

# Evidence based medicine a movement in crisis?

**Trisha Greenhalgh and colleagues** argue that, although evidence based medicine has had many benefits, it has also had some negative unintended consequences. They offer a preliminary agenda for the movement's renaissance, refocusing on providing usable evidence that can be combined with context and professional expertise so that individual patients get optimal treatment

It is more than 20 years since the evidence based medicine working group announced a “new paradigm” for teaching and practising clinical medicine.<sup>1</sup> Tradition, anecdote, and theoretical reasoning from basic sciences would be replaced by evidence from high quality randomised controlled trials and observational studies, in combination with clinical expertise and the needs and wishes of patients.

Evidence based medicine quickly became an energetic intellectual community committed to making clinical practice more scientific and empirically grounded and thereby achieving safer, more consistent, and more cost effective care.<sup>2</sup> Achievements included establishing the Cochrane Collaboration to collate and summarise evidence from clinical trials;<sup>3</sup> setting methodological and publication standards for primary and secondary research<sup>4</sup>; building national and international infrastructures for developing and updating clinical practice guidelines<sup>5</sup>; developing resources and courses for teaching critical appraisal<sup>6</sup>; and building the knowledge base for implementation and knowledge translation.<sup>7</sup>

From the outset, critics were concerned that the emphasis on experimental evidence could devalue basic sciences and the tacit knowledge that accumulates with clinical experience; they also questioned whether findings from average results in clinical studies could inform decisions about real patients, who seldom fit the textbook description of disease and differ from those included in research trials.<sup>8</sup> But others argued that evidence based medicine, if practised knowledgably and compassionately, could accommodate basic scientific principles, the subtleties of clinical judgment, and the

patient's clinical and personal idiosyncrasies.<sup>1</sup>

Two decades of enthusiasm and funding have produced numerous successes for evidence based medicine. An early example was the British Thoracic Society's 1990 asthma guidelines, developed through consensus but based on a combination of randomised trials and observational studies.<sup>9</sup> Subsequently, the use of personal care plans and step wise prescription of inhaled steroids for asthma increased,<sup>10</sup> and morbidity and mortality fell.<sup>11</sup> More recently, uptake of the UK National Institute for Health and Care Excellence guidelines for prevention of venous thromboembolism after surgery has produced significant reductions in thromboembolic complications.<sup>12</sup>

Despite these and many other successes, wide variation in implementing evidence based practice remains a problem. For example, the incidence of arthroscopic washout of the knee joint, whose benefits are unproved except when there is a known loose body, varies from 3 to 48 per 100 000 in England.<sup>13</sup> More fundamentally, many who support evidence based medicine in principle have

## Box 1 | Crisis in evidence based medicine?

- The evidence based “quality mark” has been misappropriated by vested interests
- The volume of evidence, especially clinical guidelines, has become unmanageable
- Statistically significant benefits may be marginal in clinical practice
- Inflexible rules and technology driven prompts may produce care that is management driven rather than patient centred
- Evidence based guidelines often map poorly to complex multimorbidity



