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Science and proven experience: a Swedish variety of evidence-based medicine and a way to better risk analysis?

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ABSTRACT

A key question for evidence-based medicine (EBM) is how best to model the way in which EBM should 'integrate' individual clinical expertise and the best external evidence'. We argue that the formulations and models available in the literature today are modest variations on a common theme and face very similar problems when it comes to risk analysis, which is here understood as a decision procedure comprising a factual assessment of risk, the risk assessment, and the decision what to do based on this assessment, the risk management. Both the early and updated models of evidence-based clinical decisions presented in the writings of Haynes, Devereaux and Guyatt assume that EBM consists of, among other things, evidence from clinical research together with information about patients' values and clinical expertise. On this *A-view*, EBM describes all that goes on in a specific justifiable medical decision. There is, however, an alternative interpretation of EBM, the *B-view*, in which EBM describes just one component of the decision situation (a component usually based on evidence from clinical research) and in which, together with other types of evidence, EBM leads to a justifiable clinical decision but does not describe the decision itself. This *B-view* is inspired by a 100-years older version of EBM, a Swedish standard requiring medical decision-making, professional risk-taking and practice to be in accordance with 'science and proven experience' (VBE). In the paper, we outline how the Swedish concept leads to an improved understanding of the way in which scientific evidence and clinical experience *can* and *cannot* be integrated in light of EBM. How scientific evidence and clinical experience is integrated influences both the way we do risk assessment and risk management. In addition, the paper sketches the as yet unexplored historical background to VBE and EBM.

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1. Introduction

EBM is actually only a reformulation of the motto 'science and proven experience.' (Werkö et al. 2002, 3478, our translation)

Globally, evidence-based medicine (EBM) is favoured in the public sector. EBM is often concerned with risk assessment and risk management. Consider a 77-year-old woman who is admitted with

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non-rheumatic atrial fibrillation and her first bout of mild left ventricular failure; 'What is the risk reduction for stroke from warfarin therapy in such a patient, and what is the risk of harming her with this therapy?', asks Rosenberg and Donald (1995) and presents EBM in four steps:

- Formulate a clear clinical question from a patient's problem
- Search the literature for relevant clinical articles
- Evaluate (critically appraise) the evidence for its validity and usefulness
- Implement useful findings in clinical practice

In Sweden a bipartite, partly overlapping standard that is more than 100 years older than EBM applies in the public sector and parts of the private sector as well. This Swedish standard requires decision-making and practice to be based on both science and proven experience, or *vetenskap och beprövad erfarenhet* (VBE), and indeed leading Swedish physicians often think of EBM as a reformulation of the Swedish standard. Lars Werkö, 'the icon beyond all comparison in Swedish health care' (Hont 2009) is a clear example (e.g. see Werkö et al. (2002) above). Since its first legal application in Swedish health care in the late 1800s, the VBE standard has been pressed into service in law and public policy in areas as diverse as medicine and health care, education, environmental risk assessment, veterinary care and social work. We shall primarily focus on the application of VBE in medicine. To be strict we should thus be talking about VBE-M. However, in order not to complicate matters unnecessarily we shall in this paper assume that what is true of VBE in medicine is true of VBE in general.

Swedish health law explicitly requires that health care is provided in accordance with VBE. The preparatory works have justified the requirement by stressing the important role that VBE plays in reducing patient risks (Prop. 2009/10:210, 191). Furthermore, legal scholars have pointed out that the VBE requirement itself implies a risk-benefit assessment (cf. Rynning 1994, 138; Wahlberg and Sahlin 2017).

The Swedish concept of VBE helps us to understand the ways in which scientific evidence and clinical experience both *can* and *cannot* be integrated within EBM, and thus the extent to which EBM can be used to understand and reduce risks. The similarities and dissimilarities between VBE and EBM shed light on the capacity of EBM to '[integrate] individual clinical expertise and the best external evidence' (Sackett et al. 1996). This most influential and elusive ambition of EBM (Sackett et al. 1996) is the primary focus of the current paper. In addition, however, VBE helps to bring out the historical background to EBM.

