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A Philosophical Argument against Evidence Based Policy

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1. The two components of evidence based medicine

Should one always recommend the intervention that has been shown to be best in medical trials? Evidence based medicine (EBM) tells us so but we think this is a more complicated matter than at first it seems. To show this, we will distinguish two logically separate components of EBM. One is ontological and the other concerns policy and decision making.

The *ontological component* is the assertion that there is a best way to discover and establish causal effectiveness. We call this component ontological because ontology in philosophy concerns the nature of reality – *what there is* in the world – and this is the part of EBM that professes to deliver such knowledge. The knowledge EBM gives us concerns what causes what: the causes of disease and recovery, for example.

If the correct methods are followed, according to EBM, they qualify our theories regarding subsequent interventions as evidence based. The standard sort of evidence based connection to be established is that intervention A produces effect E, for example that taking a certain trial medication has a positive effect on a particular condition or illness. As is well known, the view of EBM is that randomised controlled trials (RCTs) and their systematic review are to be placed at the heart of our methods of testing and discovery and it is causal judgements founded upon such methods that qualify as evidence based (EBM Working Group 1992, Howick 2011: 4-5). The method of RCT, systematically reviewed, could also reveal which intervention from a number of candidate possibilities is the most effective, meaning that the intervention produces the greatest net benefit (gross benefit minus any harm). This could be important to us because although intervention A might be effective, a different intervention, B, could be even more effective. The methods of EBM can discover whether this is the case. We believe that some aspects of this now standard account can be contested but we will not be discussing the ontological component of EBM here (for a detailed discussion on the relationship between research methods and philosophical notions of causation, see Anjum forthcoming, Kerry et al. 2012 and Anjum et al. 2015).

The *policy component* of EBM concerns what we do with the evidence collected in the way described above, particularly the actions and interventions that should follow. Typically, this would mean the integration of the evidence into decision-making in the form of clinical guidelines. These guidelines could include a recommendation of the intervention that has been shown to be most effective, as defined above. We should be clear that there are a number of levels within the policy component of EBM, even though our objection applies to them all. First, perhaps the biggest concern is with individual

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clinical *decision-making* that is evidence based under the terms we have described. The sort of decision in question is what intervention the clinician should prescribe, given the symptoms an individual patient is presenting. According to EBM, this clinical decision should be evidence based. Second, the most likely way in which this will happen, is that the clinician makes his or her prescription in the light of *guidelines*, where those guidelines in turn are evidence based. Thus, the guidelines should have been written in the light of the evidence provided by the ontological component of EBM. Third, our *policies* should be evidence based, too. A policy is something that we take to be stricter than a guideline but also at a higher level of generality. A very general health intervention, for example, would be the inclusion of fluoride in the drinking water supply, and this is a policy that should be evidence based, according to EBM. It is also clear that policy-making of this general kind in other spheres can be evidence based, such as in economics, education and social welfare (Shemilt et al. 2010), and our philosophical argument could easily be extended to those too.

Our aim is to present a philosophical argument against evidence based policy (EBP), specifically against what we take to be its core tenet. This core tenet is that you should always prescribe the intervention that has been shown to be best by the standards of EBM; namely the intervention that has been shown to produce most benefit under RCT and systematic reviews thereof. We might think of this as the *meta-policy commitment* of EBM as it is the statement at the highest level of generality that then is taken to inform individual policies, guidelines and, finally, clinical decisions.

There are a few more things to note before we proceed. In arguing against the core tenet of EBP, we are offering one specifically philosophical argument. There may be other arguments to be had about the virtues or otherwise of adopting the core tenet. Perhaps it is cheaper, for instance, to recommend the same intervention for all within a certain target group, but this is a financial argument rather than a philosophical one. Alternatively, there might be other philosophical arguments to be had rather than ours, such as if you thought there was an overriding principle that everyone should be treated the same regardless of personal circumstances. We will offer one specific argument against EBP as it 'ideally' should be practiced, and we have set out what we think that is. But we categorically do not want to be understood as challenging a view that our policy decisions should be empirically informed, nor that they should be based on evidence, if this is understood in a broad sense. It is also worth stating that our philosophical argument against evidence based policy would still stand even if the ontological component of EBM were accepted as correct in every detail. One of the points we wish to emphasise is the independence of the ontological and policy components of EBM, which means that separate decisions have to be made on their correctness.