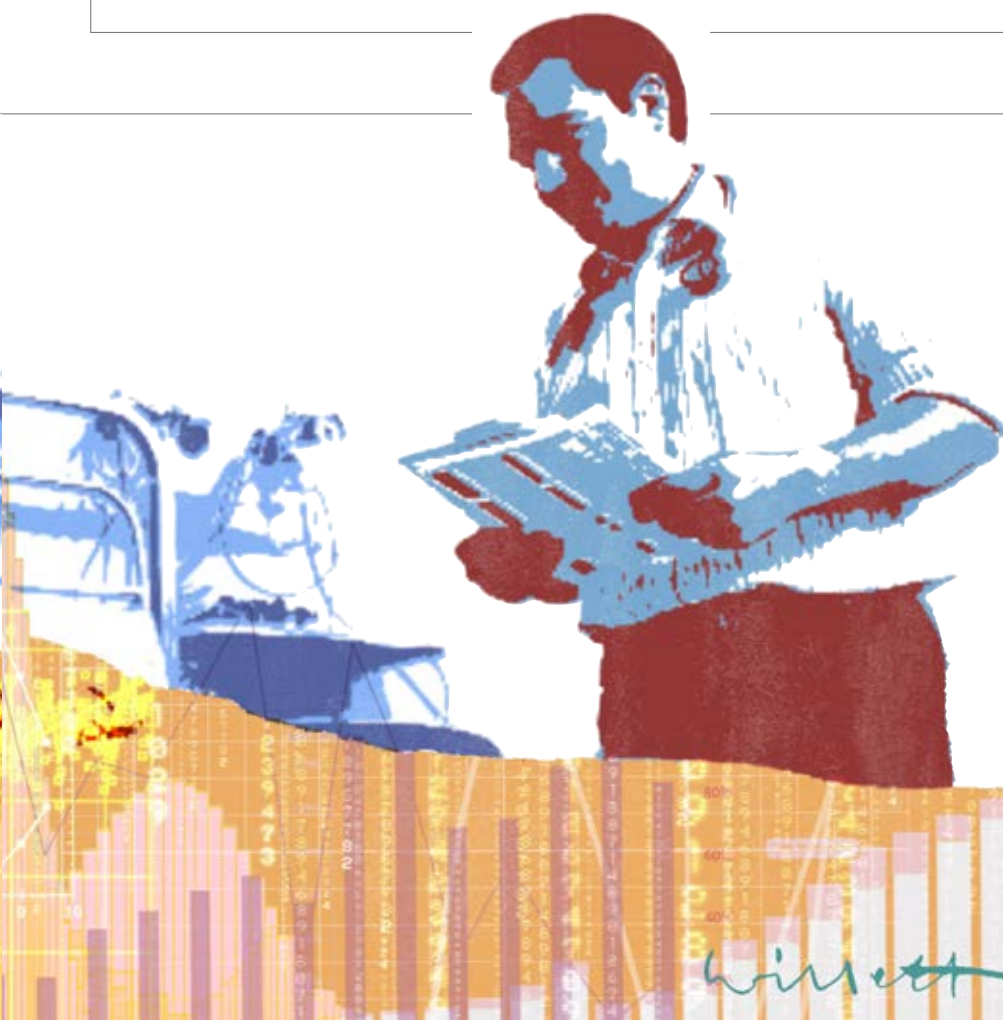
argued that the movement is now facing a serious crisis (box 1).<sup>14 15</sup> Below we set out the problems and suggest some solutions.

## Distortion of the evidence based brand

The first problem is that the evidence based “quality mark” has been misappropriated and distorted by vested interests. In particular, the drug and medical devices industries increasingly set the research agenda. They define what counts as disease (for example, female sexual arousal disorder, treatable with sildenafil,<sup>16</sup> and male baldness, treatable with finasteride<sup>17</sup>) and predisease “risk states” (such as low bone density, treatable with alendronate).<sup>18</sup> They also decide which tests and treatments will be compared in empirical studies and choose (often surrogate) outcome measures for establishing “efficacy.”<sup>19</sup>

## Too much evidence

The second aspect of evidence based medicine's crisis (and yet, ironically, also a measure of its success) is the sheer volume of evidence available. In particular, the number of clinical guidelines is now both unmanageable and unfathomable. One 2005 audit of a 24 hour medical take in an acute hospital, for example, included 18 patients with 44 diagnoses and identified 3679 pages of national guidelines



## Tools that contain quantitative estimates of risk and benefit . . . must be designed to support conversations not climb probability trees

check-up, serious non-diabetes related symptoms that the patient mentions in passing may not be documented or acted on.<sup>32</sup>

### Poor fit for multimorbidity

Finally, as the population ages and the prevalence of chronic degenerative diseases increases, the patient with a single condition that maps unproblematically to a single evidence based guideline is becoming a rarity. Even when primary studies were designed to include participants with multiple conditions, applying their findings to patients with particular comorbidities remains problematic.

