## SHARED PRACTICE AND ECONOMIC ISSUES (A AMIN, SECTION EDITOR)



# **Evidence-Based Medicine and the Art of Medicine**

Israel De Alba<sup>1,2</sup> · Alpesh Amin<sup>3</sup>

Published online: 28 October 2017

© Springer Science+Business Media, LLC 2017

## Abstract

Purpose of Review Evidence-based medicine since its inception offered the potential for increased use of effective interventions and consequently a potential to improve quality of care and to reduce health care costs.

Recent Findings One great accomplishment of the evidence-based medicine movement has been a renewed focus on the scientific process and the development of systematic reviews and meta-analysis that condense the best evidence available. However, the well-being and goals of the patient are at the center of patient-physician and at the core of the clinical decision-making process.

Summary Evidence-based medicine is a tool that contributes with the best scientific evidence available. Clinical judgment and expertise are necessary elements that help integrate the patient's specific circumstances and values with the best scientific evidence to provide therapeutic options to the patient. Applying general evidence to the individual patient is part of the art of caring and comforting, part of the art of being a physician.

This article is part of the Topical Collection on Shared Practice and Economic Issues

☑ Israel De Alba idealba@uci.edu

Alpesh Amin anamin@uci.edu

- Hospitalist Program, University of California, Irvine, Irvine, CA, USA
- <sup>2</sup> 101 City Drive South Building 26 Suite 1001, Orange, CA 92868, USA
- Department of Medicine, Hospitalist Program, University of California, Irvine, Irvine, CA, USA

**Keywords** Evidence-based medicine · Evidence · Art of medicine · Health care

#### Introduction

The health care system in the USA is at a crossroads with uncertain future. Access to health care is a particular demanding issue, but so is health care costs and quality of care. The Center for Disease Control estimates that 28 million Americans under the age of 65 are currently uninsured [1]. Furthermore, an estimated 400,000 deaths a year could be attributed to medical error in the USA [2]. Evidence-based medicine since its inception offered the potential for increased use of effective interventions and consequently a potential to improve quality of care and to reduce health care costs. Close to 30 years after the initiation of the evidence-base medicine movement, there are successes, but some criticisms persist. One great accomplishment of the evidence-based medicine movement has been a renewed focus on the scientific process and the development of systematic reviews and meta-analysis that condense the best evidence available in a specific topic. However, patients' values remain at the core of every clinical decision despite the evidence. The best evidence needs to be integrated with clinical expertise and patients' preferences; this is when the art of medicine and evidence-based medicine coalesce.

### The Origins of Evidence-Based Medicine

The concern for effectiveness and safety of medical interventions grew during the 1970s, particularly by doctor Archibald Cochrane. He famously questioned the evidence behind many interventions, tests, and procedures and was deeply concerned about the lack of evidence for their effectiveness and safety



[3]. The randomized controlled trial and epidemiological principles applied to medical care were seen as a key to improve effectiveness and safety in medical practice [4]. Evidencebased medicine as we know it today, as a potential new method for clinical decision-making, was introduced by Gordon Guyatt from McMaster University in the 1990s [5]. It was described as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients by David Sackett [6•]. Doctor Sackett also stipulates that evidence-based medicine is the integration of three important aspects: the best available evidence, clinical experience and patient's values. As Dr. Sackett states: "without clinical expertise, practice risks becoming tyrannized by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient... without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients." [6•] The goal was to utilize the best available evidence in clinical practice and deemphasize intuition, pathophysiologic rationale, and unsystematic clinical experience. Initially, the evidence-based movement was more about educating physicians on use of published research and systematic reviews to optimize patient care [7, 8]. Soon, basic instruments such as collaborations to summarize evidence from clinical trials and to make it available in clinically useful portions, evidence-based clinical guidelines and critical appraisal tools designed for clinicians became available [9]. Evidence-based medicine later evolved into a more widespread approach with incorporation of critical appraisal of the evidence and patients' preferences [7]. By erection of clinical decisions on the same evidence, evidence-based medicine would limit variations in medical practice and use of untested interventions, consequently improving patient outcomes. Although the use of some form of evidence, clinical expertise, and incorporation of patients' values has always been part of medical practice, the main contribution of evidence-based medicine is the systematic use of scientific evidence in every day clinical practice.