2. EBM and VBE: similarities and dissimilarities

Prima facie it makes sense to compare EBM and VBE. (1) Both introduce evidentiary standards for decision-making (not a standard for science as such). (2) Each promotes the goal of making more use of science and sound evidence in practical decision-making. But (3) the two approaches diverge, on the surface at least, when it comes to the types of evidence that should be allowed to influence practical decision-making and play a role in risk assessment.

(1) EBM highlights the decision-making context. It is primarily about the professions and the connection between the academic disciplines and the professions; only by implication is it about the disciplines themselves. Several of the leading articles on EBM were published in the *British Medical Journal*, which has the slogan: *helping doctors make better decisions*. Rosenberg's and Donald's well-known 1995 *BMJ* paper is entitled 'Evidence based medicine: an approach to clinical problem-solving'.

Similarly, in Swedish law VBE is the gold standard for decision-making and practice, especially in health care. For example, VBE states that medical practice must be based on science and proven experience. Health care workers who do *not* provide care in accordance with VBE can be criticized by the Health and Social Care Inspectorate and even be held responsible according to penal law. VBE also helps to define patients' rights to reimbursement for expenses associated with treatments in other European countries. The legislative use of science and proven experience illustrates that the notion is intended for policy-making, practical decision-making and reducing risks.

(2) To a large extent EBM focuses on the need to make more, and better, use of research findings in clinical decision-making:

Evidence based medicine is the process of systematically finding, appraising, and using contemporaneous research findings as the basis for clinical decisions. For decades people have been aware of the gaps between research evidence and clinical practice, and the consequences in terms of expensive, ineffective, or even harmful decision making. Inexpensive electronic databases and widespread computer literacy now give doctors access to enormous amounts of data. Evidence based medicine is about asking questions, finding and appraising the relevant data, and harnessing that information for everyday clinical practice. (Rosenberg and Donald 1995)

The focus, claims (Eddy 2005, 14), 'is on educating physicians to help them bring more research and evidence into their individual decisions about individual patients.' The same goes for VBE, but there are differences. EBM is primarily about decision-making. VBE is primarily about patient security and avoiding unnecessary risk-taking.

Before we proceed, it should be noted that, in health care at least, the Swedish notion is not explicitly defined in any official documents. One will search in vain for suitable stipulations to guide applications of the laws in which the expression occurs. Hence its characteristics have to be inferred from its intended purpose and many applications, i.e. its use and history. We will therefore present a sketch of the history of VBE (and to a lesser extent EBM).

It was probably no accident that the Swedish concept emerged in health care regulations in the late 1800s. The concept itself is, at least, somewhat older; almost exactly the same formulation occurs in the oath that were taken by those who were awarded the licentiate degree in medicine in Uppsala, Lund, and Stockholm from 1829 and onwards (SFS 1829:12, see also Kock 1939). It is sometimes argued that the mid-1800s were dominated by lack of confidence in the therapeutic methods available in Sweden and elsewhere. Scholarly work referring to this period uses terms such as 'doubt disease' (Fåhræus 1950, 98), 'therapeutic nihilism' (Danek 1969, 65), 'the bankruptcy of therapy', and 'crisis in medical self-confidence' (Stolt 1994, Chapters 4 and 5). Mid-1800s advances in basic medical science did not reach practitioners and were generally of little therapeutic consequence (Porter 1995), and this was especially so, perhaps, for the typical Swedish countryside doctor:

Practitioners in the countryside used trial and error, and as late as 1850 they had little use of medical science in their everyday practice. (Stolt 1994, 159, our translation)

Trust in medicine as taught by the universities decreased. Quackery had been an alternative for long in Sweden, and it is reported that in the nineteenth century it was equally natural to seek help from a 'wise woman' as it is to visit the doctor today (Ling 2004, 21). The period is referred to by Swedish scholars ironically as 'the golden era of public distrust and humbug medicine' (Fåhræus 1950, 102).

Whatever the connection might have been medical science advanced rapidly during the second half of the 1800s: from Louis Pasteur's 1859 suggestion that micro-organisms may cause many human and animal diseases, Joseph Lister's 1867 publication 'On the Antiseptic Principle in the Practice of Surgery', showing that disinfection reduces post-operative infections, to Robert Koch's 1882–1883 isolations of the micro-organism responsible for tuberculosis and cholera. In short, the decades before the Swedish regulation was put in place involved several breakthroughs in medical science; it was a time when medical science, finally, advanced to a position from which it could actually prove useful to medical practice. It is indeed interesting that those who explain the emergence of EBM also refer to medical breakthroughs in the late 1800s: 'The 100-year period between 1885 and 1985 brought amazing medical breakthroughs' (Howick 2011, 11).