### Return to real evidence based medicine

To address the above concerns, we believe it is time to launch a campaign for real evidence based medicine (box 2).

### Individualised for the patient

Real evidence based medicine has the care of individual patients as its top priority, asking, “what is the best course of action for this patient, in these circumstances, at this point in their illness or condition?”<sup>39</sup> It consciously and reflexively refuses to let process (doing tests, prescribing medicines) dominate outcomes (the agreed goal of management in an individual case). It engages with an ethical and existential agenda (how should we live? when should we accept death?) and with that goal in mind, carefully distinguishes between whether to investigate, treat, or screen and how to do so.<sup>40</sup>

To support such an approach, evidence must be individualised for the patient. This requires that research findings be expressed in ways that most people will understand (such as the number needed to treat, number needed to harm, and number needed to screen<sup>41</sup>) and that practitioners, together with their patients, are free to make appropriate care decisions that may not match what “best (average) evidence” seems to suggest.

Importantly, real shared decision making is not the same as taking the patient through a series of if-then decision options. Rather, it involves finding out what matters to the patient—what is at stake for them—and making judicious use of professional knowledge and status (to what extent, and in what ways, does this person want to be “empowered”?) and introducing research evidence in a way that informs a dialogue about what best to do,

### Box 2 | What is real evidence based medicine?

- Makes the ethical care of the patient its top priority
- Demands individualised evidence in a format that clinicians and patients can understand
- Is characterised by expert judgment rather than mechanical rule following
- Shares decisions with patients through meaningful conversations
- Builds on a strong clinician-patient relationship and the human aspects of care
- Applies these principles at community level for evidence based public health

(an estimated 122 hours of reading) relevant to their immediate care.<sup>27</sup>

### Marginal gains and a shift from disease to risk

Evidence based medicine is, increasingly, a science of marginal gains—since the low hanging fruit (interventions that promise big improvements) for many conditions were picked long ago.

Large trials designed to achieve marginal gains in a near saturated therapeutic field typically overestimate potential benefits (because trial samples are unrepresentative and, if the trial is overpowered, effects may be statistically but not clinically significant) and underestimate harms (because adverse events tend to be underdetected or underreported). The 74 year old who is put on a high dose statin because the clinician applies a fragment of a guideline uncritically and who,

as a result, develops muscle pains that interfere with her hobbies and ability to exercise, is a good example of the evidence based tail wagging the clinical dog. In such scenarios, the focus of clinical care shifts insidiously from the patient (this 74 year old woman) to the population subgroup (women aged 70 to 75) and from ends (what is the goal of investigation or treatment in this patient?) to means (how can we ensure that everyone in a defined denominator population is taking statins?).

### Overemphasis on following algorithmic rules

Well intentioned efforts to automate use of evidence through computerised decision support systems, structured templates, and point of care prompts can crowd out the local, individualised, and patient initiated elements of the clinical consultation.<sup>8</sup> For example, when a clinician is following a template driven diabetes

how, and why. This is a simple concept but by no means easy to deliver. Tools that contain quantitative estimates of risk and benefit are needed, but they must be designed to support conversations not climb probability trees.

**Judgment not rules**

Real evidence based medicine is not bound by rules. The Dreyfus brothers have described five levels of learning, beginning with the novice who learns the basic rules and applies them mechanically with no attention to context.<sup>42</sup>

In clinical diagnosis, for example, the novice clinician works methodically and slowly through a long and standardised history, exhaustive physical examination, and (often numerous) diagnostic tests.<sup>43</sup> The expert, in contrast, makes a rapid initial differential diagnosis through intuition, then uses a more selective history, examination, and set of tests to rule in or rule out particular possibilities. To equate “quality” in clinical care with strict adherence to guidelines or protocols, however robust these rules may be, is to overlook the evidence on the more sophisticated process of advanced expertise.

