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SCIENCE AND PSEUDOSCIENCE IN MEDICINE: EVIDENCE-BASED VS. EVIDENCE-BIASED MEDICINE

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SUMMARY

The concept of evidence-based medicine (EBM), as the highest standard of health care, came into existence in 1990s to promote a systematic approach to helping clinicians in their practice to be guided by the best available scientific evidence. However, there has been an increasing number of warning reports "that in modern research, misrepresented, false and unuseful findings may be the majority or even the vast majority of published research claims In spite of the huge scientific progress, pseudoscience and associated evidence biased medicine represent a serious threat to the concept of the EBM. Effective education in medicine, proper research motivation, sound systems and creative thinking and culture of scientific dialogue may significantly contribute to better science and evidence-based medicine. The seven key words of good science, research and publishing are: integrity, motivation, capacity, understanding, knowledge, experience, and creativity.

Key words: *science in medicine - evidence-based medicine – pseudoscience - evidence-biased medicine*

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Introduction

"Truth is a fruit which should not be plucked until it is ripe"
Voltaire

Pseudoscience and evidence biased medicine represent a serious threat to clinical practice and health service users. Differing science from pseudoscience in medicine is an old and always hot topic. The oldest article about science and pseudoscience in medicine dates from 1897 when Sternberg published the article with this title in Science which is one of the oldest and most prominent general science journals today. From time to time big scandals attracted public attention showing how easy can be for some scientists to publish fabricated data even in the most prestigious journals. In the last years there has been an increasing number of warning reports "that in modern research, misrepresented, false and unuseful findings may be the majority or even the vast majority of published research claims" (see Ioannidis 2005a,b, Fanelli 2009, Boutron 2010, Bowen & Casadevall 2015, Ioannidis 2016). Demarcations of science from pseudoscience are very important from both theoretical and practical reasons. The first reason is theoretical and it goes to the epistemology and to the core of the nature of truth, evidence and discovery ("How do we really know what we think that we know). The second reason is political and economic because a huge amount of money has been spent on biomedical research. The false and misrepresented pseudoscientific data may all contribute to evidence-biased medicine and treatment inefficiencies as well as to the wasting of limited funding and investigators' work. The third reason is ethical because pseudoscience can be harmful for patients, sometimes fatally so, and undermine public confidence in the scientific medicine.

Biomedical science has significantly empowered contemporary evidence-based medicine (EBM), prolonged longevity in general population and improved quality of life. Modern clinical pharmacology has claimed itself as scientific, rational and very much evidence-based. Evidence has become dominant driver and mantra for health policy makers, service planners, all kind of therapists, and clinical and academic researchers. At recent times, biomedical science has become a vast and powerful industry and business producing a real jungle of information in ever increasing number of medical journals and other publications. However, in spite of the huge scientific progress, pseudoscience and associated evidence biased medicine represent a serious threat to the concept of the EBM.

Evidence-based vs. evidence-biased medicine

Science has usually been considered an objective, self-correcting, truthful and reliable human endeavor. The concept of EBM, as the highest standard of health care, came into existence in 1990s to promote a systematic approach to helping clinicians in their practice to be guided by the best available scientific evidence. The antithesis of EBM is practice based on pseudoscience, tradition, vogue, marketing and authority (see Jakovljevic 2007). Isaacs and Fitzgerald (1999) reported seven alternatives to EBM: eminence-based medicine, vehemence-based medicine, eloquence-based medicine, providence-based medicine, diffidence-based medicine, nervousness-based medicine, and confidence-based medicine. The concept of EBM has strongly influenced health-care and treatment decision making, health-care programs, and the structure of medical and public health systems. The philosophy of EBM encompasses five

essential principles (Drake 2005). First, it is grounded on basic health-care values (values-based medicine). Second, it requires that scientific evidence should be a base in making health-care decisions. Third, it recognizes that the scientific evidence is complicated, hierarchical, often uncertain and ambiguous, and usually limited. Fourth, it assumes that other factors like patients' human rights, values, preferences and choices, are also important factors in medical decisions. Fifth, it argues that clinical expertise is an important component in medical decisions.