## The Evidence in Evidence-Based Medicine

The basic methodology of evidence-based medicine models the scientific method; it identifies a clinically relevant question, makes use of the best scientific evidence to answer the question, critically appraises that evidence, and integrates the evidence with the clinical scenario and patients' values [10]. One key element of evidence-based medicine is that it favors systematic clinical observations in over other forms of evidence; this is called the first principle or epistemological principle. Therefore, not all evidence is created equal and the best available evidence should guide clinical decisions [7, 11]. The traditional hierarchy of evidence included randomized controlled trials at the top, followed by cohort studies, case controlled studies, case series, and others with expert experience

at the bottom [12]. The second principle stipulates that evaluating the totality of the evidence has a greater value than evaluating only selected or hand-picked evidence [11]. This is the basis for systematic reviews and other evidence compilation systems such as systematic summaries and meta-analysis. The Cochrane Collaboration [13] has been the flagship of this effort and currently involves more than 100 countries and close to 40 thousand collaborators [14]. Practice guidelines have been another effort to synthetize the best evidence available and make it widely available for every day clinical decision-making [15]. These were the response of the US Institute of Medicine to unacceptably extensive variations in medical practice, with the goal of decreasing variation and consequently improving outcomes. The third principle of evidence-based medicine stipulates that evidence is only one element in the decision-making process and the patients' values and preference must play a key role [7]. This is a fundamental key point, since the patient is at the core of the whole medical process; their decision is the directive. The great spectrum of patient values, preferences, and goals implies that consistency and standardization of care are neither desirable nor possible.

#### Criticisms to Evidence-Based Medicine

From its beginning, evidence-based medicine found many criticisms and critics. Evidence-based medicine initially was portrayed as a new paradigm in medicine, rather than a new focus or tool for clinical decision-making [16]. A paradigm shift would imply adopting an entire new set of beliefs and values; this clearly is not what happened [17]. Evidence of some sort or another, clinical judgment, and patients' wishes have always been part of the decision-making process in medicine. Although evidence-based medicine is not a paradigm shift in the strict sense, its merit consists in making a conscious effort to systematically use the best evidence available to guide the decision-making process.

A frequent criticism of evidence-based medicine is that not all evidence is equal and it gives more credence to some forms of evidence, such as that coming from randomized controlled trials. However, not all questions in medicine are amenable to this form of evidence and some questions may require ethnographic or other forms of evidence not contemplated or considered inferior by evidence-based medicine [18]. Another area of criticism is what is called gray zones [19]. Evidence is not available to answer every question a clinician encounters in every day practice. Clinical practice generates thousands of questions that would require thousands of expensive and time-consuming randomized control trials [19], a goal practically impossible to reach at the current time. Another criticism is that the availability of evidence is uneven; interventions that have been studied with mixed results may be favored over interventions potentially equally or more



effective but less studied. For instance, the device and pharmaceutical corporations (or governmental agencies) determine the research agenda and could influence clinical practice in several ways. By defining medical conditions or interventions that need to be explored, the pharmaceutical companies decide the specific areas where evidence is generated. Likewise, deciding the control and intervention populations and selecting outcomes to measure, the device and pharmaceutical corporations may further guide the evidence available for clinical decision-making [20.]. This would generate important volume of "evidence" in specific areas of interest, leaving other areas that may be equally valuable without evidence available. Other potential strategies to increase availability of favorable evidence is to overpower studies to find a statistically significant difference (although not necessarily clinically meaningful) [20••, 21, 22], selecting narrow populations most likely to respond to treatment [23], using surrogate outcomes [24], and only publishing studies with favorable results [24–30].

Another common criticism of evidence-based medicine is the applicability of evidence generated in large groups to the individual patient. Most of the evidence is gathered from studies done in large, strictly selected populations and under ideal circumstances [31]. The evidence generated by randomized controlled trials is specific to the particular population included in the trial and may not be applicable to other populations and to specific individuals that vary substantially from the population studied. Since the evidence based on randomized clinical trials provides trends in a group and average behaviors of participants, the conclusions are applicable to a group or "model" patient that may differ in many ways even from some of the participants in a study. Therefore, the best quality evidence can be gathered only for conditions that impact large groups to constitute a statistically significant population. For smaller subpopulations, the clinical decisions need to be based on evidence considered as lower quality by evidence-based medicine [31].

Many physicians wonder about the feasibility of practicing evidence-based medicine in the current extremely hectic medical environment. A considerable amount of medical literature is published on a daily basis. Medical knowledge has reached new levels of complexity and detail. However, from the clinician perspective, very few new pieces of published literature are practice changing and most only show marginal gains in knowledge. Not all we find in the daily flood of medical literature may be sound methodologically, applicable to the patient in front of us, or compatible with our patient's values or social circumstances. Furthermore, the current medical practice environment has progressively limited the amount of time we spent with patients. Research has shown that clinical questions arise frequently, in a particular study, they arose 3.2 times for every ten patients seen in medical practice, but clinicians do not look for an answer 64% of the time [32].

