

Evidence Based Medicine and Shared Decision Making: The challenge of getting both evidence and preferences into health care

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ABSTRACT

Evidence Based Medicine (EBM) and Shared Medical Decision Making (SDM) are changing the nature of health care decisions. It is broadly accepted that health care decisions require the integration of research evidence and individual preferences. These approaches are justified on both efficacy grounds (that evidence based practice and Shared Decision Making should lead to better health outcomes and may lead to a more cost-effective use of health care resources) and ethical grounds (patients' autonomy should be respected in health care). However, despite endorsement by physicians and consumers of these approaches, implementation remains limited in practice, particularly outside academic and tertiary health care centres. There are practical problems of implementation, which include training, access to research, and development of and access to tools to display evidence and support decision making. There may also be philosophical difficulties, and some have even suggested that the two approaches (evidence based practice and Shared Decision Making) are fundamentally incompatible. This paper looks at the achievements of EBM and SDM so far, the potential tensions between them, and how things might progress in the future.

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It is 15 years since the early papers outlining Evidence Based Medicine (EBM) were published [1,2]. Early proponents of EBM emphasized the “need to move beyond clinical experience and physiological principles to rigorous evaluations of the consequences of clinical actions” [2]. Participation in decision making by patients was largely ignored—it was all about research evidence. For example, in 1992 the requirements for practicing EBM were outlined as (i) critical appraisal (involving a precise definition of the patient's problem, and finding, appraising and applying the best available research evidence to it), (ii) sound understanding of pathophysiology and (iii) sensitivity to the patient's emotional needs [1].

While it is easy to be critical of this approach, we should not overlook the enormity of the change in practice advocated by Sackett et al. in the early days of EBM. Kuhn described advances in science as occurring in paradigm shifts [3] and EBM is justifiably described as one of those paradigm shifts. To illustrate I would like to retell a story that was told to me by Sir Iain Chalmers – one of the people who have worked so hard to make Archie Cochrane's vision a reality in the form of the Cochrane Collaboration. Chalmers told me how as a young doctor he bought a copy of Benjamin Spock's

famous book *Baby and Child Care*. Spock was an American paediatrician and his book, first published in 1954, has sold 50 million copies in 39 languages and has been described as one of the most influential books of the 20th century. The young Dr. Chalmers marked the passage that advised mothers to put their babies to sleep on their tummies, advice he duly passed on to his patients. The rationale given by Spock was that babies put to sleep on their tummies would be at lower risk of inhaling vomit and choking, should they happen to vomit in the night. However, by the 1970s and 1980s evidence was accumulating that this, untested theory, was lethally bad advice. We know now that around 50,000 cot deaths worldwide were caused because of it [4,5]. In fact it is much safer to sleep babies on their backs, a finding which completely reversed Spock's health care advice on the topic.

This story and others like it convinced many, including me, that the rationale for treatment had to change from biological theory and prediction to data from population studies. In case you think that's all history here is another, recent, example, to do with the treatment of acute head injury from trauma such as motor vehicle accidents. For many years doctors were taught that when there is trauma to the head, the brain swells and that can cause long term damage and death. So intravenous steroids are given to reduce the swelling. In the 1990s the UK MRC funded the CRASH trial to test whether this theory was a sound basis for treatment. The trial recruited about 10,000 patients – it was designed to recruit 20,000

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around the world but it had to be stopped early. When this trial reported in the *Lancet* in 2003 it showed an *increase* in the risk of death (3% higher in absolute terms and 18% higher in relative terms) in the group receiving steroids. Steroid infusion should have reduced death and disability, but the trial evidence showed convincingly that it did not [6]. An accompanying editorial estimated that this ill founded treatment killed about 2500 people worldwide each year for the 30 odd years during which it was in use – about 75,000 in total.