**Aligned with professional, relationship based care**

Real evidence based medicine builds (ideally) on a strong interpersonal relationship between patient and clinician. It values continuity of care and empathetic listening, especially for people who are seriously and incurably sick.<sup>44</sup> Research evidence may still be key to making the right decision—but it does not determine that decision. Clinicians may provide information, but they are also trained to make ethical and technical judgments, and they hold a socially recognised role to care, comfort, and bear witness to suffering.<sup>45</sup> The challenges of self management in severe chronic illness, for example, are not merely about making treatment choices but about the practical and emotional work of implementing those choices.<sup>46</sup> As serious illness is lived, evidence based guidelines may become irrelevant, absurd, or even harmful (most obviously, in terminal illness).

**Public health dimension**

Although we have focused on individual clinical care, there is also an important evidence base relating to population level interventions aimed at improving public health (such as pricing and labelling of consumables, fluoridation of water, and sex education).

**Box 3 | Campaigns aligned with real evidence based medicine**



*Too much medicine*—A rapidly growing movement, led jointly by clinicians, academics and patients, aims to reduce harm from overdiagnosis, overscreening, and overtreatment.<sup>26 33</sup> The second of what will hopefully be an annual “preventing overdiagnosis” conference will be held in Oxford in September 2014 ([www.preventingoverdiagnosis.net](http://www.preventingoverdiagnosis.net))



*All trials* ([www.alltrials.net](http://www.alltrials.net))—an international initiative to ensure that all clinical trials are registered at inception and no findings are withheld from publication

*Reducing waste and increasing value in medical research* ([www.thelancet.com/series/research](http://www.thelancet.com/series/research))—A recent *Lancet* series highlighting the waste and loss of value caused by research that addresses the wrong questions, uses inappropriate study designs; is weighed down by bureaucracy, or is so badly or inaccessibly reported that practitioners and policymakers simply cannot apply it

*Improving publishing standards* ([www.icmje.org/urm\\_main.html](http://www.icmje.org/urm_main.html))—A campaign by the International Committee of Medical Journal Editors to improve the quality and transparency of medical publishing by discouraging ghost-writing and raising the standards for declarations of conflicts of interest

*Integrated medical education*—Campaign to strengthen the integration of the different components of the curriculum by developing bedside clinical skills, understanding and applying research evidence, and reflecting and deliberating about complex cases<sup>58 69</sup>

These are often complex, multifaceted programmes with important ethical and practical dimensions, but the same principles apply as in clinical care. Success of interventions depends on local feasibility, acceptability, and fit with context—and hence on informed, shared decision making with and by local communities, using summaries and visualisations of population level metrics.<sup>47</sup>

**Delivering real evidence based medicine**

To deliver real evidence based medicine, the movement’s stakeholders must be proactive and persistent. Patients (for whose care the movement exists) must demand better evidence, better presented, better explained, and applied in a more personalised way with sensitivity to context and individual goals.<sup>48</sup> There are already some models of good practice here. In arthritis, for example, patient advocacy groups that emphasise the importance of experiential evidence and patient centred strategies have existed for over 30 years and have influenced the choice of outcome measures used in comparative effectiveness studies.<sup>49</sup> Patient input has refocused several NICE guidelines (for example, on psoriasis).<sup>50</sup>

Third sector advisory and advocacy groups such as the UK’s Consumer Association ([www.which.co.uk](http://www.which.co.uk)), Picker Institute ([www.pickereurope.org](http://www.pickereurope.org)), and Sense About Science ([www.senseaboutscience.org](http://www.senseaboutscience.org)) have a crucial role in educating citizens and contributing to public debate about the use and abuse of evidence. The James Lind Alliance ([www.lindalliance.org](http://www.lindalliance.org)) brings patients, carers, and clinicians together to prioritise research questions. Such groups must remain, as far as possible, independent of vested interests and aware of the distorting influence of tied funding.