Here, a thorny question arises as to what is evidence and how we know what is it proper evidence. According to the Encarta Concise Dictionary, Student Edition (2001) evidence means "something that gives sign or proof of the existence or truth of something, or that helps somebody to come to a particular conclusion". The last meaning "something that helps somebody to come to a particular conclusion" means also facts, testimony and proof in support of a statement, claim or belief. But collected facts and data do not speak for themselves alone; they are subjects to varying thinking strategies and information processing depending on who is doing the information processing. Evidence as well as treatment effectiveness is always context dependent. The limitations of the science base including double-blind randomized controlled trials (RCTs) on which EBM stands should be acknowledged. The majority of the large RCTs undertaken in clinical pharmacology are sponsored by the pharmaceutical industry with aim to demonstrate to regulatory agencies the efficacy of investigated drug over placebo. However, there are significantly less natural, pragmatic or observational studies (see Jakovljevic 2009) demonstrating the effectiveness of drug in the real clinical context on the real patients' population which is more heterogenous and with severe disorders than those in registration RCTs. Furthermore, negative studies are very rarely published, so that what we call EBM in the form of guidelines and algorithms may be biased and become evidence-biased medicine (see Jakovljevic 2007). The individual patient needs the idiographic patient-based evidence which refers to known data about diagnostic markers and the specific and differential effectiveness of various drugs or treatment methods to that particular individual. Non-adherence to drug treatment and non-cooperation of patients may be related to nomothetic impersonal and technical rationality (see Jakovljevic 2013). Some studies have also stressed a decreasing quality of published literature due to an increasing competition for grants and jobs, the current mania for publishing papers and a disproportionate emphasis on quantity over quality in scientific outputs, huge administration, and overreliance on reductionism (Bowen & Casadevall 2015).

Science vs. pseudoscience in biomedical research

"Truth in science can be defined as the working hypothesis, best suited to open the way to the next better one"

Konrad Lorenz

As science is the most important reliable source of knowledge and progress in medicine, it is very important to distinguish scientific knowledge from its pseudoscientific look-alikes. Pseudoscience is non-science, invalid or fake science posing as real science involving varied fads and fallacies in the name of science. In medicine pseudoscience represents any theory or method that claims falsely or mistakenly to be scientific or that is falsely or doubtfully regarded as scientific although they lack supporting evidence and plausibility. Term pseudoscience also refers to a field, practice, or body of knowledge claimed to be consistent with the norms of scientific information processing and research, but in reality fails to meet these norms. In other words pseudoscience is characterized by producing irreproducible, incorrect or falsified results and non-useful research data. Pseudoscientific article seems to be scientific but actually violate the criteria of science and contain misrepresented, incorrect, untrue or falsified results and claims.

Pseudoscience can be product of misunderstanding and lack of education, fraud, and spin. Pseudoscience, fabrication, falsification, spin, and plagiarism are serious forms of scientific misbehavior that jeopardize the image of scientific journals and scientific community. While fabrication (making up data, results or cases) is evidently fraudulent scientific malpractice, pseudoscience lies somewhere between scientific fraud, bias, misunderstanding and simple careless, and it is not easy to define it. With regards to scientific fraud and spin, the intention to deceive is a key element. Falsification is defined as willful or deliberate modifications of study results, while spinning is related to the some kind of wishful thinking and subjective differences in research designing or interpreting. Researchers have great latitude in how they process data and report their results in the medical literature. Three common types of spin can be identified (Marshall 2002): 1.spinning by selective reporting (e.g. not reporting a disappointingly negative findings), 2.spinning using rating scales (e.g. evaluating outcome using multiple rating scales, or unpublished scales), 3.meta-spinning (reviewer's pessimistic or optimistic looking on inconsistent results of clinical trials). The distinction between real and artifact, true and false results and their interpretations is not an easy task. It is related to the applied mechanistic, formistic, contextual or systemic thinking or information-processing strategies. Wishful mechanistic (single-cause or single-effect thinking) and formistic binary categorical (either-or thinking) strategies of information have produced a lot of oversimplifications, false beliefs or myths in some fields of medicine (Jakovljevic 2007).