Both these examples illustrate the danger of assuming that treatments based on biological predictions will be beneficial. This is what makes EBM a paradigm shift; it focuses on empiric testing of *whether* a treatment works rather than relying on biological theories about *how* a treatment (might) work. So getting good quality evidence – by which I mean population studies, and preferably randomized trials, is essential for providing good quality health care. Indeed if you do not have the best evidence about the benefits and risks of the treatment options then the decisions that doctors and patients make – even if shared beautifully – will be flawed and patients may suffer. Therefore my argument is not only that EBM and SDM are compatible with each other but that EBM is an essential pre-requisite for SDM.

By the mid 1990s proponents of EBM had refined the concept and broadened it to recognize the importance of patients' values and preferences. From as early as 1996, Sackett et al. clearly presented the importance of integrating both evidence and patient's choices and preferences [7], although this was often lost amongst the heated arguments over basing clinical decisions on randomized trials, rather than on clinical experience.

The fundamental principles of EBM are now widely accepted. Nevertheless, there remains, however, an enormous implementation problem with EBM and it is still only patchily achieved in practice. For example, a study on the impact of guidelines from the National Institute of Clinical Excellence found the impact on prescribing practice and use of evidence-based interventions was variable [8], and research in the US reports that only about 50% of interventions that should have been used by physicians according to evidence-based guidelines were actually prescribed [9]. Grol and Grimshaw in their systematic review of strategies to increase evidence based practice reported a similarly bleak situation in Europe [10]. Straus and Jones argues the greatest challenge now is to find ways to change clinical behaviour so that evidence is actually used by clinicians in their practice '.

Let me turn now to Shared Decision Making. SDM is a move towards seeing the patient as having a central role in decision making about their own clinical care. The aim is to empower patients to express their values and preferences, to ask questions and to participate actively in decisions about their health care [12]. According to Charles et al. definition [13], Shared Decision Making includes these essential elements: (i) there is a two way exchange of information between patient and doctor including medical and personal information, (ii) the possible options and outcomes are discussed and deliberated, and (iii) together the patient and doctor arrive at a consensus about what to do.

The rationale for SDM is different from the rationale for EBM, and is based on at least two grounds. Firstly there is now very substantial evidence, collected over the last three decades, that many patients want more information from their doctors and may also want to participate in health care decisions that affect them and their families [12,14]. Secondly, SDM is based on the ethical principle of patient autonomy [15]. On both these grounds it is argued that patients should be able to participate in health care decisions. It is not to say that patients must or even should participate in clinical decision making, but that they should be able to if they so choose. There is little evidence yet that SDM improves

long term health outcomes, although increased patient participation (for example, through the use of decision aids or question prompt lists) does increase knowledge, and can reduce consultation time [16,17]. Like EBM, SDM is also a fundamental change to practice.

In summary I have argued that EBM and SDM are two of the most important paradigm shifts in medicine for a long time, maybe ever. The last decade has seen both EBM and SDM accepted in principle – and that in itself is a major change, and a splendid achievement. Nothing that I say from here is intended to diminish the magnitude of these very significant achievements.

As I noted earlier there are major problems with implementation on the ground. So, although EBM is widely accepted in *principle*, there is still much to do to get it happening widely in *practice*. Concerns about the limited use of evidence in practice are still often expressed in terms of the limited proportions of patients who receive particular interventions. However, an assessment of whether the receipt of a particular health care intervention by a particular patient is appropriate should also be informed by awareness of that individual patient's personal preferences. To accomplish this requires communication about evidence, incorporation of patient values (which have been shown to differ widely from those of doctors) and a process of involving patients in health care decisions [11,18,19]. There are very few data but what information is available suggests that this is not well achieved in practice.

A number of ways to assess the level of patient involvement have been developed, a leading one being the OPTION Scale. In work with GPs in the UK, Elwyn et al. found that in GP consultations patient involvement was low. On some items of the scale it was spectacularly low – with, for example, no or only minimal behaviours in the following areas: checking patients have understood information, asking patients about their preferred level of involvement; outlining available options and giving information about pros and cons of those options [20,21]. Loh et al. reported low levels of involvement using the OPTION scale with German patients being treated for depression [22]. Although endorsed in principle, efforts at promoting SDM by governments and health authorities have been described as floundering – Coulter suggests because they have tended to focus on including consumer representatives on policy committees and getting consumer input into guidelines and consultative processes, rather than on increasing patient participation in individual health care decisions [23].

