

The origin and future of evidence-based medicine

Mitchell Levine 

Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, L8S 4K1, Canada

Received: February 17, 2026; Revised: April 16, 2026; Accepted: April 30, 2026

ABSTRACT

The term evidence-based medicine (EBM) was first used in 1991 but its roots began hundreds of years earlier. Over the past 35 years it has evolved considerably into its present-day application. This commentary reviews the history of EBM to the present day, and where the future of EBM may lead over the coming decade. It describes how clinical practice based on personal experience, tradition and anecdotes evidence-based medicine transformed to clinical practice that relies upon a hierarchy of scientific evidence, the comprehensive aggregation and timely access of information and the incorporation of patient values.

KEYWORDS

evidence-based medicine, clinical practice, history, clinical epidemiology, hierarchy of evidence, patient values and preferences, clinical decision making

CITE THIS ARTICLE

Levine M. The origin and future of evidence-based medicine. Evidence-Based Chinese Medicine and Technology Assessment, 2026, 2: 9570033. <https://doi.org/10.26599/eCMTA.2026.9570033>

The concept of evidence-based medicine (EBM) has become ubiquitous in clinical practice, health care policy and health care research. Prior to the application of EBM in clinical practice, physicians would rely on three pillars to determine how to manage clinical scenarios. First was their personal clinical experience guiding them on how to manage subsequent clinical encounters. Second, tradition and the deference to authority was a strong determinant of clinical behaviour. Third, when looking to the scientific literature there was a heavy reliance on publications involving anecdotal reports.

While the adoption of EBM terminology into the practice of health care may have occurred a little more than a quarter of a century ago (in the 1990's) its roots date back to the 18th century. That is when James Lind conducted the first reported controlled clinical trial in 1747. To test the hypothesis that citrus fruits could treat scurvy he divided 12 sailors with scurvy into six different treatment groups that were treated with either cider, vinegar, sea water, sulfuric acid/alcohol, garlic/mustard, or lemon/oranges. The latter group recovered in six days, but not the others.¹

A century later Austin Flint in 1863 conducted a study that was the first to introduce the idea that a placebo could have an effect. In a trial for the treatment of acute rheumatism, he gave 13 patients a dilute tincture of a plant extract that was expected to have no effect on the disease, but it demonstrated that the patients receiving the placebo showed similar improvements to those receiving the active conventional therapy of the day.²

Ronald Fisher in the 1920's introduced formal hypothesis testing and rigorous experimental design. Fisher implemented statistical tests to address the issue of chance findings by determining if a null hypothesis should be rejected.³ The first randomized controlled trial (RCT) was conducted in 1947, assessing the effects of streptomycin in the treatment of pulmonary tuberculosis.⁴ It was a multicentred trial in the United Kingdom, with the trial design led by Austin Bradford Hill. Using concealed allocation, the treatment designation was randomized for patients to receive either streptomycin plus bedrest or bedrest alone (control). The results showed radiological improvement and lower death rates at six months in the streptomycin treated group of patients. But the subsequent use of the RCT to test the effectiveness of

interventions was still not widely adopted, and many years later Archie Cochrane would publish a monograph discussing the failure of the health-care system to use reliable and valid evidence to support many common healthcare interventions.⁵ Cochrane became a leading advocate for conducting RCTs to generate the information that clinical decision makers needed.

John Paul first introduced the term "clinical epidemiology" as a science for guiding preventative medicine when applying epidemiology principles to small groups of patients.⁶ The definition would later evolve to reflect a more bedside and patient specific tone, adapting to the needs of practitioners when Alvan Feinstein in the late 1960's promoted the idea that the field of clinical epidemiology would involve applying the best available evidence to clinical decision making.⁷ David Sackett, who was inspired by Alvan, then expanded the implementation of the clinical epidemiology concepts through the development of education and mentoring programs which had a heavy focus on critical appraisal of the medical literature. These concepts would determine the type of published literature that should influence clinical practice, acting as a guide for clinical practice and as a stimulus for conducting clinical research activities.

In 1981 the *Canadian Medical Association Journal* published a series of articles generated by David Sackett and his colleagues.⁸ These articles were intended to improve the critical appraisal skills of its readers. Topics included how to critique therapy articles that were assessing the usefulness or harm of interventions; articles involving the determination of etiology or causation of a disease; how to evaluate a diagnostic test and its properties; evaluating the validity and applicability of articles involving prognosis, quality of care, economic analysis or systematic reviews.

A few years later (in 1985) a group of clinical epidemiologists at McMaster University (Hamilton, Canada) published the textbook *Clinical Epidemiology: A Basic Science for Clinical Medicine*, which described in detail how these core concepts could be applied to everyday clinical practice.⁹ Six years later Gordon Guyatt wrote an editorial in an issue of the *American College of Physicians Journal Club* describing a process for using new evidence to guide clinical practice and coined the term "evidence-based medicine."¹⁰ The term was initially adopted by physicians, but it was not long before it was embraced by allied health care professionals, health policy makers, and patients. The concept even expanded outside of human health care and was taken up by veterinarians.

EBM was adopted into the curriculum of medical schools and residency

 Corresponding author.

E-mail address: levinem@mcmaster.ca (M. Levine)

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programs in North America.¹¹ A series of articles began to be published in the *Journal of the American Medical Association (JAMA)* in 1993 to further facilitate EBM practice by clinicians.¹² This led to the *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice*, which is now in its third edition.¹³

Over the next three decades EBM continued to grow in its uptake around the world. There has been a transformation in how it is applied on a daily basis due to the significant development of tools to make the practice of EBM the path of least resistance in clinical practice. What has not changed are the four fundamental principles of EBM. The first is that there remains a hierarchy of evidence for associations relevant to clinical practice. The most internally valid associations are derived from RCTs. At a lower level of validity are observational studies (cohort and case-control studies) which are more susceptible to confounding and bias. Then further down the hierarchy are the studies in basic science research. This may include *in vitro* studies, animal studies or studies involving human physiology. The weakest evidence comes from a practitioner's clinical experience or the publications of case reports. While the latter may be useful for generating hypotheses, they offer no credible evidence to support an association.