Furthermore, even if clear evidence is available, physicians and patients may opt not to implement it for multiple reasons. Among physicians, frequent reasons include the rapid development of new concepts that contradict recent ones, personal preference, or to address emotional needs of patients, prevent malpractice, or to manage patient expectations and in some cases [33]. As an effort to improve clinicians' rapid access to evidence, guidelines, templets, algorithms, and automated digital systems have been created. The goal of evidence-based medicine is to provide solid scientific base to improve effectiveness, quality, and safety of medical care. Evidence-based medicine may help solve some of overuse, underuse, and misuse of health care by limiting variations and emphasizing evidence-based health practices [6•, 34].

#### A Word on the Art of Medicine

The art of medicine is not clearly defined, but a classical medicine textbook [35] defines medicine and sheds light on the art of being a physician:

"...a profession that incorporates science and the scientific method with the art of being a physician. Even in modern times, the art of caring and comforting, guided by millennia of common sense as well as a more recent, systematic approach to medical ethics, remains the cornerstone of medicine. Without these humanistic qualities, the application of modern science of medicine is suboptimal, ineffective, or even detrimental."

The essence of medicine is the patient. The well-being and goals of the patient are at the center of patient-physician interaction and should be at the core of the clinical decision-making process. Evidence-based medicine is a tool that contributes with the best scientific evidence available. Clinical judgment and expertise is a necessary element that helps integrate the patient's specific circumstances and values with the best scientific evidence to provide therapeutic options to the patient. Regardless of strength and quality of evidence, the patient's values are the directive. There is little instruction or research on how to individualized evidence derived from large randomized clinical trials, or on effective share decision-making, as of now, this remains as an art. Accordingly, applying general evidence to the individual patient is part of the art of caring and comforting, part of the art of being a physician.

## **Conclusion**

Evidence-based medicine has been defined as the conscientious, explicit, judicious use of best evidence available to make decisions about the care of individual patients. This is a common sense and logical approach to the practice of medicine. Although it is not clear whether practicing evidence-based medicine improves patient outcomes, there are studies



that suggest that adherence to evidence-based medicine guidelines improves patient outcomes [36••]. On the other hand, there are limitations in the availability, quality, and applicability of the evidence to individual patients. Furthermore, in spite of clear evidence, patient or physicians may decide not to use it based on other factors such as cost, availability, or individual values or preferences. The patients' values remain at the core of every clinical decision despite the evidence. Therefore, the best evidence needs to be integrated with clinical expertise and patients' preferences; this is when the art of medicine and evidence-based medicine coalesce.

#### **Compliance With Ethical Standards**

**Conflict of Interest** The authors declare that they have no conflict of interest.

**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors.

## References

Papers of particular interest, published recently, have been highlighted as:

- · Of importance
- Of major importance
- FastStats Health insurance coverage 2017 updated 2017-07-19T02:19:42Z. Available from: https://www.cdc.gov/nchs/fastats/ health-insurance.htm.
- Makary MA, Daniel M. Medical error—the third leading cause of death in the US. BMJ. 2016;353:i2139.
- Cochrane AL. Effectiveness & efficiency: random reflections on health services. London: The Royal Society of Medicine Press, Limited: 1999.
- 4. Sackett DL. Rules of evidence and clinical recommendations on the use of antithrombotic agents. Chest. 1986;89(2 Suppl):2s–3s.
- Guyatt G, Cairns J, Churchill D, Cook D, Haynes B, Hirsh J, et al. Evidence-based medicine: a new approach to teaching the practice of medicine. JAMA. 1992;268(17):2420–5.
- 6.• Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ. 1996;312(7023):71–2. Fundamental article that provides the basics of the evidence-based movement.
- Djulbegovic B, Guyatt GH. Progress in evidence-based medicine: a quarter century on. Lancet. 2017;390:415–23.
- Maggio LA, Tannery NH, Chen HC, ten Cate O, O'Brien B. Evidence-based medicine training in undergraduate medical education: a review and critique of the literature published 2006-2011. Acad Med. 2013;88(7):1022-8.
- Levin A. The Cochrane collaboration. Ann Intern Med. 2001;135(4):309–12.
- Sackett DL, Rosenberg WM. The need for evidence-based medicine. J R Soc Med. 1995;88(11):620–4.
- Djulbegovic B, Guyatt GH, Ashcroft RE. Epistemologic inquiries in evidence-based medicine. Cancer Control. 2009;16(2):158–68.
- Guyatt GH, Sackett DL, Sinclair JC, Hayward R, Cook DJ, Cook RJ. Users' guides to the medical literature. IX. A method for