So what is going wrong? Is anything going wrong? Are EBM and SDM supporting or hindering each other?

Firstly, I think that whenever you have major change in a profession there is resistance. So it should not be a surprise that both EBM and SDM have been, and continue to be, quite strongly resisted. This is one of the things they have in common. In fact reported objections to EBM [24] have much in common with objections made to SDM, for example, its unrealistic (ivory tower ideal), its too time consuming, appropriate resources are not available and so on. Perhaps this reflects some of the similarities between them in terms of the challenge they present to traditional practice.

Secondly, the heart of both EBM and SDM is the clinical consultation. In EBM it is called STEP 4. In EBM parlance, the steps are to firstly develop a searchable focused clinical question (STEP 1), then search the evidence (STEP 2), find and appraise the best evidence (STEP 3) [24]. Implementation of EBM has so far concentrated on STEPS 1, 2 and 3. STEP 4 is the toughest – bringing it all together to make a decision. This is really the bit that Charles et al look at too, and it is the core of their analysis of clinical decision making models [19]. Integrating the evidence with

Combining evidence and patient preferences

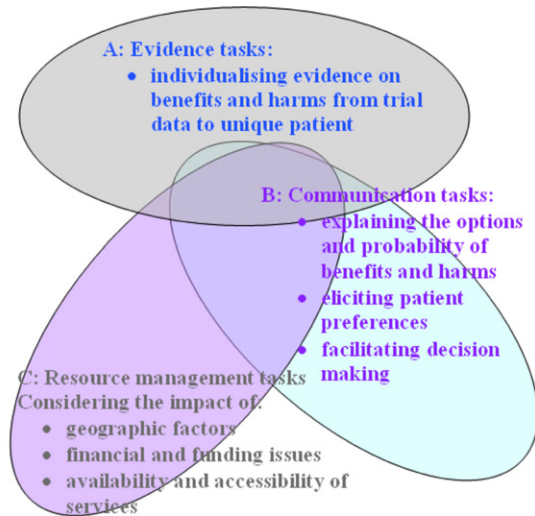


Fig. 1. A schematic representation of EBM Step 4: Applying evidence.

patient preferences has been a recognized important component of EBP for at least 5 years [25]. Yet accomplishing STEP 4 is described as the biggest single remaining barrier to the implementation of EBM [11]. So what is in STEP 4? We have been thinking about this and we think there are three components (Fig. 1).

First there is the clinical epidemiology component. STEP 4 requires the evidence based doctor to individualise the treatment benefit and side effects for a patient, according to their risk profile. This means taking data from a population in a trial and applying the results for both the benefits and the side effects to an individual patient who may be a different age or have a different degree of risk compared to the people in the trial.

To give you an example let me introduce Paola and Aditi (Figs. 2 and 3).

These women were born, at the age of 69, about 6 years ago as part of my efforts to teach EBM to our medical students, and this example has since been published in the EBM teaching tips series [26]. Paola is 69 years old; she has mild hypertension and no history of stroke. Aditi is the same age, with higher blood pressure and has already suffered a stroke; her risk of a stroke is higher than Paola's. I estimated Paola's stroke risk at 3% and Aditi's at 30% over the next 3 years. Both of them may be treated by drug X – data from



69 years, high blood pressure, no history of stroke



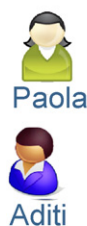
69 years, higher blood pressure, history of stroke already

Fig. 2. Introducing Paola and Aditi.

randomized trials shows that drug X lowers the risk of stroke by about a third. So if she takes drug X, Paola's risk of stroke will be about 2% and Aditi's will be about 20% – both one third lower than they would be without drug X. There is a much bigger absolute benefit for Aditi (10%) because her risk of stroke is much higher. Drug X also has side effects of course, and one of these is severe gastric bleeding. The risk of this is about 0.3% for both women without any treatment. Taking drug X triples this risk, to about 0.9% for both women. So for Paola the benefit – about a 1% reduction in stroke risk is about twice the increase in gastric bleeding risk. For Aditi the stroke benefit is much bigger than the gastric bleeding risk. So its likely they may make different decisions about taking drug X, simply based on the benefits to harm tradeoff which is different because of their different risks. That is without considering their preferences for the different possible outcomes. The point is that the doctor has this task – of individualizing the benefit harm trade off depending on the patient's risk.