2. Evidence based policy as rule utilitarianism

Evidence based policy, we argue, is form of rule utilitarianism. Utilitarianism is a theory of moral philosophy which says that the good is that which produces the greatest happiness of the greatest number (Bentham 1789, Mill 1861). It has developed into two versions: act utilitarianism and rule utilitarianism. Rule utilitarianism recommends adoption of the rules that produce the greatest happiness

of the greatest number, for instance, the rule that you should always tell the truth or that you should always pay your debts.

We will consider this in detail but we first wish to distinguish utilitarianism from consequentialism more generally, as they are often treated as the same. In principle, any moral theory that appeals to consequences is consequentialist, such as Hume's (1739, Book III). But even the devil could be a rule consequentialist if he thinks the right rule is the one that procures the greatest misery of the greatest number. Similarly, a follower of Leopold's (1949) land ethic might think that the right thing is that which increases biodiversity in nature, irrespective of its effects on human happiness. For our purpose here, therefore, it is essential that we speak of rule *utilitarianism*, where the issue concerns the specific consequence of producing the greatest happiness of the greatest number, or *utility maximisation*. We will see the importance of this distinction when we come later to the discussion of Hooker.

A rule utilitarian might claim that we should always tell the truth because that is the approach to truth that overall produces the greatest benefit. It might be that, in some individual case, telling a lie would produce more happiness, and this is where we can see the difference between act and rule utilitarianism. An act utilitarian considers the consequences of an individual act in some set of particular circumstances and judges the act to be right if it produces the greatest happiness of the greatest number. In some instance, telling a lie might, then, be the right thing to do. A rule utilitarian, in contrast, could point out that if people were permitted to lie when it's expedient, we would be unable to trust each other. In that case, the rule utilitarian thinks it best to have a rule of truth-telling. It may be that in a few cases, offence or harm is caused from telling the truth, but a rule utilitarian thinks that greater overall happiness is produced from having a rule to always tell the truth than if people pick and choose when to be truthful.

Another example makes the contrast very clear. If there is a hospital ward of people waiting for organ transplants of different organs and an innocent, healthy person walks by, act utilitarianism might pronounce it right to capture and kill the innocent person and harvest her organs. One person dies but perhaps five then live after transplants (example adapted from Foot 1967). The rule utilitarian could reject this judgement by arguing that, as a general moral rule, it would produce more unhappiness if people lived in fear of being sacrificed for the benefit of others.

It should now be easy to see the analogy between rule utilitarianism and EBP. In both rule utilitarianism and EBP, it is deemed best to have a single rule that applies to everyone rather than make separate individual judgements about particular cases. Furthermore, the rule that one should adopt under EBP, according to the core tenet, is that one should prescribe the intervention that has been shown by RCT to produce the greatest benefit. As medicine deals with many different illnesses, diseases and conditions, it concerns a number of different target groups, such as people with low back pain, people with Ebola, people with bipolar disorder, and so on. The core tenet tells us in each of these cases that one should prescribe the intervention that produces greatest benefit. The clinical guidelines, according to EBM, should have taken into account the evidence from RCTs that shows what intervention works best, and the clinician then has an imperative to prescribe this intervention rather than trusting her own judgement, which might not be in agreement with the evidence.

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EBP then looks to be a close analogue to rule utilitarianism. In a very similar way, utilitarianism asks us to perform a calculation of net benefit for any possible act, which means gross benefit minus any 'negative benefit'. Bentham's (1789: ch. 4) utilitarian Felicific Calculus works just like this. EBM has to make the same calculation except that instead of benefits being hypothetical or conjectured, we can record the actual benefits and negative side-effects of an intervention when we test it in an RCT. We also think that the best way to understand the close analogy between EBP and rule utilitarianism is to say that EBP is a form or species of rule utilitarianism, the latter being at a higher level of generality than the former.

Now suppose we were to agree that the best evidence should inform the clinical decision and that systematic review of RCTs provides the best form of evidence. There still remains the question of *how* that evidence should inform the decision or policy. What principle should we adopt concerning policy when we are presented with the evidence? Rule utilitarianism is just one option and, contrary to the core tenet of EBP, we say that it is a problematic one, as we will explain next. Furthermore, the problem has not been sufficiently acknowledged or answered within the context of evidence based decision making.