**Training must be reoriented from rule following**

Critical appraisal skills—including basic numeracy, electronic database searching, and the ability systematically to ask questions of a research study—are prerequisites for competence in evidence based medicine.<sup>6</sup> But clinicians need to be able to apply them to real case examples.<sup>51</sup>

Too often, teaching resources use schematic, fictionalised vignettes in which the sick patient is reduced to narrative “factoids” that can populate a decision tree or a score sheet in an objective structured clinical examination. Rather than focus on these tidy textbook cases, once they have learnt some basic rules and gained some experience, students should be encouraged to try intuitive reasoning in the clinic and at the bedside, and then use formal evidence based methods to check, explain, and communicate diagnoses and decisions.<sup>43</sup> They must also be taught how to share both evidence and uncertainty with patients using appropriate decision aids<sup>52</sup> and adapt their

bmj.com

See our video resource on the history of evidence based medicine at [bmj.com/about-bmj/article-clusters/evidence](http://bmj.com/about-bmj/article-clusters/evidence)

approach to individual needs, circumstances, and preferences.<sup>39</sup>

Likewise, there is a strong argument for extending the continuing medical education curriculum beyond “evidence updates.” Peer observation and review, reflective case discussion in small groups (with input from patients who want to articulate their experiences, choices, and priorities) and ongoing conversations with fellow professionals can help hone and maintain the ability to manage the challenges of applying evidence based medicine in the real world.<sup>53</sup>

#### Evidence must be usable as well as robust

Another precondition for real evidence based medicine is that those who produce and summarise research evidence must attend more closely to the needs of those who might use it. Lengthy and expensive reviews that are “methodologically robust” but unusable in practice often fail to inform, inspire, or influence.<sup>55</sup> A recent systematic review of diabetes risk scores revealed that the authors of most studies were primarily concerned with the intellectual concept of improving the predictive value of the score but had given little or no thought to how their score might be used, by whom, or for what—nor what the implications would be for real people who would be designated “at risk” by the score.<sup>56</sup>

Evidence users include clinicians and patients of varying statistical literacy, many of whom have limited time or inclination for the small print.<sup>41</sup> Different approaches such as brief, plain language summaries for the non-expert (as offered by NICE), visualisations,<sup>57</sup> infographics,<sup>52</sup> option grids,<sup>58</sup> and other decision aids<sup>59</sup> should be routinely offered and widely used. Yet currently, only a fraction of the available evidence is presented in usable form, and few clinicians are aware that such usable shared decision aids exist.

#### Publishers must raise the bar

This raises an imperative for publishing standards. Just as journal editors shifted the expression of probability from potentially misleading P values to more meaningful confidence intervals by requiring them in publication standards,<sup>60</sup> so they should now raise the bar for authors to improve the usability of evidence, and especially to require that research findings are presented in a way that informs individualised conversations.

Given that real evidence based medicine is as

much about when to ignore or over-ride guidelines as how to follow them, those who write guidelines should flag up the need for judgment and informed, shared decision making. The American College of Cardiology recently published new cholesterol guidelines;<sup>61</sup> *JAMA* followed with a pragmatic, patient focused article on how to apply this guideline and when to consider ignoring it, including an online visualisation tool to support conversations with patients.<sup>62</sup> As the authors commented, “the target for performance measures is not the percentage of patients who . . . are prescribed statins, but the proportion of eligible patients who participate in shared decision making about statin use.”<sup>62</sup> Their approach deserves to be emulated widely.

#### Research must transcend conflicts of interest

To support real evidence based medicine, and in particular to reassure policy makers, clinicians, and the public that research and the guidance derived from it can be trusted,<sup>63</sup> the infrastructure for research and guideline development must show the highest standards of probity. Independent funding of national bodies for medical research is crucial.