Can doctors do this? This goes to the heart of whether EBM and SDM will be compatible allies or not. While currently many doctors will rely on guidelines to provide evidence based guidance, in time it should be possible for doctors trained from the beginning of their professional lives in EBM, to undertake the sort of analysis presented above.

The second other task of STEP 4 is to communicate the individualized evidence to the patient, to seek the patient's views and preferences on the options and to facilitate a deliberative decision making process. To communicate the evidence well, the sort of data I showed earlier, for Paola or Aditi, should be shown to the patient so that the benefits and harms of each option are clear. The data should be shown as event rates for each option (in EBM lingo), or as natural frequencies (in risk communication lingo). Then the patient's preferences need to be discussed, considered and integrated. So if STEP 4 is done well then both EBM and SDM can be achieved.



Benefit and Harm table				
	Event rate for stroke over 3 years		Event rate for severe gastric bleeding over 3 years	
	No treatment	With treatment (Drug X)	No treatment	With treatment (Drug X)
At lower risk	3 per 100	2 per 100	0.3 per 100	0.9 per 100
At higher risk	30 per 100	20 per 100	0.3 per 100	0.9 per 100

*Based on data from randomized controlled trials of drug X reporting a 33% relative risk reduction for the outcome (stroke) over 3 years and 3 fold increase for the adverse effect (severe gastric bleeding) over the same period.

Fig. 3. Estimated benefit and harm of treatment for Paola and Aditi.

But as has been acknowledged before, there is potential for conflict between EBM and SDM – if EBM is implemented poorly. I think that the risk of conflict comes from two main quarters, and both are strategies that are being used to encourage, or bludgeon might be a better word, doctors to implement evidence based practice.

The first of these is guidelines. Well developed guidelines should be evidence based, in the sense of being based on the latest best quality evidence. (Incidentally, unfortunately this is not always the case, as demonstrated recently by Oxman et al. [27].) However, they are not usually evidence based if one defines evidence based to include the integration of patient values and preferences. Guidelines are rarely that flexible. Nevertheless many doctors will not develop the skills to apply evidence as I have outlined above AND integrate patient values and preferences within their professional lifetimes. For these doctors, guidelines are a relatively quick and simple means of increasing the quality of care patients receive.

A problem arises if we require doctors to implement guidelines, without individualizing evidence and without incorporating patient preferences. Then EBM and SDM can and will be in conflict. I think it is really important therefore that future doctors are trained to individualise treatment to patients – because that is necessary for doing a good job of both EBM and SDM. Evidence based guidelines are useful, and they can be excellent sources of evidence for treatment decisions, and many doctors and patients will be happy to follow them. But we should not have a view that good practice REQUIRES doctors – and patients – to follow or comply with guidelines. Otherwise we could have doctors who practice superb EBM and SDM arriving at an evidence based, shared decision with their patients and yet be perceived by health authorities, lawyers, juries and maybe the patient's family as providing care which does not meet accepted standards because it does not comply with guidelines.

Thus successful implementation of EBM should not just be measured as the proportion of treatment decisions that comply with guidelines. Doctors should not be required to comply with them in order to comply with professional standards. Rather doctors should be able to demonstrate they can practice EBM to comply with professional standards. A correspondent of mine has suggested a register of EBM accredited doctors. I think this a wonderful idea – one that government could and should take the lead on.

