How should we understand â??clinical equipoiseâ?• when doing RCTs in development?

Description

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World Bank Blogs

Submitted by David McKenzie on 2013/09/02

While the blog was on break over the last month, a couple of posts caught my attention by discussing whether it is ethical to do experiments on programs that we think we know will make people better off. First up, **Paul Farmer** on the Lancet Global Health blog writes**:**

â??What happens when people who previously did not have access are provided with the kind of health care that most of The Lancetâ??s readership takes for granted? Not very surprisingly, health outcomes are improved: fewer children die when they are vaccinated against preventable diseases; HIV-infected patients survive longer when they are treated with antiretroviral therapy (ART); maternal deaths decline when prenatal care is linked to caesarean sections and anti-haemorrhagic agents to address obstructed labour and its complications; and fewer malaria deaths occur, and drug-resistant strains are slower to emerge, when potent anti-malarials are used in combination rather than as monotherapy.

It has long been the case that randomized clinical trials have been held up as the gold standard of clinical researchâ?¦ This kind of study can only be carried out ethically if the intervention being assessed is in equipoise, meaning that the medical community is in genuine doubt about its clinical merits. It is troubling, then, that clinical trials have so dominated outcomes research when observational studies of interventions like those cited above, which are clearly not in equipoise, are discredited to the point that they are difficult to publishâ?•

This was followed by a post by Eric Djimeu on the 3ie blog asks what else development economics should be learning from clinical trials, in which he writes:

â??In public health research, the justification for randomly assigning participants is based on clinical equipoise. This means that clinical trials are implemented only when, the researchers have substantial uncertainty (doubt) about the expected impact (efficacy) of the intervention (drug).The researchers may arrive at this conclusion after having reviewed the available research in the field. Clinical equipoise is then a necessary condition for the ethical justification of conducting RCTs. Hence, in public health, the first function of the Institutional Review Board is to ensure that clinical equipoise exists for new RCTs. But in the development sector, economists are not aware of the need to establish clinical equipoise before conducting RCTs of development interventions. Since RCTs are being increasingly used by development economists, we should start thinking about how clinical equipoise can be established for impact evaluations of development interventions.â?•

How should we understand clinical equipoise?
My problem with these posts is that they seem to be understanding clinical equipoise in terms of needing uncertainty about whether or not some intervention makes people better off, without taking into account the costs of doing so relative to â??how muchâ?• better off the intervention makes people. But we donâ??t live in a world of no budget constraints, and so the standard of clinical equipoise needs to be more along the lines of doubts over whether this use of funds makes people better off relative to any other possible use of funds in the country, or for international organizations, the world. Anyone who thinks there is not considerable uncertainty about this question is likely deluding themselves.

What does this mean in practice?

- We need to **do a much better job of documenting intervention costs** in our studies â?? this should include both the direct costs of any treatment given to individuals (e.g. the amount of grants given as transfers, or the cost of malaria nets) as well as the administrative costs involved in implementing these. It is hard to justify a study on the grounds of it being needed to compare the cost-benefit of different interventions if cost is not provided! This also relates to recent discussion by Chris Blattman on his blog of whether we should be benchmarking interventions against simply giving individuals the equivalent amount in cash: as Chris notes â??Iâ??ve seen many, many, many projects that spend $1500 training and all the â??other stuffâ?• in order to give people $300 or a cow. Is it fair to ask, what if weâ??d just given them $1800? Or what if weâ??d given six people cows? Seriously, your one guy does six times better than that?â?•
- There are hardly any treatments where entire world coverage is the likely outcome, so we are almost always in the case of having to choose who to give something good to, and of someone who could benefit from it not receiving it. This presents two reasons for randomization and experimentation: first, experimenting to learn **how to better target individuals**, when there is uncertainty as to the distribution of benefits. E.g. if we have 1000 more malaria nets to give, should we give them to pregnant mothers in Sierra Leone or families with young children in Chad? Second, the usual story of random assignment being an ethical way to give everyone who would benefit the same chance from doing so applies once you have narrowed it down to groups who you expect to benefit most.
- Finally, even in the rare cases where it is possible to try to get 100% world or country coverage, there is debate about the ethics of doing so compared to spending the money on other things. This shows up in the case of trying to eradicate polio â?? where there is debate over whether disease eradication is ethical (here is the case for). So Paul Farmerâ??s point that we know better healthcare is good is surely not sufficient â?? we need to know how good relative to other things we could be doing with the same money.
- Finally, we need to think beyond individuals and also think about the role of the collective good. This comes about most strongly in the case of interventions that may be privately undesirable but publicly desirable, but also applies when there are positive or negative spillovers â?? another area we need more research about.

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Date
16/11/2026
Date Created
02/09/2013
Author
admin