#### Conclusion

Much progress has been made and lives have been saved through the systematic collation, synthesis, and application of high quality empirical evidence. However, evidence based medicine has not resolved the problems it set out to address (especially evidence biases and the hidden hand of vested interests), which have become subtler and harder to detect. Furthermore, contemporary healthcare’s complex economic, political, technological and commercial context has tended to steer the evidence based agenda towards populations, statistics, risk, and spurious certainty. Despite lip service to shared decision making, patients can be left confused and even tyrannised when their clinical management is inappropriately driven by algorithmic protocols, top-down directives and population targets.

Such problems have led some to argue for the rejection of evidence based medicine as a failed model. Instead we argue for a return to the movement’s founding principles—to individualise evidence and share decisions through meaningful conversations in the context of a humanistic and professional clinician-patient relationship (box 2). To deliver this agenda, evidence based medi-

cine’s many stakeholders—patients, clinicians, educators, producers and publishers of evidence, policy makers, research funders, and researchers from a range of academic disciplines—must work together. Many of the ideas in this paper are not new, and a number of cross sector campaigns with similar goals have already begun (box 3). We hope that our call for a campaign for real evidence based medicine will open up debate and invite readers to contribute (for example, by posting rapid responses on [bmj.com](http://bmj.com)).

**Trisha Greenhalgh** dean for research impact, Barts and the London School of Medicine and Dentistry, London E1 2AB, UK

**Jeremy Howick** senior research fellow, Centre for Evidence-Based Medicine, University of Oxford, Oxford OX2 6NW, UK

**Neal Maskrey** professor of evidence informed decision making, Keele University, Staffs ST5 5BG, UK

For the Evidence Based Medicine Renaissance Group

Correspondence to: T Greenhalgh  
[p.greenhalgh@qmul.ac.uk](mailto:p.greenhalgh@qmul.ac.uk)

We thank Ruth Davis and Sarah Hardy for administrative support. The workshop was funded by a National Institute for Health Research senior investigator award for TG and by the Oxford Centre for Evidence Based Medicine. We also thank Bernard Higgins for advice on sections of the manuscript and Michael Rawlins and *BMJ* editors for helpful comments.

**Contributors and sources:** Other members of the Evidence Based Medicine Renaissance Group are: Jon Brassey, Drui Burch, Martin Burton, Hasok Chang, Paul Glasziou, Iona Heath, Carl Heneghan, Michael P Kelly, Richard Lehman, Huw Llewelyn, Margaret McCartney, Ruairidh Milne, and Des Spence. This essay is partly the product of a workshop held at Kellogg College, Oxford, on 13-14 January 2014 and organised collaboratively by the Centre for Evidence Based Medicine, University of Oxford and the Centre for Primary Care and Public Health, Barts and the London School of Medicine and Dentistry. TG, in correspondence with CH, conceptualised the idea for a reappraisal and renaissance of evidence based medicine and developed the plan to hold a workshop to progress this idea. TG and JH facilitated the workshop. All authors attended the workshop and contributed to the development of key themes for the paper. TG wrote the first draft of the paper and refined it with important intellectual contribution from JH and NM. All authors provided some feedback on earlier drafts of the paper and approved the final manuscript.

**Competing interests:** NM and MK have senior roles in the National Institute for Health and Care Excellence; RM is employed by, and TG and JH’s salaries are part funded by, the National Institute for Health Research; MB is director of the UK Cochrane Centre. JB is a director and shareholder in the TRIP database, which offers a rapid search service. RL is a founder member, and TG a member, of the AllTrials campaign. IH is chairing the scientific committee for the preventing overdiagnosis conference in September 2014, and PG and HL have also been active in the preventing overdiagnosis campaign. RL is currently a consultant to the Yale Open Data Access project, which receives funding from Johnson and Johnson to develop methods to promote clinical trial data sharing; the project has also received funding from Medtronic.

**Provenance and peer review:** Not commissioned; externally peer reviewed.

This is an edited version of this essay. The full version, complete with references, is on [bmj.com](http://bmj.com).

Cite this as: *BMJ* 2014;348:g3725