The second threat that may bring EBM and SDM into conflict is the tendency of governments to introduce incentives for doctors to reach certain practice targets. In Australia in general practice its called PIP – practice incentive program payments. There are similar initiatives in other countries. For example, in Australia, family doctors can receive these incentive payments for taking a cervical smear from an unscreened or underscreened woman, for completion of an annual cycle of care for patients with diabetes, and for completing an asthma plan. The aim is to try to improve quality of care, a laudable aim but one which potentially conflicts with patients' rights to be involved in their care and to make choices which may or may not comply with what is set down as the standard of care. This is potentially not in the interest of patients who may be coerced into complying with management plans that they do not wish to follow. I think we need to resist efforts to build in practice incentives which conflict with patient choice, and rather reward doctors who have demonstrated SDM competencies.

So to the way forward. What can we do to promote EBM and SDM? I have a list of three things (although I am sure there are others):

- (1) better evidence and better sources of evidence;
- (2) consumer power;
- (3) better tools.

- (1) We need to prioritise funding for trials which answer patients' questions, which may not be the questions of big pharma, or of academics. Consumer representation on funding committees which review research grant applications is one way forward on this, as are efforts such as the James Lind Alliance (<http://www.lindalliance.org>). We also need to support access to better sources of evidence for doctors and patients. This should include easy access to the Cochrane Library and clinical trial registers, for example, <http://www.isrctn.org> and <http://www.clinicaltrials.gov>.
- (2) *Consumer power*: Coulter has already noted that more than getting consumers onto committees needs to be done. The action needs to be at the point of decision making, and for many health care decisions that will mean in the consultation room, not in a committee room. Karen Carey Hazell is an experienced consumer advocate. She is a member of the Consumers Health Forum, the peak Australian health consumers' organization. Karen's view is that patients asking questions may be a powerful way to start breaking down doctors' resistance to EBM. As she says doctors will have to know the evidence to answer. It will be confronting to some doctors, but on the other hand, doctors like to do what their patients want so it may well encourage a more evidence based approach to care. Some patients may feel uncomfortable asking questions and potentially challenging doctors who they perceive as more knowledgeable and perhaps more powerful. A number of people have contacted me to say that it is unfair to put this responsibility onto consumers; they would not feel able to do it. I can understand their concern, however, social norms – such as the behaviour of both patients and doctors can change. If you are doubtful of this, we only need to think of the momentous social changes that took place last century. A century ago, in 1906, Finland was the first country in Europe to give women the right to vote (Germany 1918, UK 1928, France 1944 and Switzerland 1971), gay rights did not exist and discrimination on the grounds of skin colour was legal. If these and so many other social norms can change, surely the attitudes and behaviours of doctors and patients can change too.

We also have to move towards a different model of consultations, in which patients do their homework or preparation, including working out their questions, in advance of the consultation. There is some evidence that this approach can reduce consultation time [17]. Nevertheless, if governments are serious about endorsing EBM and SDM, which they claim to be, will need to seriously look at reimbursement arrangements that allow for at least some longer consultations in which evidence and patient preferences can be discussed. This may reduce the number of future consultations and potentially may improve compliance.

- (3) *Tools*: As researchers and developers of decision support tools we can ensure we have the tools that doctors and patients need. Specifically we need tools that (i) provide doctors with the data they need to answer patients evidence based questions, and (ii) help them elicit and integrate patient preferences. So we need to develop and evaluate a range of tools that provide quantitative best evidence for a wide range of clinical decisions – all the important ones really – and design and develop attractive, easy to understand tools to display that evidence. That requires both evidence from good quality trials and baseline risk data for the local population (Fig. 4).

Here is an example of one decision aid we have made on Hormone Replacement Therapy (HRT) – showing the event rates