The boundaries and indicators separating science from pseudoscience and evidence-biased medicine are very fuzzy. Pseudoscience is like pornography: it is very hard to be defined, but one knows it when he sees it. According to the relevant literature (Ross 1995, Coker 2001, McNally 2003, Lilienfeld et al. 2015) pseudoscience can be characterized by the next features:

1. over-use of ad hoc hypotheses to account for negative research findings and to plug holes in the theory in question (after-the-fact escape hatches or loopholes); however, it may be a legitimate strategy);
2. avoidance of peer review that is the best, although not ideal, mechanism for self-correction in science identifying errors in the reasoning, methodology, analyses, and explanations;
3. emphasis on evidence that supports an hypothesis and failing to take into account evidence that refutes it (confirmation bias – weighing hits more than misses);
4. lack of connectivity with basic or applied research, and other scientific disciplines;
5. over-reliance on anecdotal evidence which can be very useful in the early stage of scientific research, but usually not enough for satisfactory and fruitful research;
6. thinking in false dichotomies; simplistic, mechanistic and reductionistic thinking; illusory correlation and causation, and other errors of logic;
7. tendency to place burden of proof on opponents so that proponents of pseudoscience neglect the principle that the burden of proof in science is primarily on the scientist making a claim, not on the opponent;
8. use of vague, exaggerated or untestable terms, or impressive sounding jargon and nonscientific language that gives an illusion of the science and false scientific legitimacy;
9. absence of borderline conditions because the well-supported scientific theories possess well-articulated boundary conditions, while pseudoscientific phenomena are suggested to operate across wide range of conditions;
10. mantra of holism because proponents of pseudoscientific claims in medicine and mental health often resort to this mantra to explain away negative findings.

The greater the number of such features, the more likely is pseudoscience in action, but these indicators are only probabilistically related to pseudoscientific studies. It is important to have in mind that the frontier lines between science and pseudoscience are disputed and difficult to determine strictly. Scientific journals have an important role in ensuring the integrity of scientific research and promoting evidence-based medicine.

How to make more published research more scientific, true and useful?

"Our wretched species is so made that those who walk on the well-trodden path always throw stones at those who are showing a new road"

Voltaire

Term pseudoscience refers to a field, practice, or body of knowledge claimed to be consistent with the norms of scientific information processing and research, but in reality fails to meet these norms. Pseudoscientific article seems to be scientific but they actually violate the criteria of science. According to the majority of scholars we need guidance how to distinguish between science and pseudoscience in medicine, but some like Burke (2016) are against using the term pseudoscience. What is labeled pseudoscience in both popular media and scholarly studies has as much to do with culture and ideology as it does with logic and fact. The term pseudoscience inherently creates framing issues as "us versus them" and "kto-kavo" ("who will eliminate whom"), pitting those who believe in "real" science against those who believe in "false" science (Burke 2016). It leads to unnecessary polarization, mistrust, disrespectfulness, and confusion around science issues. Scientists and health workers would better serve science by avoiding it. If people trust alleged pseudoscience over science, it should be discussed why, rather than dismiss their values and beliefs. Instead of the term pseudoscience it is politically more correct to say what kind of scientific evidence is available and what is scientifically in conclusive, or scientifically debated or lacking scientific evidence. If scientific evidence is missing or contradicting it is useful to discuss why that might be. Plenty of stuff that sounded crazy at one point, but turned out to be legitimate, was thought to be pseudoscience, including many areas of psychology.

