



# An epistemological problem for integration in EBM

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## Abstract

Evidence-based medicine (EBM) calls for medical practitioners to “integrate” our best available evidence into clinical practice. A significant amount of the literature on EBM takes this integration to be unproblematic, focusing on questions like how to interpret evidence and engage with patient values, rather than critically looking at how these features of EBM can be implemented together. Other authors have also commented on this gap in the literature, for example, identifying the lack of clarity about how patient preferences and evidence from trials is supposed to be integrated in practice. In this paper, I look at this issue from an epistemological perspective, (looking at how different types of knowledge in EBM can be used to make sound judgements). In particular, I introduce an epistemological issue for this integration problem, which I call the epistemic integration problem. This is essentially the problem of how we can use information that is both general (eg, about a population sample) and descriptive (eg, about what expected outcomes are) to reach clinical judgements that are individualized (applying to a particular patient) and normative (about what is best for their health).

## KEYWORDS

clinical reasoning, evidence-based medicine, philosophy of medicine

## 1 | INTRODUCTION

Since the beginnings of the movement in the 1990s, evidence-based medicine (EBM) has claimed to advocate the integration of evidence alongside patient values, clinical reasoning, and expertise. Early pioneers of EBM like Sackett, Rosenberg, and Guyatt explicitly reject the view that evidence can replace the role of the expert.<sup>1-3</sup> The BMJ's 2017 “manifesto” for evidence based medicine similarly calls for clinicians to “integrate relevant evidence” into their decision-making.<sup>4</sup> This skill has also been identified as one of 36 “core competencies” in evidence-based practice.<sup>1</sup> Critics of the movement, however, still argue that EBM does not take these other aspects of clinical practice seriously. They say that EBM does not focus enough on things like the patient-doctor relationship, empathy, or clinical reasoning, and that EBM lacks an adequate account of how these are supposed to be taken into consideration alongside evidence from trials in clinical contexts.<sup>5-8</sup> (The 2017 manifesto, for example, focuses almost entirely on creating better, more trustworthy evidence, rather than assessing the role that this evidence could play

in practice). Kelly et al, for instance, argue that even though it is recognized that the practices of EBM are value-laden, the role that these values play in the EBM processes has been “almost completely ignored.”<sup>8</sup> Similarly, Mercuri et al claim that “the problem of integration has plagued all aspects of EBM,” and that the question of how evidence should be used alongside patient preferences has been overlooked.<sup>9</sup> For example, the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) framework has been criticized for not providing adequate clarification about how the criteria should be integrated into medical practice.<sup>10-12</sup> Ultimately, there appears to be a lack of clarity about how the integration that EBM calls for is actually supposed to work, or how this is even possible.

In this paper, I suggest a way of getting to grips with this issue by looking at it through an epistemic lens: looking specifically at what makes a medical judgement correct, meaningful, or appropriate. Medical practice involves dealing with both normative claims (eg, about health, and what would be best for the patient) as well as descriptive ones (eg, about risk, predicted outcomes, and diagnostic measures).

The former tells us what doctors or patients should do from the point of view of patient health, whilst the latter tells us facts about what a patient's health is or will be, regardless of which outcomes or states of affairs are preferable. EBM also deals with both general claims about populations or expected outcomes (eg, number needed to treat) as well as claims about individual patients (eg, about how she in particular will respond to a test or treatment). The former claims are about outcomes we would expect to see within a certain group taken as a whole, whilst the latter are about the single patient we are currently dealing with, along with her unique circumstances, demographics, and values. This diversity in the types of information used in clinical decision-making leads us to the question of how these can all be brought together to make sound clinical judgements.\*

I will attempt to illustrate this problem by first looking at the roles of evidence, values, and communication in EBM. Then, I will outline what the epistemic integration problem is, and why it matters for clinical practice. In the first section, I will discuss some of Sackett's work on the need for EBM for reducing bias in medicine. In the second section, I will discuss the role of patient values, communication, and idiosyncratic features of health in the practice of EBM. My aim in this section is not to provide a full or systematic account of the aspects of medical practice that EBM cannot account for, but rather to provide some illustrative examples of problems that cannot be resolved solely by looking to our best evidence. Finally, I will give an outline of the epistemic integration problem, and illustrate this with examples.