3. A problem for rule utilitarianism

We saw that rule utilitarianism *prima facie* seemed a better option than act utilitarianism, since it purportedly avoids the consequence that harming one for the benefit of many could be morally justified. Let us call this the problem of minority sacrifice. On further examination, however, we see that the problem re-emerges in a different form in rule utilitarianism. By insisting that the rule should always be applied that benefits the most, the rule utilitarian is willing to accept rules that produce no benefit, or even harm, to individuals that are in the minority. This is, then, also a form of minority sacrifice. We will show that the same problem afflicts EBP, since it is a form of rule utilitarianism.

Rule utilitarianism has been criticised for this. A utility maximiser, it is said, should always have reason to break the rule in any instances where failure to do so will have a negative effect. This has been argued by Smart (1973: 10-12) and Williams (1972: 102). Smart's argument against rule utilitarianism, originally from 1956, is summed up as:

...the rule utilitarian presumably advocates his principle because he is ultimately concerned with human happiness: why then should he advocate abiding by a rule when he knows that it will not in the present case be most beneficial to abide by it? ...Hence to refuse to break a generally beneficial rule in those cases in which it is not most beneficial to obey it seems irrational and to be a case of rule worship. (Smart 1973: 10)

Williams (1972) had a similar criticism, arguing that from a utilitarian perspective, there will be some situations in which it seems irrational to follow the rule rather than breaking it.

Whatever the general utility of having a certain rule, if one has actually reached the point of seeing that the utility of breaking it on a certain occasion is greater than that of following it, then surely it would be pure irrationality not to break it? (Williams 1972: 102)

Smart's objection has been pushed further, by him and others, into the charge that rule utilitarian collapses into act utilitarianism (Lyons 1965: 182-95). One could for instance make a rule that says that in some exceptional cases, one can break the general rule. But then one needs another rule that can be applied instead when the first rule does not apply, and so on. So either we end up with as many rules as there are types of exceptions, or we admit that the rule is only a guideline not to be applied if it fails to maximise utility (Habib 2014). In both alternatives, rule utilitarianism seems to collapse into act utilitarianism, where one must consider what to do case by case.

4. Application to EBM

Given that EBP can be regarded to be a special case of rule utilitarianism, we should expect a version of this objection to apply to EBP; and it does. In the case of EBP, we make a rule of intervention for all in the target group based on evidence that the intervention is the one that brings most benefit. However, there is an acknowledgment that some in the target group will get no, or even negative, benefit from that intervention. As suggested by Smart, a utility maximising clinician would have good reasons to ignore the rule and not prescribe that intervention if she feels confident that the individual in front of her can gain no benefit. In cases where she thinks a patient can be harmed from the intervention, it seems irrational, if not immoral, to follow the rule. If the intervention produces no direct benefit or harm for a particular patient, there is also a potential indirect harm to her because of the opportunity cost: there could have been a different intervention that would have worked for this individual, even if not for most others. And should anything else matter in a clinical situation other than the needs of the one individual in front of the clinician?

Mill, one of the most influential utilitarians, considered this problem in a book chapter titled 'Of the Logic of Practice, or Art; Including Morality and Policy'. The discussion reveals the tensions within Mill's work. He explicitly mentions the role of the physician:

To the judge, the rule, once positively ascertained, is final; but the legislator, or other practitioner, who goes by rules rather than by their reasons, like the old-fashioned German tacticians who were vanquished by Napoleon, or the physician who preferred that his patient should die by rule rather than recover contrary to it, is rightly judged to be a mere pedant, and the slave of his formulas. (Mill 1843: VI, xii, 2, p. 944)

Mill's point applies to EBM. A clinician can accept that a particular intervention, A, applied as a strict rule, is the rule that produces the most benefit, while recognising that even more benefit can be produced by offering a different intervention, B, in those cases where no benefit, or even harm, will follow from intervention A. Suppose, then, that there is a particular medical condition for which the evidence identifies intervention A as most beneficial. The clinician could know and accept this, but still have good reason to believe that intervention A will not work for the patient in front of her.

