwriting of medical journal articles and continuing medical education, academics become agents for the promotion of commercial products. When scandals involving industry-academe partnership are exposed in the mainstream media, trust in academic institutions is weakened and the vision of an open society is betrayed (BMJ).

The corporate university also compromises the concept of academic leadership. No longer are positions of leadership due to distinguished careers. Instead, the ability to raise funds in the form of donations, grants, royalty revenue and contracts, dominates the requirements for University leaders. They are now must demonstrate their profitability or show how they can attract corporate sponsors.

As the US government, particularly NIAID, controls a significant amount of the grants and contracts of most academic institutions in the USA, NIAID employees also can determine what research is conducted and who is funded to conduct that research.

US government employees also control the narrative. Take for example the use of the media, CDC and

the FDA to control the narrative about early treatment for COVID-19. By now we should all know about the corruption of the early clinical trials of hydroxychloroquine. On the basis of these faked studies, one of the safest drugs in the world was recommended to not be used in an out patient setting – most likely, in order to increase vaccine acceptance. Or how our government used propaganda to control the use of ivermectin by such tactics as calling it unfit for human use and labelling it as a "horse wormer." All indications are that these efforts by the US government were to dissuade early treatment to stop vaccine hesitancy.

Beyond our government skewing evidence-based medicine for their own purposes, then there is the university system, which is more interested in generating income than creating a research program that is free from bias.

> Those who succeed in academia are likely to be key opinion leaders (KOLs in marketing parlance), whose careers can be advanced through the opportunities provided by industry. Potential KOLs are selected based on a complex array of profiling activities carried out by companies, for example, physicians are selected based on their influence on prescribing habits of other physicians. KOLs are sought out by industry for this influence and for the prestige that their university affiliation brings to the branding of the company's products. As well paid members of pharmaceutical advisory boards and speakers' bureaus, KOLs present results of industry trials at medical conferences and in continuing medical education. Instead of acting as independent, disinterested scientists and critically evaluating a drug's performance, they become what marketing executives refer to as "product champions."
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> Ironically, industry sponsored KOLs appear to enjoy many of the advantages of academic freedom, supported as they are by their universities, the industry, and journal editors for expressing their views, even when those views are incongruent with the real evidence. While universities fail to correct misrepresentations of the science from such collaborations, critics of industry face rejections from journals, legal threats, and the potential destruction of their careers. This uneven playing field is exactly what concerned Popper when he wrote about suppression and control of the means of science communication. The preservation of institutions designed to further scientific objectivity and impartiality (i.e., public laboratories, independent scientific periodicals and congresses) is entirely at the mercy of political and commercial power; vested interest will always override the rationality of evidence (BMJ).

Regulators (ergo the FDA) receive funding from industry and use industry funded and performed trials to approve drugs, without in most cases seeing the raw data. What confidence do we have in a system in which drug companies are permitted to "mark their own homework" rather than having their products tested by independent experts as part of a public regulatory system? Unconcerned governments and captured regulators are unlikely to initiate necessary change to remove research from industry altogether and clean up publishing models that depend on reprint revenue, advertising, and sponsorship revenue.

Some proposals for reforms include:

- Regulators must be freed from drug company funding. This includes the FDA funding -which must come directly from the government, as opposed to pharma fees, as now is the case. Tying

employee salaries to pharma fees creates a huge conflict of interest within the FDA.

- The revolving door between regulators like the FDA, the CDC and big pharma (as well as tech/media) must stop. Employment contracts for regulatory government positions must have “non-compete” clauses whereby employment opportunities are limited upon leaving these regulatory agencies. Likewise, big pharma executives should not fill leadership positions at regulatory agencies.
- Taxation imposed on pharmaceutical companies to allow public funding of independent trials; and, perhaps most importantly, anonymised individual patient level trial data posted, along with study protocols. These data to be provided on suitably accessible websites so that third parties, self-nominated or commissioned by health technology agencies, could rigorously evaluate the methodology and trial results.
- Clinical trial data must be made public. Trial consent forms are easily changed to make this anonymized data freely available.
- Publication of data must be open and transparent. The government has a moral obligation to trial participants, real people who have been involved in risky treatment and have a right to expect that the results of their participation will be used in keeping with principles of scientific rigor.
- The government and it’s employees has a moral obligation to the public to conduct clinical trials in ways that are non-biased by industry.
- The Foundation for the CDC and the Foundation for the NIH, which runs clinical trials and studies for these organizations (while their boards are made up of pharma industry executives and employees) must be decommissioned. We have laws in this country whereby the government does not accept volunteer labor, or direct donations to influence government decisions. These NGOs are doing just that. These practices must be stopped. They are intentionally using these organizations to bypass federal laws concerning exertion of undue influence on federal decision making.
- Off label drugs must continue to be used by the medical community. The early treatment protocols, which have saved countless lives, have documented the important role that physicians have played in finding cheap and effective treatments for COVID as well as many other diseases. Let doctors be doctors.
- Scientific and medical journals must be stopped from taking monies from big pharma. This includes the sales of reprints, banner ads, print ads, etc.
- Government must stop interfering with the publishing of peer reviewed papers and social media. A free press must remain free from coercion from government. We all know countless examples, such as the Trusted News Initiative (TNI) and White House meetings with big tech to influence what is allowed to be printed. And the billion dollars spent by the US Government to promote these EUA/unlicensed “vaccine” products that do not prevent infection or transmission of the SARS-CoV-2 virus. This is a direct assault on our first amendment rights. It also skews evidence based medicine.
- Informed consent, one of the foundations of modern medicine, has been stymied by the FDA, NIH, the CDC hospitalists, big tech and social media. They have been hiding data and skewing results. When people can not get the information they need to make an informed decision, evidence-based medicine can not function correctly.
- The government and it’s employees must stop picking winners and losers. Evidence-based medicine requires a non-biased playing field.
- Industry concerns about privacy and intellectual property rights should not hold sway.

If we are ever trust and support the concept of evidence based medicine again, significant changes to

the system must be enacted. The only question is… is our government and our HHS bureaucrats up to the job?

by Robert W Malone

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