It makes sense to ponder what happened in Finland during this period. For centuries – until 1809 – Finland and Sweden were joined. Considerable overlap with regard to the requirement of science and proven experience between the two countries would come as no surprise. The Medical Society of Finland (*Finska läkaresällskapet*) was founded in 1835 with the dual purpose of developing medical science and health care. It was followed by The Finnish Medical Society (*Duodecim*) in 1881, which aimed to develop medical science and practice in Finland.¹ Nowadays, the overwhelming majority of Finnish physicians who are members of The Finnish Medical Association (*Lääkäriliitto*), founded in 1910, are committed to treating patients in accordance with science and proven experience through the code of

medical ethics approved by the association's delegate committee (Läkäriliitto 2014). Moreover, it is a legal requirement in Finland since 1994 that all health care personnel should only apply methods that there is proven experience of (since 2000 the same requirement holds for those in veterinary care).² Much of the development leading to the current role of VBE in Finland has happened after 1809. Thus, the overlap is not a mere historical artefact. So what we refer to as the Swedish concept has a perfect match in Finland, although it is much more widespread in its Swedish applications. The motivation behind the requirement in Finland is arguably the same as in Sweden since the two countries had so much in common during the concept's pre-history. Ideas similar to VBE occur in eighteenth-century writings by, for instance, the father of paediatrics in Sweden, Nils Rosén; moreover, a predecessor from 1733 resembles in some respects the 1829 oath we have referred to above (e.g. Eklöf 2000).

In fact, one could claim that VBE is a Nordic concept rather than exclusively Swedish. For instance, since 1998 psychologists in the Nordic countries are committed to VBE through *Yrkesetiska principer för psykologer i Norden* (Sveriges Psykologförbund 1998, 6)

Certainly, it was not only in the Nordic countries that it was acknowledged, around 1890, that medical science ought to guide medical decision-making. Failure to consider medical science in the medical profession was criticized in *The Boston Medical and Surgical Journal* too:

... medical art without science is not only unprogressive, but almost inevitably becomes quackery. As soon as we treat our patients by rule of thumb, by tradition, by dogmas, or by metaphysical axioms, we do injury to ourselves as well as to them. (Pye-Smith 1900, 173)

Still, if we (simplistically) compare occurrences of the expression 'science' (*vetenskap*) with occurrences of the expression 'experience' (*erfarenhet*) in sources such as *The Transactions of The Medical Society of Finland (Finska läkaresällskapets handlingar)* in the latter half of the 1800s we immediately find that, whereas quite a few reports contain the word 'experience', there is less mention of 'science'. Hence it is understandable that further measures, such as the requirement of VBE, were put in place to ensure that doctors made more use of science in practice.

There is arguably a similar story to be told about the emergence of EBM exactly 100 years later. Here both Guyatt and Sackett report on the need to be sceptical vis-à-vis received medical wisdom (Howick 2011, chapter 2).

(3) However, it seems that experience of a specific kind – *proven* experience – was also identified as important as a result of the arrival of VBE. Somewhat paradoxically, it seems that the development of relevant scientific evidence was accompanied by a corresponding development (or upgrading, or rating-up) in the role of evidence of a certain kind from experience as well. This is the third relevant comparison point between EBM and VBE. Looking at the recent introduction of science and proven experience in the Swedish Education Act (2010:800), we can see that Swedish schools and education authorities have developed a growing interest in proven experience. In particular, these discussions highlight the evidential relevance of experience within the professional collective. A third comparison between EBM and VBE can therefore be based on the way they deal with the relationship between two different types of evidence: evidence that is 'scientific' and evidence that is 'experienced based'.