## 2 | EPIDEMIOLOGICAL PRINCIPLES IN EBM

EBM is an approach to medicine that emphasizes the use of our "best available evidence" in clinical decision-making. This is usually understood to involve things like randomized control trials (RCTs) and meta-analyses, with evidence hierarchies (eg, EBM pyramids) sometimes being used to rank types of evidence.<sup>13</sup> These can be in the form of conditional hierarchies, heuristic approaches, or other models that appraise the reliability of different types of evidence.<sup>14</sup>

EBM as a movement began in the 1990s, following the influence of Sackett's work on this topic. EBM has come a long way since Sackett, with new developments in medical technologies, research, and education deeply effecting the way that EBM is used and understood. Nonetheless, it is worth looking at some of Sackett's main arguments in support of EBM as a kind of mission statement for the movement. This will be helpful to us for two reasons. First is that elsewhere in the EBM literature, we do not really get the same kind of systematic defence of EBM that we find in Sackett's work. Other authors talk about features of EBM (like what counts as our "best evidence," and the role that patient values play in EBM) but rarely defend the whole idea of EBM as a movement in general.<sup>†</sup> Second, it is useful

\*"Sound clinical judgements" can be understood as judgements that are ethically and economically reasonable, based on valid clinical inferences, and are likely to optimize patient outcomes/well-being.

<sup>†</sup>For example, the EvidenceLive manifesto aims to "implement solutions for better evidence and healthcare,"<sup>14</sup> rather than defending the very idea that better evidence goes hand-in-hand with better health care as we see with Sackett's work.

to us to see what aspects of EBM have endured since these early foundations, and what problems remain unresolved or unaddressed.

Sackett defends EBM as a methodology which emphasizes "epidemiological principles" over clinical reasoning and intuitions. These intuitions, Sackett claims, are prone to false-positive results.<sup>3</sup> In this paper, Sackett is unclear about exactly why clinical intuitions/reasoning should have this effect, but we might suggest that it has something to do with bias.<sup>‡</sup> Cognitive biases (such as anchoring or confirmation bias) can have an irrational influence on clinical decision-making in much the same way that cognitive biases can influence all forms of decision-making. In the context of clinical studies, biases can skew the conclusions we draw from a study, both in the way a study is conducted and the interpretation of its results. Here, however, we can try and account for the influence of bias by addressing problems and limitations in a given study design.

In this latter context, biases can be generally understood as flaws in a study's design or conduct which causes the results of that study to underestimate or overestimate the effect they are observing.<sup>16</sup> For example, these might be the result of our beliefs having an unconscious effect on our actions and decisions.<sup>17</sup> Fair clinical trials are able to avoid some forms of bias through the use of blinding and randomization. With randomization, the possibility of a clinician unconsciously influencing the outcomes of a study (eg, by allocating one treatment to a particular type of patient) is reduced.<sup>18</sup> With blinding, the chances of the patient or clinician being unduly influenced by their expectations of the outcomes is reduced.<sup>18</sup> In a fair trial, this will (hopefully) mean that the results of the study are down to the treatment effect. Clinical judgements based purely on clinical reasoning (without using the evidence from fair trials) may be more likely to be biased since it does not use these bias-reducing techniques.

This quantitative evidence, however, is not to completely replace the role of clinical reasoning. This would risk turning into what Sackett calls "cookbook medicine," where guidelines and evidence are applied to patients without regards to that patient's individual needs.<sup>3</sup> Rather, it is to be "integrated" together alongside traditional clinical reasoning. What is unclear here, however, is (a) exactly what this clinical reasoning involves; exactly which "habits, protocols, and traditions" inform clinical practice and (b) how this reasoning is to be integrated with the quantitative evidence we get with clinical studies.

## 3 | CLINICAL REASONING IN EBM

One thing that Sackett leaves ambiguous in these two papers is exactly what is meant by "clinical reasoning." It seems that clinicians rely on multiple different kinds of reasoning to reach medical judgements. For example, philosophers of medicine have identified the following reasoning processes as playing a role in making medical decisions:

<sup>‡</sup>Sackett himself wrote about the influence of bias in analytic research a few decades before these papers.<sup>15</sup>

- A consideration of “patient goals and values.”<sup>7,8</sup> For instance, how and to what extent a given treatment will affect the patient's livelihood, or what it means for a patient to be healthy and well. If the patient is a vulnerable person (eg, a child) questions about autonomy may need to be considered.
- Tacit understanding of the patient's behaviour and symptoms.<sup>19</sup> For instance, an experienced clinician may be able to differentiate between diagnoses on the basis of tacit clues about the patient's body language or the presentation of symptoms.
- Clinical intuitions that enable the doctor to make the right judgements and inferences, using tools like abductive or syllogistic reasoning.<sup>20</sup>

Sackett explicitly rejects a picture of EBM where this quantitative evidence is taken to overrule or de-emphasize the role of values and the individual patient in clinical practice. He claims that “clinicians who fear top down cookbook [medicine] will find the advocates of evidence based medicine joining the at the barricades.”<sup>3</sup> However, Sackett does not provide us with much insight about how we can prevent EBM from becoming cookbook medicine in the first place. Without a coherent understanding of how evidence can be used in conjunction with these other aspects of clinical practice, it is unclear what role they ought to play alongside judgements about evidence.