- grading health care recommendations. Evidence-Based Medicine Working Group. JAMA. 1995;274(22):1800–4.
- Chalmers I. The Cochrane collaboration: preparing, maintaining, and disseminating systematic reviews of the effects of health care. Ann N Y Acad Sci. 1993;703:156–63. discussion 63-5
- Cochrane | Trusted evidence. Informed decisions. Better health. 2017. Available from: http://www.cochrane.org/. Accessed 1 Sept 2017.
- Institute of Medicine (US) Committee to Advise the Public Health Service on Clinical Practice Guidelines; Field MJ, Lohr KN, editors. Clinical practice guidelines: directions for a new program. Washington (DC): National Academies Press (US); 1990. Summary. Available from: https://www.ncbi.nlm.nih.gov/books/ NBK235753.
- Crawley L. Evidence-based medicine: a new paradigm for the patient. JAMA. 1993;269(10):1253. author reply 4
- Sehon SR, Stanley DE. A philosophical analysis of the evidencebased medicine debate. BMC Health Serv Res. 2003;3(1):14.
- Barton S. Which clinical studies provide the best evidence?: The best RCT still trumps the best observational study. BMJ. 2000;321(7256):255-6.
- Naylor CD. Grey zones of clinical practice: some limits to evidence-based medicine. Lancet. 1995;345(8953):840–2.
- 20. •• Cohen D. FDA official: "clinical trial system is broken". 2013 2013-12-05. en. Article that lays down fundamental critiques to the evidence-based movement.
- Bhardwaj SS, Camacho F, Derrow A, Fleischer AB Jr, Feldman SR. Statistical significance and clinical relevance: the importance of power in clinical trials in dermatology. Arch Dermatol. 2004:140(12):1520–3.
- 22. Hochster HS. The power of "p": on overpowered clinical trials and "positive" results. Gastrointest Cancer Res. 2008;2(2):108–9.
- Hewitt DJ, Ho TW, Galer B, Backonja M, Markovitz P, Gammaitoni A, et al. Impact of responder definition on the enriched enrollment randomized withdrawal trial design for establishing proof of concept in neuropathic pain. Pain. 2011;152(3): 514–21.
- Prasad V, Kim C, Burotto M, Vandross A. The strength of association between surrogate end points and survival in oncology: a systematic review of trial-level meta-analyses. JAMA Intern Med. 2015;175(8):1389–98.
- Every-Palmer S, Howick J. How evidence-based medicine is failing due to biased trials and selective publication. J Eval Clin Pract. 2014;20(6):908–14.
- Turner EH, Matthews AM, Linardatos E, Tell RA, Rosenthal R. Selective publication of antidepressant trials and its influence on apparent efficacy. N Engl J Med. 2008;358(3):252–60.
- 27. Hart B, Lundh A, Bero L. Effect of reporting bias on meta-analyses of drug trials: reanalysis of meta-analyses. BMJ. 2012;344:d7202.
- McCarthy M. Nearly half of US pediatric trials are unfinished or unpublished, study finds. BMJ. 2016;354:i4358.
- Roest AM, de Jonge P, Williams CD, de Vries YA, Schoevers RA, Turner EH. Reporting bias in clinical trials investigating the efficacy of second-generation antidepressants in the treatment of anxiety disorders: a report of 2 meta-analyses. JAMA Psychiatry. 2015;72(5):500–10.
- Saini P, Loke YK, Gamble C, Altman DG, Williamson PR, Kirkham JJ. Selective reporting bias of harm outcomes within studies: findings from a cohort of systematic reviews. BMJ. 2014;349: g6501.
- Dearlove O, Sharples A, O'Brien K, Dunkley C. Evidence based medicine. Many questions cannot be answered by evidence based medicine. BMJ. 1995;311(6999):257–8. author reply 9
- Ely JW, Osheroff JA, Ebell MH, Bergus GR, Levy BT, Chambliss ML, et al. Analysis of questions asked by family doctors regarding patient care. BMJ. 1999;319(7206):358–61.



- Epstein D. When evidence says no, but doctors say yes— ProPublica2017 2017-02-22. Available from: https://www. propublica.org/article/when-evidence-says-no-but-doctors-say-yes.
- 34. Bero LA, Grilli R, Grimshaw JM, Harvey E, Oxman AD, Thomson MA. Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. The Cochrane Effective Practice and Organization of Care Review Group. BMJ. 1998;317(7156):465–8.
- Goldaman L. Goldman-Cecil medicine. Philadelphia: Elsevier Saunders; 2015.
- 36.•• Jernberg T, Johanson P, Held C, Svennblad B, Lindback J, Wallentin L. Association between adoption of evidence-based treatment and survival for patients with ST-elevation myocardial infarction. JAMA. 2011;305(16):1677–84. Relevant article that supports the link between use of evidence-based medicine and improved patient outcomes.