Whether the prominence of proven experience is to be counted as a similarity between EBM and VBE depends on whether EBM and VBE have the same effect of rating up experience of the proven kind. We are ready to argue that they do, but this assessment depends on an assumption few advocates of EBM endorse. The assumption is that there is no strong link between EBM and science – or rather that the link, such as it is, is no stronger than that connecting EBM and proven experience. For a related observation, see Stoyanov, Machamer, and Shaffner (2012, 150). In other words, the scientific classification here is not straightforwardly guaranteed by the use of certain methods or methodologies recommended by EBM such as, for example, randomized controlled trials (RCT). Much of what is regarded as being at the core of EBM could then equally well be classified as proven experience. To the extent that this assumption is accepted there is reason to think that EBM would simply prioritize experience of a certain kind. Advocates of EBM might be dissatisfied with that implication because they wish to preserve the link between basic science and clinical research:

Evidence-based medicine focuses on these systematic studies simply because they represent the most advanced stages of testing to ascertain whether the innovations of basic science work, how well they work, and for whom they work when applied in the clinical setting. Thus, evidence-based medicine is not in competition with basic science; rather it depends on it and builds on it. (Haynes et al. 1996, 196–97)

A clear dissimilarity – no matter how EBM is construed with respect to science and proven experience – would be that EBM *downgrades* certain kinds of science, such as science that is not based on RCTs (e.g. cohort studies), but this is not the case with VBE, at least not explicitly. In the next section, we will look more closely at the way EBM and VBE handle the notion of evidence.

A further dissimilarity between EBM and VBE can be detected. The meaning of VBE varies with context among medical practitioners. (Persson and Wahlberg 2015) reports that the BE (or proven experience) component is sometimes taken to report a property of doctors and sometimes used to refer to a fact about how seriously a therapy has been tested in practice. By contrast, EBM seems fixed. Indeed, if it were not fixed, it would be difficult to understand the need for instruments such as the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework. GRADE is a framework for synthesizing and rating the quality of evidence, and for providing clinical practice guidelines addressing alternative management options. It is used by many important actors in health care all over the world, including WHO and the Cochrane Collaboration.

To the extent that EBM introduced a new paradigm – see, for instance, Evidence-Based Medicine Working Group (EBMWG 1992) – it ought to follow that something of fundamental importance remains fixed through various applications of EBM. The primary candidate for this static role is the EBM position on evidence (see next section, and Howick 2011, 4).

3. EBM and VBE: the question of evidence

There is a clear sense in which medicine must always be based on some kind of evidence. If evidence is merely a ground for belief, there will not be anything new about EBM. The ‘evidence’ in EBM, and in the ‘science/vetenskap’ (V) and ‘proven experience/beprovdad erfarenhet’ (BE) of VBE, is all about what medical practitioners, or policy-makers, can *justifiably* base their decisions and risk analyses on.

EBM is a procedure, or approach, that ensures, or perhaps maximizes, justifiable decisions. However, as we will argue, it is far from clear that it is a good risk analysis approach. VBE, as it stands, is a criterion for evaluating whether a decision or risk analysis is warrantable. This does not entail that VBE is only put to use *post hoc*. VBE – even its BE-component – can be used prospectively, too, as can be seen from the discussions in the *Journal of the Swedish Medical Association* cited in Persson and Wahlberg (2015) and in the oath taken by Finnish physicians – which requires that one to tries to advance proven experience in one’s field.

So, what is this evidence that makes EBM different from medicine practised before 1990? There are two suggestions, both present in the prehistory of EBM. Archie Cochrane wrote in 1972:

It is surely a great criticism of our profession that we have not organised a critical summary, by specialty or sub-specialty, adapted periodically, of all relevant randomised controlled trials. (quoted from Sønbø Kristiansen and Mooney (2004, 2))

The first suggestion is that EBM builds on the principle that all relevant evidence should be taken into account.

The second is that EBM builds on an idea of levels of evidence which not only identifies but also ranks the relevant kinds of evidence. For Cochrane in 1972, it was randomized controlled trials that constituted the relevant level. In the case of EBM, the Oxford Centre for Evidence-Based Medicine (CEBM) presents a comprehensive list of levels of evidence for different clinical questions. For therapy/prevention these are, from the top down: systematic review of RCTs, individual RCTs (all or none), systematic reviews of cohort studies, individual cohort studies, ‘outcomes’ research, ecological studies, individual case-control studies, case series, and last, expert opinions either without explicit critical appraisal or based on physiology, bench research or ‘first principles’ (CEBM 2009).