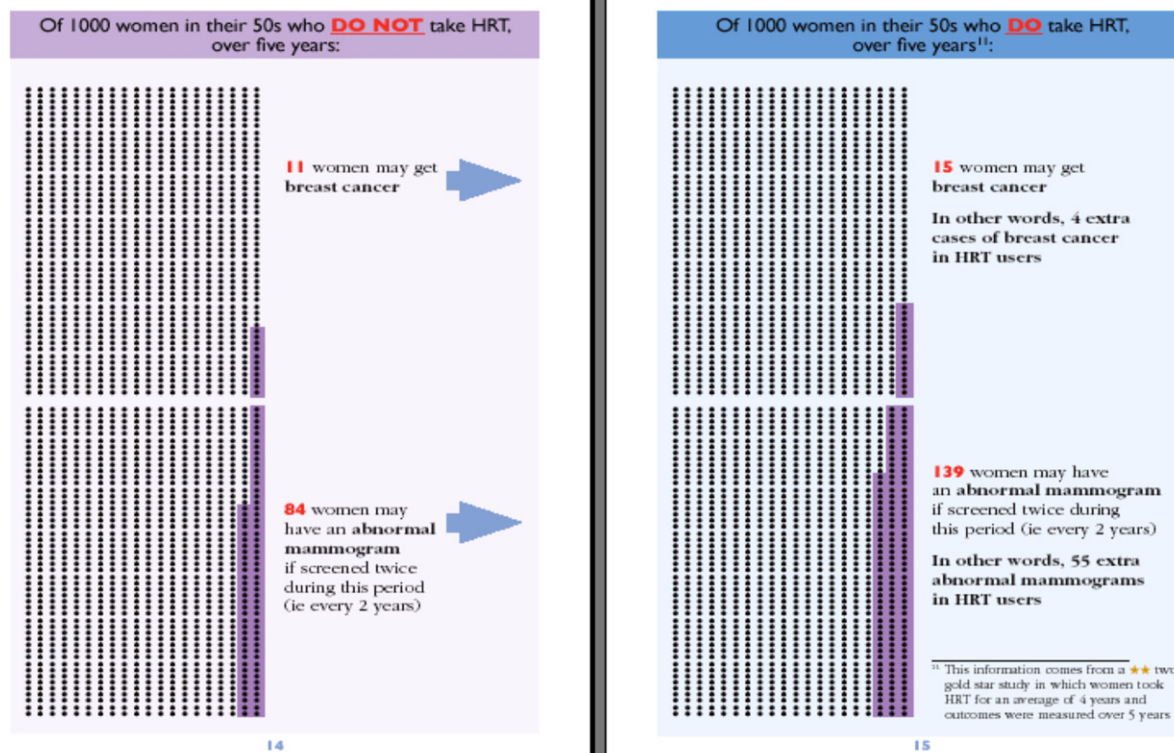


Fig. 4. Extract from a decision aid, Making Decisions: Should I use Hormone Replacement Therapy.

for breast cancer and for having an abnormal mammogram, both per 1000 women over 5 years (full decision aid available http://www.health.usyd.edu.au/shdg/resources/decision_aids.php or <http://www.nhmrc.gov.au/publications/synopses/wh35syn.htm>). On the left you see the event rates without HRT and on the right with HRT. To get these probabilities we needed the relative risks from the Women's Health Initiative trial, and the age specific baseline risks for Australian women. It was not a trivial task, but it was one that was well worth doing and the tool is very popular with clinicians and patients. Increasingly more sophisticated tools than this – that individualise risks based on good quality trial evidence PLUS local baseline risk data – will be developed. Making them interactive – so patients can enter their own risk data, and available on line will be essential.

We also need to develop tools that help elicit and integrate patients' preferences into the decision. Some consumers will want to use intuitive means, such as decision aids, to integrate evidence and preferences. Methods like weigh scales, intuitively rather than mathematically combine probabilities and utilities. Other patients are more analytic and will want something closer to decision analysis – in other words, computer software that calculates the best option based on weighting probabilities with their personal utilities. Jack Dowie's Anna Lisa package (<http://www.annalisa.org.uk/>) does this without being as demanding as full decision analysis and can be adapted to any decision.

In short, I think it is critical that we are innovative and wide ranging in the ways we explore to help implement EBM and SDM. There will not be a single solution and there is no magic bullet. Rather it will require a multitude of solutions for diverse patients and doctors operating in range of contexts and health services. It will require substantial change to practice to achieve the widespread implementation of EBM and SDM – but we have already seen substantial changes in medicine in the last decade. It will be

exciting to observe the achievements of both these fields, separately and together, in the next decade.

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Conflict of interest

I have no conflict of interest to declare.

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