It might be that a patient belongs to a relevant target group of which she is clearly atypical or marginal. For instance, if the guideline applies to everyone over 55 it also applies to a former top athlete on her 55th birthday (example from Greenhalgh 2015). The ideal of EBP is that one should stick to the rule that has received scientific support from RCTs and their systematic reviews. Following Mill's point above, however, the morally right, and clinically most effective, decision on some occasions might be to ignore the rule or recommend a different intervention completely. This is not to say that it is easy for a clinician to know, with adequate certainty, that a particular patient cannot benefit from the rule. But, given that we have argued that it will sometimes be right to ignore evidence based policies, there should be more research into the question of when it is appropriate to ignore strict rules, whereas rigid adherence to the central tenet of EBP discourages any such research. We hope that acceptance of our argument can, therefore, encourage progress on this issue.

5. The argument

We are now in a position to set out clearly our philosophical argument against EBP. The argument, it can be seen, is in line with the criticism against rule utilitarianism but is made against its specific instance in the medical case. We need to make explicit three assumptions, which will then constitute premises in the argument. The assumptions are:

1. The intervention to be prescribed for all those in the target group is the one that the evidence (e.g. from RCTs) shows to bring most net benefit.
2. There is individual variation.
3. There is no single intervention that benefits everyone.

Assumption 1 is the core of all evidence based policy and decision-making, stated in a way that makes it clearly a form of rule utilitarianism. Rather than evaluating each situation individually, one should use the intervention that, according to the evidence, brings most benefit. This is benefit in the net sense, thus taking account of any negative benefit produced. Assumption 2, that there are individual differences, is accepted within EBM and even incorporated in the methodology. It is why one uses randomisation over large numbers, since this is supposed to ensure that the two or more groups are similar in spite of the many individual variations. Assumption 3 seems valid on the grounds that RCT has

rarely, if ever, produced a 100 percent recovery within the treatment group, and it is not expected to do so. Not all respond positively to the intervention even when it is the intervention that when adopted as a rule has the overall most positive outcome.

Once these three assumptions are made, the objection to rule utilitarianism is straightforwardly applicable to EBP. If a clinician's aim is to secure the outcome with the greatest health benefit, and a general rule is employed in order to do so, then there will always be some cases where it is desirable to break the rule; namely where there is sufficient reason to believe that in a particular case, applying the rule will bring no benefit at all and may even bring harm. To adhere to the rule in such circumstances would be unmotivated and constitute a form of rule worship. This argument applies, to reiterate, even if the rule concerned is the one that has been shown under RCTs to be best.

Can the argument be avoided? Can we jettison any of the three assumptions, for instance? Assumption 2 is a truth we cannot get around. There is always some degree of individual variation, and this just seems to be a fact of human physiology and psychology. Health issues are often complex (Craig 2008), involving a range of factors, such as genetics, diet, lifestyle, medical history and social context. Arguably, there is more than just variation: perhaps there is medical uniqueness, especially for complex illnesses (Eriksen et al. 2013). Variation is also no doubt connected with the explanation of why a single intervention cannot benefit everyone. The drug that helps the most people might not help an individual who has an atypical set of medical circumstances.

Assumption 3 is a contingent truth, in the sense that it doesn't have to be true. If a single kind of intervention was found that really did give everyone benefit and no harm, then our argument would not affect it. The argument applies, therefore, only to cases where the most effective treatment still fails to benefit some people, and might actually do them harm. However, this is what appears to be the case for every intervention recommended under EBP. A 'successful' RCT might show, for instance, that there was a recovery rate of 40% in the treatment group, 30% in the placebo group, and 15% in a control group that had no intervention. Perhaps no other intervention produces a better recovery rate than this. An intervention might be recommended on such a basis, if there are no significant negative effects discovered. Some of the top prescribed medications are shown to have the intended effect only in a minority of users, with numbers sometimes as low as 1-in-25 (Schork 2015).

Assumption 1 is then the only one that we have the power to change or reject. We can cease the application of a strict rule. In the analogy with moral philosophy, this would be the equivalent of abandoning a rule-based system of morals. Perhaps one could wonder what alternatives there are. But there are credible alternatives because not every moral philosophy is premised on rule-following. There are theories of act utilitarianism (Bentham, Smart), virtue ethics (Foot 2002) and other forms of moral particularism (Dancy 2004), which have ethics without principles. Common for these moral theories is that they take the particular context into account when determining right action. A moral agent, choosing how to act, would be encouraged to consider the contextual factors of the situation carefully, rather than applying a single rule irrespectively. This is the view we would promote.