It is obvious that evidence from basic medical science (physiological processes) and institutional or individual experience are not held in high regard.³ The evidence on which decisions should be based is that deriving from clinical research. This evidence has high predictive value. An early presentation of EBM from the EBMWG (1992), states that:

Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research. (EBMWG 1992, 2420)

Given this understanding of evidence, which is clearly based on clinical *research*, the question becomes what to do about clinical *experience*. Needless to say, clinical experience is often decisive for predictive purposes (see, for instance, Cartwright and Hardie (2012)).

It is certainly plausible to say that EBM cannot be based *solely* on evidence from clinical research. Results from clinical research are not always there to be had, and where they are unavailable unsystematized clinical experience can be used as evidence:

... systematic attempts to record observations in a reproducible and unbiased fashion markedly increase the confidence one can have in knowledge about patient prognosis, the value of diagnostic tests, and the efficacy of treatment. In the absence of systematic observation one must be cautious in the interpretation of information derived from clinical experience and intuition, for it may at times be misleading. (EBMWG 1992, 2421)

This is not the situation with regard to VBE. Good therapeutic decision-making rests, according to VBE, on two *evidential* sources – science and proven experience. In EBM, by contrast, acknowledgement of the importance of clinical experience as evidence seems to be limited to cases where there are no relevant research findings.

This way of conceiving of EBM might not be shared by Swedish doctors. Trained as they are in thinking about VBE, it is natural for Swedish practitioners to assume that EBM has a place for BE as evidence, too (EBM replaces, as it were, the older idea of science (V), in VBE):

It is a misunderstanding to assume that EBM no longer involves what we have called ‘proven experience’ ... The right way to use personal experience is to contrast experience against the literature when a current problem is analysed. (Werkö et al. 2002, 3478–3479, our translation)

However, as we shall argue in the next section, the combination of EBM and BE is sometimes problematic. EBM’s take on evidence, in what appears to be the most common version of EBM internationally (the *A-views* subsection, see below), is too restrictive to allow for full incorporation of BE.

4. EBM and VBE: integrating science and experience

In an influential statement of EBM by Sackett et al. (1996), it is clear from the subtitle of the paper that *individual clinical expertise* is also important in EBM:

Evidence based medicine: what it is and what it isn’t

It’s about integrating individual clinical expertise and the best external evidence

However, in connection with EBM it is sometimes unclear whether this integration means (A) that EBM consists of several parts, with evidence from clinical research being one part and clinical expertise being another, or (B) that EBM is one part of the total decision situation, with such things as clinical experience and patient preferences being other components. Eddy (2005) introduces a somewhat similar distinction between evidence-based medicine and evidence-based guidelines, arguing that the former concept is built around individuals (decision-makers as well as patients) but could usefully be widened so as to include the latter phenomenon (often including multi-disciplinary teams). Our point, however, is that the A-view is ‘internally’ problematic.

4.1. A-views

(A) is clearly the more common version of EBM. A number of introductions to EBM present flow charts like that in Figure 1:

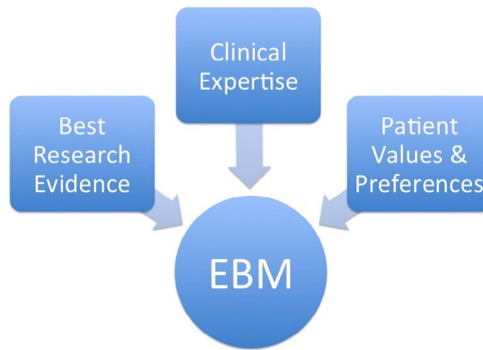


Figure 1. The A-view, adapted from <http://guides.mclibrary.duke.edu/c.php?g=158201&p=1036021> (downloaded 1 February 2016).

An influential position paper remarks that:

Initially, evidencebased medicine focused mainly on determining the best research evidence relevant to a clinical problem or decision and applying that evidence to resolve the issue. This early formulation deemphasised traditional determinants of clinical decisions, including physiological rationale and individual clinical experience. (Haynes, Devereaux, and Guyatt 2002)

These remarks concern the very first EBM-formulations. Sackett et al. (1996) are conceived as the original attempt to integrate evidence and clinical experience in a better way. Sackett et al. (1996) seemingly advocate a version of the A-view. The position paper continues:

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. (Haynes, Devereaux, and Guyatt 2002)

According to this statement, EBM includes both evidence *and* clinical experience. EBM does not complement clinical experience; it includes it. However, it should be noted that Sackett et al. (1996) discuss evidence only in connection with external clinical experience, which is to say research. Haynes, Devereaux, and Guyatt (2002) picture the position in Sackett et al. (1996) in a way that makes it very similar to the A-view shown in Figure 1.

