



# The 11th hour—time for *EBM* to return to first principles?

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In accordance with our editor's challenge to write about the translation of evidence into policy and practice,<sup>1</sup> I have been reflecting on why this is seemingly so hard to do.

First, let us remember how Sackett defined evidence-based medicine (EBM).<sup>2</sup> "Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research .... Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights and preferences in making clinical decisions about their care."

The story of evidence-based medicine is one of incredible success. In the last 20 years, the field has exploded, and done a lot of good. Therapies in wide use have been found to be unhelpful or dangerous<sup>3</sup>; there is increased knowledge of the characteristics of a trustworthy clinical trial<sup>4</sup>; there have been exponential advances in our ability to access literature and we have created new ways to synthesise and summarise our knowledge.

With this success, where is the rationalist dream of seamless translation? EBM is now the dominant paradigm in academic medicine – and this is problematic for several reasons.

In an address to the North American Primary Care Research Group (NAPCRG) professor Trisha Greenhalgh explored the meaning of evidence and knowledge.<sup>5</sup> The crux of the problem as she saw it, is that EBM has become the standard by which all of medicine's questions are judged, resulting in measures that constrain how interventions are translated into practice. In the process, however, much of Sackett's elegant definition has been forgotten.<sup>2</sup>

There is an illusion that the ability to synthesise evidence provides all of the knowledge needed to practice medicine: that one has only to read the literature, or to adopt the guideline, to gain a mastery of the field. Governments, policy makers and payers have been seduced into believing that the rationalist EBM paradigm holds the solution to, for example, the task of providing high-quality medical care to an ageing population with complex needs. There is a push to codify and regulate the practice of medicine, to apply guidelines, and to pay for performance to standardise care, in the hope that this approach to evidence translation will reduce cost and improve outcomes that are of *importance to institutions*; Sackett warned of the risk of evidence-based medicine being hijacked to this purpose in 1996.<sup>2</sup> There has been an expensive rush to innovate in the area of health informatics, prior to truly understanding which elements of informatics are the most important for supporting clinical care. Detailed qualitative-case study analyses provide context and colour to enhance understanding of these

complex initiatives, but the lessons learnt have not been embraced.<sup>6</sup> These health informatics efforts are now in danger of collapse. On 22 September 2011, the UK Department of Health announced that it is dismantling the National Health Service's National Programme for Information Technology, a 9-year, multi-billion pound effort, on the grounds that it has not and cannot deliver on its original promise.<sup>7</sup>

For those who hew to Sackett's view of EBM, there are four needs to make it relevant: first, is the need to enhance the quality of the evidence base; second, is the need to attend to patient-oriented outcomes, values and preferences; third, is the need to tackle the problem of clinical effectiveness, particularly in the area of multimorbidity; finally, there is a need to embrace mixed-methods approaches to study complex health systems at the patient, provider, institutional and system levels.

Clinicians face 'information chaos': there are 2000 MEDLINE articles daily, direct-to-consumer advertising, and a plethora of conflicting clinical practice guidelines.<sup>8-10</sup> More ominously, there are serious claims that the 'evidence' is corrupted with bias, spin and selective reporting to such a degree that it mocks the concept of evidence-based practice. Furthermore, there is an over-emphasis on surrogate biomedical outcomes, rather than patient important outcomes. Is it any wonder that implementation falters in the face of our continual neglect of our patients' values, preferences and circumstances?<sup>11-14</sup>

The volume of systematic research is astonishing and, as has been clearly demonstrated, it is not possible for individual clinicians to stay on top of it. The problem is exacerbated when we consider that patients with multimorbidity are frequently excluded from clinical trials.<sup>15</sup> The inherent complexity of clinical practice is at odds with the reductionism inherent in the current paradigm of evidence translation. Sackett and Greenhalgh emphasise the need for the capacity to exercise judgment – or 'phronesis' (practical wisdom) – predicated on a depth of knowledge of the patient, the patient's circumstances and the best available evidence.<sup>2,5,16</sup>

It is time for a new paradigm to underpin medical care and health system design – one that emphasises interventions with large effects on patient-oriented outcomes, and systems that optimise care delivery in patient-oriented ways. How do we begin to conceive of this transformation? Greenhalgh and colleagues provide one example in the case of a national ehealth programme demonstrating that robust qualitative case studies can shed light on these complex problems; a practice very familiar to research colleagues in organisational behaviour and the social sciences.<sup>6</sup>

In 2009, the USA allocated \$1.1 billion under the Patient Protection and Affordable Care Act for comparative effectiveness research (CER) on healthcare practices. This legislation resulted in the establishment of the Patient Centred Outcomes Research Institute (PCORI), which on 23 January 2012 released, for public comment, its draft national priorities for research.<sup>17</sup> This

investment has caused considerable interest in CER. The PCORI is proposing to put systems and funding in place to ask patient-oriented questions, with new research infrastructure and support. A strong emphasis on this work in the UK and elsewhere continue to inform this area.<sup>18</sup>

In conclusion, the evolution – or perhaps a return to first principles – of EBM must continue. The sooner we realise that what matters is not mitigating illness but optimising health, the better off we will be. We need to re-emphasise the full definition of EBM and explore strategies to help clinicians learn how to incorporate knowledge of patient values, preferences, circumstances and their clinical expertise with the best available evidence. This is really the first principle of Medicine. Dr Ian McWhinney once wrote<sup>19</sup>:

“My commitment to you is not just look after the one particular illness, but to care for you as a person, whatever problem you may have. As a patient said to me once: ‘I want a doctor who specialises in me.’”

Successful translation of evidence-based medicine captures both the structure and rigour of science, with the nuance and wisdom of relationships. It is through study of the methods of how clinicians can do this that the translation of evidence into practice can be realised. In a similar way, complex health systems also need to be informed by both qualitative and quantitative tools in order to dynamically and iteratively evolve to address principles of person-focused care, with the nuance to respond to local needs and circumstances.

**Competing interests** None.

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