6. Hooker's defence and the development of evidence based medicine

It has to be conceded that the argument we have invoked against rule utilitarianism has not gone uncontested. There are still rule utilitarians. Hooker (1995, 2002), for example, offers a defence of rule consequentialism against Smart's objection that it collapses into act consequentialism. He points out, for instance, that a system of rules in which there was a separate rule for every possible case would be too complicated to learn, and would therefore be impractical (2002: 97). He also points out that rule consequentialism does not require blind obedience to the rule. In cases where disaster would follow from following the rule, for instance, you should not follow it (2002: 99).

It is clear that Hooker's 'defence' is not a defence of utilitarianism as it has been understood traditionally. Instead of a simple utility maximising principle, he recommends the following of an 'ideal code' of impartially justified rules whose general acceptance would produce the most good (2002: 109). He further moderates the application of this ideal code in a number of ways, as we shall see. While he might be right that Smart's argument does not count against his own variety of rule consequentialism, then, this does not mean that Smart's point is ineffective generally. It might still hold against some forms of rule utilitarianism. And, more importantly for our purposes, it still seems to hold for the form of rule utilitarianism of which EBP is an instance.

It is noteworthy, too, that the moderated form of rule consequentialism defended by Hooker takes it in a similar direction that others have realised EBM must go. Hooker points out, for instance, that in his view:

- a. A rule should not tell you what you should do, only what you can do.
- b. One should be sensitive in application of the rule.
- c. There can be 'hard cases', where two rules conflict.
- d. The rules can include sub-rules about when you should break them, e.g. if disaster would result from adhering to them (all from Hooker 1995).

Similarly, the original 'hard line' EBM applied the core tenet more strictly. But what we have found as EBM has evolved is that it has gradually moved more in a direction that reflects Hooker's moderated consequentialism. Whereas original evidence ranking schemes for a time tended to be hierarchical (such as USPSTF 1989), more schemes now are flatter, or at least aspire to be so (GRADE, for example: Guyatt et al. 2008), meaning that RCTs do not automatically trump all other evidence. Clinical judgement can, for one thing, play more of a role (Sackett et al. 1996, Greenhalgh et al. 2014). We welcome this aspiration as a positive development, with all requisite precautions, because it makes clinical practice less of an exercise in rule following. We hope to have demonstrated that there is a rational basis for this shift.

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Similarly, the view that policies should be informed by evidence seems hard to dispute. But what we have shown should be a warning that policy cannot be dictated by evidence alone, no matter how scientific that evidence. Policy is a normative matter which requires a separate set of considerations. On the one hand there are considerations around whether the outcomes of RCTs can be transferred to other contexts (Cartwright and Hardie 2012). But we have raised a different concern that is not based on a challenge to the scientific methodology. Rather, we think the inevitability of a rule-based policy can be questioned. Now if one is to operate policy in a rule-based way, it seems reasonable to adopt the rule that produces most benefit. But what if even more benefit could be produced by following no rule at all? We have tried to show that there is no inevitability in policy being rule-based. Where the aim is to produce most benefit and least harm, there are solid grounds to say that no single type of intervention will deliver that. Other considerations should be allowed to enter. Would following a guideline lead to disaster, which is quite possible in medical cases? Are there complex matters of medical history that mean contrary prescriptions have to be evaluated? Perhaps more important, are the guidelines merely suggestions of possible interventions rather than prescriptions? Even EBM seems willing to allow that the answer to these questions can legitimately be 'Yes.'

Clinical judgement can in some cases certainly be bad, ill-informed and prejudiced. The method of RCT adds to the evidence base, in a potentially useful way. We have argued, however, that there is a danger if the scientific credentials of the ontological aspect of EBM lead us to think that the resulting policies are unquestionable because they are empirically valid. Such a view, which did for a time prevail, risks a by-passing of the normative debate, with the accompanying danger that certain assumptions could go through unchallenged. A strong rule-based approach to policy is one such normative assumption.

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