While the hierarchy of evidence remains useful, the evolution of more sophisticated statistical means for analyzing observational studies has improved the validity of these studies. This is important because observational studies have become more frequent as the use of real-world data is increasingly embraced by health care analysts, particularly for highly multivariate events. But even with advanced analyses for observational studies, readers need to remember that the primary value of the RCT is that it provides the best opportunity to balance important prognostic variables that are either unknown or unmeasured. Over time reproducible analytical methods have been developed and employed to determine the certainty of evidence. This was done to assist the users of evidence by providing a transparent assessment of the evidence's certainty. One such system is Grading of Recommendations Assessment, Development and Evaluation (GRADE), which has been adopted by more than 120 organizations worldwide.¹⁴

The second principle of EBM is that one should aggregate all the available evidence on the topic rather than using just one or a few sources. The RCT is the starting point for obtaining evidence, but when there is more than one study that will address a clinical question, the preferred path is to use a systematic summary of the trials. Or even better, a meta-analysis or a network meta-analysis.

Archie Cochrane recognized that individual RCTs on the same topic may not always generate the same conclusions. As a result, he promoted the idea that the results of clinical trials on a specific topic should be organized into a critical summary that could be updated as new RCT evidence became available. Inspired by Cochrane, Iain Chalmers created a database of RCTs in obstetrical and perinatal medicine.¹⁵ This led to the eventual creation of the Cochrane Collaboration, and subsequently the Cochrane (<https://www.cochrane.org/>) as an accessible repository of high-quality health evidence.

The third principle is that there must be timely access to the evidence. Sometimes this can mean relying upon colleagues who are well versed in the evidence and can provide a quick answer to a clinical question. Turning to databases such as PubMed (<https://pubmed.ncbi.nlm.nih.gov/>) to identify the best evidence through a literature search continues to remain an option, but this can be quite burdensome. Summaries of evidence that impose rigorous thresholds on evidence quality such as those available at Cochrane are valuable to clinicians. Also clinical guidelines that are evidence-based and provide specific help with clinical decision making have become particularly use-

ful for busy clinicians, as long as the guidelines are regularly updated with the latest evidence.

Another modality to put the best evidence in the hands of clinical decision makers is through digital services involving processes like push notifications. Healthcare organizations increasingly use structured dissemination programs to push evidence to clinicians through newsletters, dashboards, executive summaries, and targeted messaging. The Agency for Healthcare Research and Quality's communication and dissemination strategies emphasize translating complex evidence into actionable, clinician-directed messaging to ensure timely practice changes, rather than waiting for clinicians to seek out systematic reviews.¹⁶ Over the past two decades there has been a substantial increase in methods and technologies used to get evidence into the hands of the clinical decision makers.¹⁷ Clinical decision support systems have become more integrated into electronic health records allowing clinicians to access evidence-based recommendations at the point of care.¹⁸

The fourth principle of EBM is the incorporation of patient values and preferences. While some may have not appreciated that EBM includes this importance concept, it has always existed at the core of EBM.¹⁹ From the EBM perspective the patient has always been at the center of a clinical decision. Hence, it is inconceivable that the evidence would be considered more relevant than the patient's perspective. The true practice of EBM is to understand patient preferences and values and identify the best evidence to achieve the goals that are consistent with the patient's values.

The history of EBM has been very western medicine centric. In current times EBM is now being applied to traditional Chinese medicine and technologies, and the four principles described above continue to hold true. It is still important to have the steps of evaluation use the most valid methods available. In situations where the most ideal methods are unavailable or not feasible, it is important to acknowledge these limitations. The role of real-world data evaluating traditional Chinese medicines and technologies will continue to be important as the goal remains that patients and their health care providers have access to the best available evidence to make decisions that are in synchronization with patient values.

So what is in the future for EBM? The foundation of EBM began long before the term was introduced in 1991. It started with adopting good scientific methods to help us understand observable clinical phenomenon. Then the knowledge gained was brought to bear on bedside clinical decision making. With an ongoing explosion of knowledge feeding the evidence base, there was a need to aggregate the information and place it into comprehensible and clinically useful packets. In addition, the explosion of new information includes misinformation, hence the further importance of applying EBM's critical appraisal standards to all the available information that is disseminated (Table 1).

The current frontier for EBM's evolution involves the actions of knowledge synthesis and dissemination. We need to keep developing better methods to ensure that clinical decision makers will have the most relevant and highest quality evidence in a just-in-time format. To achieve this, the future work of enhancing EBM will increasingly involve the integration of artificial intelligence (AI) into the latter process. AI can improve the communication of evidence-based risks, such as the number-needed-to-treat, which can be delivered proactively using digital tools to support more effective decision making. Analytics with AI can push personalized recommendations that are based on the patient's characteristics or the clinician's specialty.²⁰ Thus the future of EBM will inevitably involve the products of the AI revolution.

Table 1 The old and the current paradigms of clinical practice

Pre-evidence-based medicine	Evidence-based medicine
Personal experience	Hierarchy of evidence
Tradition	Aggregation and timely access to information
Anecdotes	Patient values and preferences

Funding

None.

Data Availability

Not applicable.

Author Contribution Statement

Mitchell Levine: Conceptualization, writing – original draft, and writing – review & editing.

Use of AI Statement

None.

Declaration of Competing Interest

The author has no competing interests to declare that are relevant to the content of this article.

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