



HEAD TO HEAD

Do doctors have a duty to take part in pragmatic randomised trials?

For society to benefit from new clinical knowledge the expectation should be to participate in research, writes **Marion K Campbell**, **Charles Weijer** and colleagues agree but argue that the fundamental need for consent makes this an imperfect duty

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Yes—Marion K Campbell

Doctors require knowledge of the potential benefits and harms of different treatment options to inform clinical decision making. Patients also require 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. For this knowledge base to advance, doctors and patients must be willing to take part in studies.

Randomised trials are the most rigorous way to evaluate effectiveness because they aim to compare interventions fairly.¹ Many trials have shown that treatments that were thought to be beneficial before rigorous testing were actually of minimal benefit or harmful (for example, oxygen therapy in acute myocardial infarction²). Pragmatic randomised trials evaluate treatments as they are delivered in routine clinical practice, aim to answer clinically relevant questions, and directly inform clinical decision making.³

Trials can occur only if doctors and patients take part—without their involvement, this knowledge would not exist. Doctors routinely use, and their knowledge benefits directly from, information gathered from trials (for example, when using evidence based clinical guidelines).

Everyone benefits

If society wishes healthcare to improve, doctors and patients must continue to participate in such endeavours. There is also the concept of reciprocity: if you benefit from other people's participation then you have a duty to reciprocate,⁴ especially in a publicly funded health system such as the UK's NHS. Some ethicists go further and argue that we all have a moral obligation to take part in medical research because its aim is to significantly

benefit humankind (grounded in the concepts of beneficence towards others, fairness, and the public good).⁵

Patients can benefit from taking part in trials. A meta-ethnography of reasons why participants took part in trials reported perceived benefits such as more follow-up and longer consultations.⁶ Doctors too benefit from participation, gaining clinically relevant knowledge while training in good clinical practice; experiencing the rigour of high quality clinical research; and learning how to apply it in their clinical practice. Advances in infrastructure (for example, the UK Clinical Research Network, which supports the delivery of trials in the NHS⁷) have eased the administrative commitment for doctors participating in trials, which has been a concern.⁸

Consent and equipoise

Doctors' ethical considerations about whether to participate in a pragmatic trial depend on whether they are the direct recipients of the research intervention or whether they are consenting for their patients to be approached to participate in a trial.

For knowledge translation and health services trials—for example, to test different ways to facilitate the adoption of evidence based results into practice—doctors arguably should have a high threshold for withholding consent to participate.⁹ By withholding consent they would effectively be denying their patients access to the potential benefits of participation. Some ethicists have argued that individual doctors' consent may not be needed for these types of trial.⁹

When doctors are agreeing to their patients to be approached to take part in a trial, clinician equipoise (being sufficiently uncertain about the best treatment for a patient) becomes a critical ethical concern.¹⁰ Many doctors decline to participate in a trial because they believe they are not in equipoise. If,

however, the wider community of doctors differs in the perception of what treatment is best—and therefore there is collective equipoise¹⁰—doctors should routinely participate in trials to answer this uncertainty.¹⁰ If they do not, patients will be the recipients of conflicting information about the best treatment option depending on which doctor they see—and not all can be right.

Of course, the decision to take part in a clinical trial must remain ethically justifiable to the trial participant because trials come with risk (especially for patients who agree to receive trial treatments). So 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 essential). 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.

No—Charles Weijer, Cory E Goldstein, Sarah J L Edwards

Conducting timely pragmatic randomised controlled trials is a social priority that requires patients and doctors to participate. But there is no enforceable duty to participate.

Informed consent is a cornerstone of research ethics. Respect for autonomy requires that research participants—be they patients or doctors—make an informed choice to take part, as enshrined in the United Nations International Covenant on Civil and Political Rights.¹¹

But lack of consent is reported to be the most common barrier to enrolment in randomised trials.¹² If a duty exists to take part in pragmatic trials, some ethicists argue that participants' consent may not be required.^{5 13} If true, this would speed enrolment and help broaden the applicability of study results.

John Harris, a bioethics professor at Manchester, argues that because patients benefit from the medical advances produced by research they have “a clear moral obligation to participate . . . in certain specific circumstances.”⁵ Because patients accept these benefits, they have an obligation grounded in fairness or reciprocity to “contribute to the social practice that produces them.”⁵ And, in principle at least, participation in research could be viewed as somehow mandatory; the research enterprise would collapse without enough patient participation. As with other public goods, such as taxes or jury duty, does this justify compulsory research participation in some cases?

Even were we to accept this position generally—despite the theoretical difficulties such as in establishing a fair estimate of what we owe and of reciprocating in kind to all those from whom we have benefited (assuming these do not conflict)—a gap exists between ethical argument and sensible policy.

Free choice

Voluntary participation in public projects is preferable, Harris argues.⁵ People should be able to choose how to discharge any duties of beneficence towards others, whether or not they are willing or unwitting beneficiaries themselves. As a result, a policy of educating and encouraging patient participation in research is preferable to conscription. And patients themselves clearly express that their consent to research should be sought,

even in low risk pragmatic trials comparing treatments used routinely in practice.¹⁴

Must doctors participate in pragmatic trials? Gelin and colleagues argue that efforts to ensure the quality of care fall within the hospital's sphere of control and that the consent of doctors is therefore not required.¹³ Doctors “do not have a general right to resist institutional attempts to improve care.”¹³ It is certainly true that hospitals are ultimately responsible for care delivered. They have the right to set policies regarding the credentials of doctors and patient safety initiatives. Additionally, they can audit and enforce these policies, and these measures typically offer support and remedial intervention within a framework of employment law.

But when hospitals conduct pragmatic randomised trials they are no longer merely setting policy, they are doing research, which comes with its own ethical regulations. Respect for these protections is essential because research exposes participants to risks primarily for the benefit of other people. Consider Haugen and colleagues' pragmatic cluster trial of a surgical safety checklist to improve patient outcomes.¹⁵ For research purposes, surgeons were required to participate in an educational initiative, and their compliance with a safety checklist was observed and recorded. Poor compliance could have implications both for their employment and reputation, and neither of these risks is negligible. The fact that the benefit of the checklist was unknown and the potential for harms to participants highlight the importance of the general principle that doctors have a right to be free of research without their consent.

Consent is important

A duty to participate in research would probably eliminate the need for consent. But neither patients nor doctors have an enforceable or perfect duty to participate in pragmatic trials; their consent is therefore required.

But a weaker version of the duty to participate in research is plausible. In the same way that we have imperfect duties to choose how to contribute to our community or help poorer people, we should also contribute to the public good of research as we see fit. This understanding gives patients and doctors a reason to say “yes” when their consent to participate in a pragmatic trial is sought.

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