**"Do doctors and patients have an obligation to take part in pragmatic RCTs?" Yes**

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The primary aim of clinical practice is to improve the health and wellbeing of patients, whether through prevention or treatment of disease.  Doctors require knowledge of the benefits (and potential harms) of different treatment options to inform their clinical decision-making.  Patients also require access to this information to make an informed choice between different treatment options.  This knowledge base is generated from robust clinical research such as randomised controlled trials (RCTs). For this knowledge base to advance as new treatments develop, doctors and patients must be willing to take part in future studies.

RCTs are the most rigorous way to evaluate the effectiveness of new treatments as they compare treatments in a fair and unbiased manner [1]. There are many examples of RCTs which have shown treatments previously thought to be beneficial (prior to rigorous testing) to be of minimal benefit or even harmful (e.g. oxygen therapy in acute myocardial infarction [2]). Pragmatic RCTs specifically evaluate different treatment options as they are delivered in routine clinical practice, address clinically relevant questions and directly inform clinical decision-making [3].

Trials can only be delivered if doctors and patients take part - without their involvement, this robust, clinical knowledge will not be realised.  On a day-to-day basis doctors use, and their knowledge benefits directly from, information gathered in previous trials (e.g. through the use of evidence-based clinical guidelines). If, as a society, we wish healthcare to improve further, there remains a societal need for doctors and patients to continue to participate in such endeavours. One could also appeal to the concept of reciprocity, that if one benefits from the participation of others they have a duty to reciprocate [4] – especially relevant in a publicly funded health system such as the UK NHS. Harris [5] goes further and argues that there is a moral obligation on all of us to take part in medical research when that research is targeted to providing significant benefits to humankind.

There are benefits to patients and doctors from taking part in trials. A meta-ethnography of reasons why participants took part in RCTs reported perceived benefits such as increased levels of follow-up and increased consultation time [6]. Doctors too benefit from participation in clinical trials research; gaining clinically relevant knowledge whilst training in good clinical practice; experiencing the rigour of high quality clinical research and learning how to apply it in their clinical practice. With the advances in infrastructure to support the delivery of RCTs (e.g. the UK Clinical Research Network [7]) the administrative commitment expected of doctors participating in trials, traditionally raised as a concern [8], has also been substantially ameliorated.

For doctors, the ethical considerations about whether to participate in a pragmatic trial depend on whether they are the direct recipients of the research or whether they are consenting for their patients to be approached for trial participation. Where doctors are the direct recipients of service-type pragmatic trials (eg as part of a trial to test different ways to facilitate the adoption of evidence based results into practice), Hutton et al [9] have argued eloquently that doctors should have a very high threshold for withholding consent to participate in such studies (and indeed argue that individual doctor consent need not be required in some circumstances), as they are effectively denying their patients access to the potential benefits of participation.

In the situation where doctors are consenting for their patients to be approached to take part in a treatment trial, clinician equipoise becomes a critical ethical concern [10]. Many doctors decline trial participation because they believe they are not in equipoise. If the wider professional community, however, is in collective equipoise - across the profession doctors differ in their perception of what treatment is best and are, therefore, collectively uncertain [10] – I would argue, in line with Freedman [10], that doctors should routinely take part in such trials to address this evidence gap. If they do not, patients will be the recipients of conflicting information about the best treatment option depending on which doctor they are referred to – and, by definition, not all can be right.

One has to acknowledge, of course, that the decision to take part in a clinical trial must remain ethically justifiable to the trial participant as trials are not without risk (especially for patients who are to receive trial treatments directly). Thus, it would be wrong to insist that a moral obligation to participate in trials mandates compulsory participation for all. For patients in particular, individual informed consent will likely remain the norm (although, as with doctors, individual consent for patient participation in service-level trials of the roll out of evidence-based practice may not be an essential requirement). Rather, a moral obligation to participate implies a different starting point – where the expectation is that doctors routinely participate in trials and that their patients expect to be approached to take part.

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**Conflict of interest:**

MKC designs and conducts RCTs; she has received grant funding to undertake publicly-funded RCTs; and has written on the design, methods and reporting of RCTs.