It is said that the 'concepts of evidence-based medicine are evolving as limitations of earlier models are addressed' (Haynes, Devereaux, and Guyatt 2002). However, in our view this has not led to the abandonment of the A-view. That view is perhaps even more clearly relied on in later formulations of EBM – e.g. in what is often presented as the 'contemporary definition':

... the integration of the best research evidence with clinical expertise and patient values. (Sackett et al. 2000, 71)

Now, as we have already touched upon, the A-view makes it difficult to talk about evidence as something other than *research* evidence. As Haynes, Devereaux, and Guyatt (2002) puts it:

Evidence-based medicine recognises that such evidence is not "created equal" and provides detailed guides for finding the most rigorous and pertinent evidence for a specific clinical decision.

As a consequence, the use of clinical experience as evidence has been downplayed in later developments of EBM, and clinical experience is nowadays almost exclusively mentioned as that which is needed to implement scientific evidence in a specific decision context. An example of this is the entry on 'Making a decision' on the CEBM website, www.cebm.net. Here, a decision is made by:

Incorporating the findings of valid, important and applicable research with your patient values and preferences and your clinical expertise to arrive at the right decision about their individual health care. (CEBM 2016)

Duke University Medical Center, from whose work we adapted the flow chart in Figure 1, presents the issues in a similar way:

The evidence, by itself, does not make the decision, but it can help support the patient care process. The full integration of these three components into clinical decisions enhances the opportunity for optimal clinical outcomes and quality of life. (<http://guides.mclibrary.duke.edu/c.php?g=158201&p=1036021> [downloaded 1 February 2016])

In other words, the original idea behind EBM highlights the need to *integrate* research findings with individual clinical expertise, but on the A-view it is clear that this integration cannot be one in which two types of *evidence* are integrated, since that would violate EBM's paradigmatic view of evidence. Remaining within the paradigm might work in some cases, for certain types of clinical experience (proven experience of a certain kind), but normally the difference between evidence from the two sources would be too pronounced for anything but research evidence to count, according to EBM. This creates considerable tension within A-views, since they also wish to acknowledge the role of other kinds of 'information':

We title this component of clinical decisions 'research evidence' to distinguish it from other forms of information that have always been part of clinical decisions, such as the patient's history, physical findings, diagnostic tests, circumstances, and stated preferences. (Haynes, Devereaux, and Guyatt 2002)

When viewed as a framework for medical risk analysis, it is hard to interpret this A-view of EBM as anything else than that research evidence alone belongs to risk assessment. Clinical experience and patient values are both parts of risk management. While not obviously problematic in decisions about effectivity, the barring of clinical experience from risk assessment becomes a definite problem for the cautious decision-making that is generally viewed as a virtue of risk analysis.

4.2. B-views

The B-view, where EBM is one part of the total decision situation, also has advocates. It is perhaps not surprising that Swedish perspectives sometimes express B-views, since these are much easier to interpret in terms of VBE. For example, in a much quoted passage in a letter to a physician, the Swedish National Board of Health and Welfare explains:

In the exercise of her profession, the medical doctor must take account of both science and proven experience. [...] When a new method is introduced, proven experience of it is trivially lacking, and the scientific evidence can suffice for acceptance [...]. At other times, long clinical experience might be the dominating evidence in favour of accepting the medical treatment whereas theoretical and/or experimental evidence for its effectiveness might be lacking. (quoted from SOU 1989:60, our translation)

Asplund (2001) presents a picture captured in the following flow chart:

The B-view is not a uniquely Swedish phenomenon. For instance, Haynes et al. (1996, 1996), define evidence-based medicine thus:

Evidence-based medicine is the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients.

