Symposium

History of evidence-based medicine

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ABSTRACT

This essay reviews the historical circumstances surrounding the introduction and evolution of evidence-based medicine. Criticisms of the approach are also considered. Weaknesses of existing standards of clinical practice and efforts to bring more certainty to clinical decision making were the foundation for evidence-based medicine, which integrates epidemiology and medical research. Because of its utility in designing randomized clinical trials, assessing the quality of the literature, and applying medical research at the bedside, evidence-based medicine will continue to have a strong influence on everyday clinical practice.

Key words: Evidence-based medicine, randomized controlled trials, policy, epidemiology, translational research, history

In the spring of 1990 the young McMasters University Internal Medicine residency coordinator, Dr. Gordon Guyatt, had just introduced a new concept he called "Scientific Medicine." The term described a novel method of teaching medicine at the bedside. It was built on groundwork laid by his mentor Dr. David Sackett, using critical appraisal techniques applicable to the bedside. However, the response from his fellow staff was anything but warm and inviting. The implication that current clinical decisions were less than scientific, although probably true, was nonetheless unacceptable to them. Guyatt then returned with a new title that described the core curriculum of the residency program: "Evidence-Based Medicine" (EBM). The coined term appeared in a subsequent 1991 *ACP Journal Club* editorial.[1]

Although this term was introduced in 1991, the foundation for this new strategy was accomplished through years of work by many others. In fact, EBM encompasses a broad range of topics, from clinical epidemiology to biomedical informatics to evidence-based guidelines. In this short essay, we hope to briefly describe one particular aspect of EBM—the growth of clinical epidemiology and its incorporation into clinical practice. The concept and impetus for EBM can be attributed to an increasing awareness of the weaknesses of standard clinical practices and their impact on both the quality and cost of patient care in the United States.[2,3] The effort to bring more certainty to clinical decision making spurred this novel approach. Clinical practice was historically viewed as the "art of medicine." Expert opinion, experience, and authoritarian judgment were the foundation for decision making. The use of scientific methodology, as in biomedical research, and statistical analysis, as in epidemiology, were rare in the world of medicine. Historical precedence and indoctrinated political mistrust of these other disciplines posed barriers to incorporating these tools into medicine.[4] However, several events in different parts of the world during the 1960s paved the way for EBM.

Trained at Harvard Medical School, Stanford Medical Center, and Johns Hopkins University, Suzanne Fletcher and Robert Fletcher were early 1960s pioneers in this movement.[5] They recognized a deficit in medicine: biomedical science often had no translational application to clinical medicine. These two enrolled in the clinical scholars program funded by the Carnegie Foundation in 1969 (later named Robert Wood Johnson Clinical Scholars Program) and obtained training in public health and clinical care. Graduates of this program were challenged with the task of straddling the political extremes of public health and medicine. They fortunately found opportunity at McGill University, where they taught epidemiology at the medical school. In 1982 they published a textbook that described the scientific basis for clinical care, *Clinical Epidemiology: The Essentials.*

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During this same period Alvan Feinstein, a mathematician turned physician, was attempting to resolve the uncertainty inherent in medical practice at the bedside. He proposed that uncertainty in decisions could be minimised by using a new form of medicine. This medicine incorporated principles of basic science. He began his earliest work at a rheumatic fever hospital in New York, where an epidemiological study was ongoing. He was not a primary investigator; he merely asked to provide care for the children and collect data.[5] He recognized uncertainty in distinguishing benign from pathological murmurs and that the basis for diagnosis was purely clinical authority—not scientific criteria.[6] His successful classification of the disease led to improved outcomes and, ironically, the closing of the rheumatic fever hospital due to lack of sufficient patients. He proposed the term "clinical epidemiology"[7-9] in a set of three *Annals of Internal Medicine* articles that detailed a new discipline of medical teaching. This teaching would combine statistical methods of epidemiology with clinical reasoning to study clinical populations. He saw the public health institution by itself as unable to provide clinicians with the necessary tools to improve clinical care. He criticised public health studies as lacking rigour with respect to specified hypotheses, bias, poor data, and unsound attribution of cause.[10] Feinstein bridged the world of epidemiology and medical research, which had long been separated, hence propelling the utility of medical research beyond its traditional anecdotal works.

Clinical epidemiology became a formal course of study first at McMaster University's new medical school in 1967 under their first dean, John Evans, and pathology chairman, Fraser Mustard, with the introduction of the new Department of Clinical Epidemiology and Biostatistics. The new department was headed by a young clinician, Dr. David Sackett, who had Harvard School of Public Health training but shared the vision that clinical epidemiology was "the application, by a physician who provides direct patient care, of epidemiological and biometric methods to the study of diagnostic and therapeutic process in order to effect an improvement in health."[11] Other future department chairmen instrumental in propagating this new philosophy included Drs. Jack Hirsh, Peter Tugwell, George Browman, and Brian Haynes.

In 1981 a series of articles from the *Canadian Medical Association Journal* (CMAJ) written by David Sackett, Brian Haynes, Peter Tugwell, and Victor Neufeld introduced a new method for physicians reading the literature. The term that described this new technique was called "critical appraisal." Sackett and his colleagues saw the need to not only teach methods to understand the literature but also teach the application of new information to the physicians at the bedside.