Science- or evidence-based medicine addresses very important issues like how best to search the literature, how best to rate the quality of the relevant studies, and how best to synthesize the available data. Effective education in biomedicine, proper research motivation, sound systems and creative thinking and culture of scientific dialogue may significantly contribute to better science and evidence-based medicine. There are positive controlled trials of teaching critical appraisal to medical students and medical doctors. The seven key words of good science, research and publishing are: integrity, motivation, capacity, understanding, knowledge, experience, and creativity. Without integrity motivation is dangerous, without motivation capacity is impotent, without capacity understanding is limited, without understanding knowledge is meaningless, without knowledge experience is blind, without experience creativity is impossible, without creativity there is no progress According to Ioannidis (2014) possible interventions that can improve the credibility and efficiency of scientific research are represented at table 1.

Table 1. Some research practices that may help increase the proportion of true research findings (Ioannidis 2014)

- Large-scale collaborative research
- Adoption of replication culture
- Registration (of studies, protocols, analysis codes, datasets, raw data, and results
- Sharing (of data, protocols, materials, software, and other tools)
- Reproducibility practices
- Containment of conflicted sponsors and authors
- More appropriate statistical methods
- Standardization of definitions and analyses
- More stringent threshold for claiming discoveries or "successes"
- Improvement of study design standards
- Improvements in peer review, reporting, and dissemination of research
- Better training of scientific workforce in methods and statistical literacy

Table 2. Features to consider in appraising whether clinical research is useful (Ioannidis 2016)

- Problem base: Is there a health problem that is big or important enough to be fixed?
- Context placement: Has prior evidence been systematically assessed to inform (the need for) new studies?
- Information gain: Is the proposed study large enough to be sufficiently informative?
- Pragmatism: Does the research reflect real life? If it deviates, does this matter?
- Patient centeredness: Does the research reflect top patient priorities?
- Value for money: Is the research worth the money?
- Feasibility: Can this research be done?
- Transparency: Are methods, data, and analyses verifiable and unbiased?

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It sounds very optimistic that "interventions to make science less wasteful and more effective could be hugely beneficial to our health, our comfort, and our grasp of truth and could help scientific research more successfully pursue its noble goals" (Ioannidis 2014).

In addition to improving the credibility and efficiency of scientific research in medicine, producing more clinical research that is useful, is of great importance from the EBM perspective. According to Ioannidis (2016) "useful clinical research lead to a favorable change in decision making (when changes in benefits, harms, cost, and any other impact are considered) either by itself or when integrated with other studies and evidence in systematic reviews, meta-analyses, decision analyses, and guidelines." Studies that satisfy all utility criteria or majority of them (see table 2) are extremely rare, even in the most highly selective journals (Ioannidis 2016).

At the end of the day, when all is said and done, EBM is here to stay integrating evidence-based practice and practice-based evidence. It is important to have in mind that EBM should be the integration of 1. best research evidence (clinically relevant patient centered research), with 2. clinical expertise (to identify unique health states and diagnosis, individual risks and benefits, as well as personal values and expectations, and with 3. patients values (unique preferences, concerns and expectations) which should be integrated into effective clinical decision.

Instead of conclusion

All clinicians have a professional ethical obligation to follow, understand and share the scientific evidence. Considering the scientific evidence includes the ability of clinicians to access the information and scientific literature, understand its content and limitations, explain the information in an understandable way to patients, collaborate appropriately with patients and their families, and apply the evidence properly to particular and specific situations. However, many clinicians are confronted with the fact that the evidence that they learned in the school or official training programs has changed, often fundamentally. The problems with pseudoscience and evidence-biased medicine are manifold and not easy to be resolved. To get beyond pseudoscientific deceptions and spins, medical students and doctors need to be familiar with different strategies of thinking and information processing and able to read between the lines. Biomedical science is getting more and more complicated, and should be understood as more as possible in an integrative, holistic and transdisciplinary way. Each study should be evaluated in the context of what we really know and what we don't know about the object of study, existing data and what make sense from different perspectives (biological perspective, person-centered perspective, narrative perspective, value-based perspective, systems perspective, etc.). In spite of all difficulties, evidence-based medicine is here to stay to provide better quality and efficiency of health care and education in medicine.

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