

Towards Improved and More Transparent Ethics in Randomised Controlled Trials in Development Social Science

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Abstract

Randomised controlled trials in development economics, political science, and other social science fields have been on the rise in recent decades. Recent awards and trials in development economics have re-ignited active discussions of the ethics of these trials. This note surveys common ethical concerns and proposes a series of practical suggestions to help researchers and policymakers be more mindful of and transparent about ethics as they consider, design, implement, and report randomised controlled trials and other impact evaluations in development settings.

Keywords: randomised controlled trials, ethics, evaluation

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Motivation

Randomised controlled trials (RCTs) have been increasing in international development research in recent decades (Cameron, Mishra, and Brown 2016; McKenzie 2016). Against that backdrop, researchers, practitioners, and citizens have been discussing the ethics and the efficacy of RCTs in development, including development economics (Green 2020). This discussion is not new (Angell 1997; Heckman 1991), and many of the critiques of RCTs are not unique to RCTs, rather applying to prospective field research more broadly. These debates are also not unique to economics or even to the social sciences (Concato, Shah, and Horwitz 2000; Farmer 2013). Indeed, evaluations focused on policy action may have less well developed ethical norms than research (Barnett and Camfield 2016). But the lack of novelty or uniqueness does not exempt implementers of social science RCTs from facing up to these ethical issues.

These debates can (and have) engendered much thought (Ogden 2017; Bédécarrats, Guérin, and Roubaud 2020; Rodgers et al. 2020). Defenders of RCTs argue for methodological advantages and critics challenge them (Deaton and Cartwright 2018; Banerjee and Duflo 2009). Critics highlight the ethical problems with excluding individuals from potentially beneficial treatments; defenders highlight that initial coverage for many social programs is incomplete anyway, and that random assignment of beneficiaries may be fairer than assignment through other, existing mechanisms (Mulligan 2014; Goldberg 2014; Duflo, Glennerster, and Kremer 2006). Critics propose that RCTs distract development economics from big, transformative questions; defenders argue that RCTs are still a minority of development research and that many important policy questions can be influenced by RCTs (McKenzie 2016; Chelwa 2020; McKenzie 2020). Critics highlight that informed consent (for RCT participation, not just survey participation) can be problematic with cluster randomised trials; ethicists suggest that it may not be necessary in the case of certain services (Hoffmann 2020; MacKay and Chakrabarti 2019). Critics highlight that some social science RCTs are used to test interventions that are already known to be effective; defenders propose that if an intervention can be successfully implemented in a given context or if it represents the best use of resources in that context, the intervention may still merit testing with an RCT (McKenzie 2013). The list goes on (Williams 2016).

The focus of this piece is on practical ways to improve the ethics—and the discussion of ethics—of randomised controlled trials in the social sciences. Again, many of the issues discussed are not unique to RCTs, and so many of the proposed practices would likewise be relevant to any other research involving data collection. The topics I cover in this note are not the only ones; other articles also offer practical suggestions on this topic (Glennerster and Powers 2016; Cronin-Furman and Lake 2018; Asiedu et al. 2021). I hope that readers will not only consider the suggestions offered here, but also read the deeper discussions of challenges and solutions in the research cited.

Suggestions for Planning Potential RCTs

Ask if an RCT is the best way to learn what you want to learn

If you're a practitioner, monitoring your activities and evaluating their impact is important. But not every operation is conducive to an RCT (or even an impact evaluation). Quasi-experimental methods can be effective, although practitioners should be aware that some methods (including a badly implemented RCT) can yield less useful information than no impact measure at all (Evans and Wydick 2016). As Gugerty and Karlan write, "Despite the demonstrated value of high-quality impact evaluations, a great deal of money and

time has been wasted on poorly designed, poorly implemented, and poorly conceived impact evaluations” (Gugerty and Karlan 2018). This does not mean fewer program evaluations should take place: on the contrary, many taxpayer dollars support programs with little empirical evidence of their benefit. An RCT is one of the available tools to provide that evidence.