At first blush this definition seems very similar to those we have referred to as A-views, and that is probably how it was intended to be presented. Here too, however, it might be argued that EBM is but one part of a larger decision context, the management of individual patients and risks associated with that management. But this is not normally how proponents of EBM picture it. They distinguish between early and updated models (Haynes, Devereaux, and Guyatt 2002), and this would be one of the earliest – a model that 'deemphasised traditional determinants of clinical decisions, including physiological rationale and individual clinical experience.' The alternative B-view reading would be that the early models present EBM as one component of the decision.

On a B-view, it is much easier to understand EBM and its evidential levels. 'The doctor as clinician' (see Figure 2) can bring evidence into the decision as well, but it is not the type of evidence EBM speaks of, which concerns research findings only. On the A-view, the clinician's expertise is only a means of applying research evidence to a particular case (expertise has a role only in risk management, not in risk assessment). That expertise does not provide any additional evidence. On the B-view, by contrast, the individual and collective clinical experience that the clinician adds to the decision basis qualifies as relevant evidence too. Clinical experience underwrites risk assessment as well as risk management.

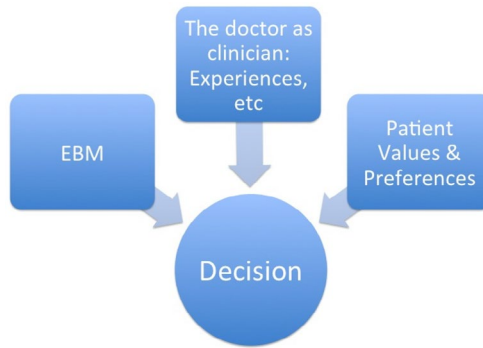


Figure 2. The B-view, modified from Asplund (2001).

Consequently, according to the B-view EBM does not really set a standard for decision-making. Its capacity to help doctors make better decisions is clearly weakened. EBM becomes much more of a *partial* tool for decision-making than advocates of EBM normally assume.

4. Concluding remarks

Advocates of EBM struggle to model the way evidence-based medicine should '[integrate] individual clinical expertise and the best external evidence' (Sackett et al. 1996). We have argued that the formulations and models available in the literature today are variations on a common theme. On these A-views, EBM describes all that goes on in a specific justifiable medical decision. For matters of risk, this entails that clinical experience can be relevant for risk management but not for risk assessment. A-views inevitably create tensions in the concept of evidence they require.

For that reason alone B-views are of interest. On a B-view, EBM describes just one component of the risk assessment (a component usually based on evidence from clinical research). Together with other types of evidence, EBM leads to a justifiable clinical risk assessment, but it does not describe the decision itself. The B-view is inspired by a 100-years older version of EBM, a Swedish standard that requires medical decision-making and practice to be consistent with 'science and proven experience'.

In sum, the Swedish concept of 'science and proven experience' clearly resonates with several characteristics of evidence-based medicine. Like EBM it focuses on evidence (rather than opinion), on science, and on the need for integration. However, the Swedish concept also differs from the concept of evidence-based medicine in that it clearly identifies two sources of evidence as special: science (*vetenskap*) and proven experience (*beprövad erfarenhet*). Comparing EBM and VBE, one is struck by the relative clarity of the Swedish notion.

Finally, a version of evidence-based medicine, modelled on the Swedish notion of science and proven experience, would be much more in line with contemporary risk assessment, focusing on the integration of 'hard' and 'soft' data. The official version of EBM, the A-view, has to rely on that clinical experience informs risk *management* not risk *assessment*. Whereas it is an open question whether it is preferable that patients' *values* should enter risk assessment, it is difficult to see the rationale for why certain kinds of evidence – i.e. clinical experience – should be excluded from the risk assessment.

Notes

1. The Medical Society of Finland was set up specifically for the Swedish speaking community of practice, whereas the explicit aim of Duodecim was to promote medical practice and uptake of medical science in Finnish. A third society, Suomen Lääkäriliitto (The Finnish Medical Association), was established in 1910. Many thanks to Matti Sintonen for generously helping us to navigate the various medical associations of Finland.

2. *Lag om yrkesutbildade personer inom hälso- och sjukvården* (1994/559) section 15; *Lag om utövning av veterinäryrket* (2000/29) section 13; Lääkäriliitto (2014).
3. Holly Andersen provides an interesting argument explaining why this is the case (Andersen 2012). In general the fact that our bodies are complex evolved systems makes it likely that relevant variables will be masked.

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