A Solution to Some of the Ethical Dilemmas of Randomized Clinical Trials

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Randomized clinical trials (RCTs) give rise to well-known ethical problems—and clinical equipoise is often mooted as a solution to what may be the most serious of these problems. This is, specifically, the concern that RCTs seem to inappropriately "use" patients as means for the acquisition of medical knowledge, which leads immediately to the question of whether it is possible to ensure that patients are not used as *mere* means when performing medical research. Clinical equipoise exists just in case there is uncertainty about the efficacy of a medical intervention amongst the community of clinicians with expertise in the area of the intervention itself. The potential of a proposed RCT to ameliorate clinical equipoise appears, therefore, to be an attractive solution to the problem. If evidence generated by a proposed RCT seems likely to eradicate any clinical equipoise about the efficacy of intervention being tested, then patients will not be used as mere means by the RCT, and thus the RCT is ethically justified (or, if not that, at least not ethically unjustified because the study uses its patients as a *mere* means).

Our proposed contribution to the conference engages with this argument by investigating the interaction between the principles of evidence-based medicine (EBM) and the ethics of RCTs. We shall argue that accepting EBM leads almost automatically to the conclusion that almost any new RCT is a study about which there *should be* clinical equipoise, whether or not there in fact is. From this it follows, with only a few more trivial assumptions, that almost any RCT whatsoever is ethically justified (or at least not unjustified, as per above).

In more detail, our proposed talk will do three things. First, we shall explore the conceptual links between EBM and clinical equipoise which entail that accepting EBM leads to the conclusion that almost any novel RCT is a study about which clinical equipoise *should* obtain. Here, our argument rests upon an interesting logical symmetry. From the perspective of EBM, the existence of clinical equipoise about some medical intervention is *ipso facto* evidence that no RCT has tested the relevant intervention, because clinical equipoise (or its absence) is an evidential standard, and EBM holds that it is epistemologically inappropriate for clinicians to remain indifferent to the results of RCTs. But since, according to EBM, only RCTs can generate maximal certainty, evidence of clinical equipoise is evidence of the absence of an RCT testing the relevant intervention. But going in the other direction, it follows that, if a particular RCT has *not* tested the relevant research question, then there *should* be at least a minimum amount of clinical equipoise about the research question, because, again, EBM holds the only RCTs are able to generate maximal certainty about medical hypotheses. Either way, any novel RCT will turn out to be ethically justified.

Our second aim will be to introduce two methodological principles which can resolve this

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dilemma. The first principle requires that the ex ante ethical evaluation of any RCT be conducted from a position that is neutral with respect to EBM. The second principle requires that there be positive evidence that the RCT in question is not scientifically redundant.

Our third and final aim will be to document some of the practical considerations that favour adopting our proposed principles as criteria for evaluating the ethical warrant of RCTs. These include evidence that our two principles are compatible with the existing practice of assessing RCTs for their potential to ameliorate clinical equipoise, and the fact that researchers already have developed a number of techniques for determining whether research is scientifically redundant; integrating our principles into, for instance, IRB procedures does not seem to require any dramatic changes from existing practices, thus.

And at a more abstract level, then, our proposed conference contribution will illustrate how a detailed investigation of the epistemology of medicine can lead to a number of interesting ethical and methodological insights that, in turn, can potentially be used to improve both the scientific and moral quality of medical practice.