We can see some of the implications of this over-emphasis of evidence in EBM by looking at the role of idiosyncratic features of illness, communication between doctor and patient, and patient values. These require patient-centred skills, like responding to patient cues, agreeing on a problem, and selecting treatment options, which go beyond just asking a patient for their symptoms and then diagnosing/testing/treating accordingly.<sup>21</sup>

This is a potential problem for EBM because these features are, by their nature, not things that can be wholly accounted for by looking at the evidence. These are practical skills that cannot be learned through reading population studies or guidelines.<sup>22</sup> Overemphasizing the evidence in EBM therefore risks neglecting the impact that these other aspects of medicine can have on clinical outcomes.

The limitations of evidence for dealing with things like communication, idiosyncratic features of illness, and values is acknowledged to some extent in EBM guidelines. For example, the Programme Development Group for public health does not currently offer any guidance for primary prevention of domestic abuse.<sup>23</sup> This is clearly something that can have clinically significant harms without intervention, and so clinicians will have to rely on things like patient testimonies and communication, rather than acting solely according to guideline recommendations. This is complicated further because it's often the case that patients will not explicitly frame their problems as related to abuse. National Institute for Health and Care Excellence (NICE) explicitly acknowledges that children who have experienced domestic abuse “may not recognise their own experiences as abusive or neglectful.”<sup>24</sup>

Other medically significant problems can also be difficult for patients to talk about upfront. This has given rise to a phenomenon sometimes described as “doorknob syndrome” or “doorknob revelations.”<sup>25</sup> This is when a patient is bothered by a certain problem, but does not bring it up with the doctor until the end of their consultation, when they practically have their hand on the doorknob ready to leave.

For instance, a patient might say “oh and by the way...” and then reveal something clinically important. Graham Jackson talks about this problem specifically in relation to erectile dysfunction, where the problem can be embarrassing to talk about or bring up. He suggests using humour as a way of putting the patient at ease and helping them open up.<sup>25</sup> In breast cancer prevention, this has also been recognized as a factor that delays the identification of tumours; patients often only bring up concerns about breast lumps at almost the end of a consultation, when there is little time left to properly address the concern.<sup>26</sup> It has been suggested that patients who express concern about benign breast lumps in this context should be “validated as part of building a trusting therapeutic relationship and encouraging future presentation with breast concerns.”<sup>26</sup> This validation can make patients feel more comfortable about opening up to their doctors about these problems earlier, and hence can lead to better monitoring of their symptoms. A recent review of studies on doctor-patient communication found that having “doctor-patient relationship building” showed a positive effect on objective health parameters in 60% of the studies analysed. Communication skills, in particular, “enabled treatment-related emotions and behaviour.”<sup>27</sup>

The effective practice of EBM, therefore, needs to integrate these other aspects of clinical reasoning alongside the judicious use of our best available evidence, if it is to avoid Sackett's worries about cookbook medicine.

## 4 | THE EPISTEMIC INTEGRATION PROBLEM

In order to provide optimum care, therefore, the practice of EBM requires quantitative evidence to be integrated alongside a diverse range of other kinds of information and skills. To neglect these skills is to risk overemphasizing the role of epidemiological principles and underemphasizing the role of context-dependent factors like patient values and communication.

Importantly, the clinical reasoning processes that we have looked at so far do not merely aim to reach accurate descriptive claims about the state of the patient's health or the effects of a treatment. They also make normative claims about what should be done to improve the patient's health. For instance, if I recommend a certain treatment plan to a particular patient, I am not only making a predictive claim about what will happen if she follows the plan correctly. I am also recommending the treatment to her, and claiming that it would be good for her to follow it. In some circumstances, I might also be trusting that she will choose and be able to follow the plan as it is intended.