Gordon Guyatt along with Deborah Cook, Roman Jaeschke, Jim Nishikawa and Pat Brill-Edwards, and Akbar Panju refined the work of evidence-based medical teaching at McMasters through the 1990s. They then collaborated with U.S. academicians forming an international EBM Working Group.[12] Two distinctly different concepts emerged from their work: 1) exposure to critical appraisal drastically changed the practice of medicine at the bedside; 2) the CMAJ articles had some limitations. Specifically, these articles had primarily focused on the quality of evidence—less on the application of evidence to a particular clinical scenario. Literature has always had varying levels of evidence but how does one not only assess the quality but then apply the sometimes only existing, yet suboptimal, evidence. Moreover, these articles lacked consistency in the explanation of bias, validity, and precision, leaving the reader potentially confused with their meaning. The need to create a "user's" not just a "reader's" guide became obvious to these pioneers. Hence, the *Journal of the American Medical Association* (JAMA) User's Guide concept was born. Twenty-five articles from 1993 to 2000 were written to assist the everyday physician in understanding and then applying the literature to the particular patient at hand. With the instrumental help of Drummond Rennie at JAMA the series was born, becoming the basis for the current text *User's Guide to the Medical Literature* (now in 6th printing). What began as a series of articles explaining basic concepts, such as magnitude of effect and level of certainty (precision), evolved into what now is considered equally as important—the balance of patient values and preferences (personal conversation with Dr. Gordon Guyatt, April 2010).

Three men can be credited with the formation of the current Cochrane Collaboration: Tom Chalmers, Ian Chalmers, and Murray Enkin. The institution's name is a tribute to Britain's Archie Cochrane and his pioneering efforts to eschew bias in clinical research through the promotion of the randomized control trial (RCT). Imprisoned during World War II, Cochrane performed his first trial on fellow prisoners of war, comparing the effect of yeast extract on deficiency diseases. His compassion for the subjects of his trial, who were also his comrades and fellow prisoners, influenced his future work. The principle that RCTs must provide benefit to subjects is a hallmark of the Cochrane Collaboration.[13] Cochrane's first landmark work occurred in Cardiff, South Wales, where he spent many years trying to determine the effect of tuberculosis versus dust in causing progressive pulmonary fibrosis—the Rhondda Fach study. Some of the most valuable lessons he learned from the Rhondda Fach study included the value of epidemiological studies and the threat of bias to a study.[14]

Tom Chalmers expanded Cochrane's work. He asserted that RCTs are the foundation of a hierarchy of evidence that culminates with pooled data from multiple trials. He added that publication bias, the fact that studies with positive results are more likely to be published than those with negative results, must be taken into account when summarizing the evidence. He is credited with introducing meta-analysis.[5]

Meanwhile, the obstetrician Ian Chalmers was moved to seek effective treatment during his 1960s experiences in Palestinian refugee camps. Traditionally, antibiotics were only indicated if clear signs of infection existed. When parents brought their sick children to Chalmers, he insisted they return for antibiotics only after these indications were present. However, by that time, the bacteria had already consumed the malnourished, immunocompromised children. Chalmers thus recognized the dangers of surrendering to medical dogma and the vital importance of searching for the truth.[5]

Chalmers teamed with obstetrician Murray Enkin to create a massive database of published, unpublished, ongoing, and planned trials and meta-analyses. The Oxford Database of Perinatal Trials provided the foundation for a landmark book, *Effective Care in Pregnancy and Childbirth*.[15] This two-volume edition provided sometimes shattering evidence of unsupported and dangerous practices, such as the now abandoned practice of administering diethylstilbestrol during pregnancy.[5]

The work of these pioneers culminated in the 1993 Cochrane Collaboration. Duplicating the work from the Oxford Database of Perinatal Trials, numerous other medical specialties committed to 10 principles: collaboration, building on enthusiasm of individuals, avoiding duplication, minimizing bias, keeping up-to-date, striving for relevance, promoting access, ensuring quality, continuity, and worldwide participation.

Although EBM is now formally taught in many centres of higher education, such as the renowned McMasters Workshop, the Oxford University workshop, the University of North Carolina, and Duke University, there has been substantial criticism of its inherent weaknesses. Critics claim that EBM lacks utility on several levels. Some claim that it transforms the complex process of clinical decision making—which includes data gathering, years of medical knowledge, experience, and astute intuition—into an algorithmic exercise that is not individualized for specific clinical scenarios and therefore subject to error in patient care. Even Alvan Feinstein himself critiqued the work of McMasters University. The argument that EBM incorporates the "the best available external clinical evidence from systematic search"[16] requires an understanding of what constitutes "best…evidence." For questions about treatment, the RCT and systematic review/meta-analysis are the "gold standard" for EBM, over non-experimental approaches. And yet Feinstein highlighted that both insulin for diabetic acidosis and penicillin for bacterial endocarditis were introduced through single study articles and therefore would never have been included in the work of the Cochrane Collaboration. He argued EBM proponents have an over-reliance on the RCT. RCTs are simply a comparison of one treatment to another treatment, not some superior form of truth. In relying on these epidemiological tools, EBM does not incorporate the "soft" data that clinicians use to formulate diagnoses and treatments. These "soft" data include type and severity of symptoms, and rate of growth of illness.[17] Additionally, social and political contexts within which patients live are equally not addressed in EBM[5] Lastly, critiques of EBM cite the potential for abuse of the label "best available evidence." Health care policy makers and both government and private payers can coerce and justify reimbursement based on the "best available evidence" and marginalize practice that does not conform to these standards.

Notwithstanding these potential deficiencies, EBM has made a clear and probable permanent mark on the face of medicine. The introduction of clinical epidemiology into the daily practice of clinicians has offered a systematized, scientific approach to the practice of medicine. There have been and continue to be many contributors to this movement, far beyond the scope of this brief description, all of whom deserve mention. Their work has and will continue to have a profound effect on daily clinical practice.

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