This contrasts with the comparatively more descriptive, scientific information we get from clinical studies. Quantitative and qualitative evidence provides us with information about what outcomes we can expect from treatment, prognosis, and diagnosis. However, they do not offer their own insight into how we should weigh up these outcomes. For an example of this, say a doctor is deciding between which of two different drugs to prescribe her patient. Systematic evidence may give us the most accurate idea about what the relative costs and benefits of the two drugs are. They can tell us what the number

**TABLE 1** The epistemic integration problem

	General (or "average")	Individual ("this" patient)
Mainly descriptive	A - quantitative and qualitative evidence (RCTs, meta-analyses, specific studies)	B - descriptions of symptoms, patient history, contextual information, and results of diagnostic tests
Descriptive and prescriptive	C - EBM guidelines	D - advice on how patient should act; clinical judgements

Abbreviations: EBM, evidence-based medicine; RCT, randomized control trial.

needed to treat is, what the possible side effects are, and how likely it is that the patient will experience these side effects. What this does not tell us is how we should weigh up the relative likelihood and significance of these possible outcomes, or how we can ultimately decide that one treatment is the better option for this particular patient.

To arrive at conclusions about best treatments, systematic evidence needs to be incorporated alongside ethical concepts like health, risk, wellbeing, and patient choice. This leads to the question of how, exactly, these descriptive claims about outcomes can be used to reach normative claims about what's best for a given patient.

To some extent, we can address this issue by looking at the role of evidence-based guidelines. These look at the evidence generated by quantitative studies and use this and try to offer informed guidance about how doctors should act. These are still, however, focused on how doctors in general should act, given evidence about what works best for patients in general. This may not directly inform us about what doctor should offer this patient, in this clinical scenario, given potential confounders (eg, multi-morbidity, demographic factors, age, gender, and personality). For instance, they do not tell us how a patient's individual values and lifestyle should be factored into clinical decision-making. Even in cases where advice discriminates between different subgroups (eg, elderly or pregnant patients), it is virtually impossible for guidelines to count for all of the unique possible circumstances and values. In this way, guidelines lie on the intersection of these two kinds of evidence. On the one hand, they do seem prescriptive/normative—they tell medics what they ought to do in certain circumstances. However, the guidance they offer is in the form of general rules for how many or all patients should be treated, rather than dealing with individual patient, with her own unique set of values, beliefs, concerns, etc. For this reason, rules can rarely be easily copied-and-pasted from a set of guidelines to a clinical setting.

The distinct epistemic features of evidence-based practice that I have described can be briefly summarized as follows (Table 1)<sup>5</sup>:

The challenge for EBM, then, is how information can be translated from three very different kinds of evidence (A, B, and C), so that we can ultimately arrive at sound clinical judgements (D). From an epistemic lens, this is far from straightforward, because we are not only making judgements based on lots of different pieces of evidence, but crucially on evidence of different kinds. The risk that this problem poses for EBM, if unacknowledged, is for us to assume that we can easily make inferences from one type of information/evidence to another, without recognizing this epistemic jump. In some cases, this may not be a practical issue—in some sense, we obviously can infer

<sup>5</sup>I say "mainly descriptive" here since some of these examples will also involve normative judgements. For instance, patient history may include normative elements about, eg, what past treatments they preferred as well as descriptive aspects of, eg, pre-existing conditions.

that we should give a patient a prescription for antibiotics from the evidence that this patient has a bacterial infection, and that antibiotics are effective at these. When we consider more nuanced aspects of cases like this though, the epistemic problem becomes more apparent. For example, consider the following:

- The available evidence about the infection and its treatments may not be reflective of the patient's circumstances; eg, say she has co-morbidities that have not been accounted for in the evidence, or if her demographic is understudied. This raises a problem for A and B.
- There may be a gap between the evidence and the guidelines; eg, say a newer drug has been shown to be very effective for this patient's type of infection, but the guidelines have not yet been updated to include recommendations for it. This raises a problem for A and C.
- The patient's unique personal circumstances may not be accounted for in the available relevant guidelines; eg, say she has a history of forgetting to take her medications, or has suffered badly from side effects from antibiotics in the past. This raises a problem for B and C.
- The patient's values and priorities may not be reflected in the evidence and guidelines; eg, say that despite what the guidelines suggest and what the evidence shows to be effective, the patient has a strong preference not to take any medications unless absolutely necessary, and she insists that unless the infection is likely to become much more serious, she should not have to take anything. This raises a problem for A, B, and C.

This list is not extensive, but I hope it illustrates some possible ways that the epistemic integration problem might lead to dilemmas in medical decision-making. As I have analysed the problem, this is fundamentally an epistemological issue. It is about how different kinds of information can come together to make judgements that are correct, appropriate, and normatively sound. However, it is an epistemological problem that has substantial upshots for medical practice.

The epistemic integration problem, therefore, is an issue in EBM that needs addressing. The different kinds of information that EBM requires us to integrate into practice cannot simply be welded together to reach effective and ethical clinical judgements. We instead need a more developed account of how clinicians can make inferences about what is best for their patients, based on the different kinds of information they have about evidence, values, and patient symptoms and histories.

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