If you’re a researcher, draw on the full range of theoretical and empirical methods (Glennerster 2018). Contrary to anecdotal narratives in economics, RCTs are not the only way to publish a development paper: in 2015, less than one-third of development papers in the top five economics journals were RCTs (McKenzie 2016). Even the profession’s most high-profile proponents of RCTs identify impacts with quasi-experimental or descriptive analysis (Banerjee, Duflo, and Qian 2020).

Ask if an RCT is justified in this situation

Two conditions which may justify a policy RCT, as Mackay writes, are policy equipoise—i.e., there is genuine doubt as to the merits of an intervention—and “just allocation of a scarce good” (MacKay 2020). As you consider an RCT, ask if there is genuine doubt about the merits of the intervention. In some cases, interventions that intuitively seem obviously beneficial have resulted in no clear impacts, as with textbook distribution in Kenya and Sierra Leone, thus whether it is possible to implement a given program effectively in a given context may also be in question (Glewwe, Kremer, and Moulin 2007; Sabarwal, Evans, and Marshak 2014). Further, economists have made the case that there is value in understanding the size of an impact locally, to understand the best way to use local resources (McKenzie 2013). If there is little doubt about the benefits of an intervention (e.g., distributing cash), then ask: are there more potential beneficiaries with equally good claims to the program than could be covered by the program? In both cases, weigh the knowledge to be gained against any risks to participants, and err on the side of caution. As Cronin-Furman and Lake put it, “The social science community at large is obligated to relentlessly question whether the scientific contribution of the final product genuinely warranted sensitive firsthand research” (Cronin-Furman and Lake 2018).

Take potential risks to participants and implementers seriously

Researchers conducting any RCT should carefully consider and document potential risks to participants. This applies beyond RCTs, to any research that involves interviewing or interacting with subjects, but RCTs require heightened scrutiny because they manipulate treatment in addition to eliciting information. In Côte d’Ivoire, implementers were concerned with risks of a political education campaign during a contentious election year, so the researchers shifted the timing of the intervention (Davis 2020).

Based on the risks, are there mitigation efforts your RCT can take? Most importantly, is the expected benefit of the results worth the risks? Interventions in humanitarian settings, often targeting extremely vulnerable beneficiaries, are a salient case of potential risks of excluding participants. One design to learn from such interventions while mitigating such concerns is to omit the control group and rather test two alternative treatments; a second is to provide benefits to all of the most vulnerable and then only randomise treatment among less vulnerable households (Quattrochi et al. 2020).

A related point arises with any survey research: if RCTs include surveys that ask about sensitive topics (such as domestic violence), how will participants be protected and supported (Alderman, Das, and Rao 2016)? In medicine, the principle of essentiality is sometimes invoked: “The research being carried out should be

essential for the advancement of knowledge that benefits patients, doctors and all others” (Sanmukhani and Tripathi 2011). While essentiality is not universally accepted as a condition for RCTs and views on what constitute essential research will vary, researchers can use this principle as a benchmark to weigh against any risks imposed (McKenzie 2016).

Engage effectively with local scholars and local populations

Local authors often have greater knowledge and understanding of institutions, as well as more of a vested interest in the well-being of the country. This is neither an encouragement of tokenism (i.e., including local authors in name only) nor a pretense that a social scientist in a given country has much in common with participants in a study on extreme poverty (Abimbola 2019). As Deaton writes, “Even in the US, nearly all RCTs on the welfare system are RCTs done by better-heeled, better-educated and paler people on lower income, less-educated and darker people” (Deaton 2020). This critique is not unique to RCTs: by one recent count, economics papers about Africa were “78 times to be written by authors without an institutional affiliation in Africa” (Panin 2020). But neither are RCTs exempt from the critique. Engaging local authors is one way to increase engagement with the research community in the country and improve the quality of the work.

In years past, one concern with engaging local scholars as authors could be a fear of adding co-authors and thus diluting credit for the work, but economics has seen a steady increase in the number of authors over time, with 80 percent of papers having multiple authors as of 2011 (Hamermesh 2013). Kuld and O’Hagan put it this way: “If present trends continue, the number of papers with four or more authors could soon exceed the number of solo-authored papers” (Kuld and O’Hagan 2017). Public health has a long history of many-authored papers.

Research participants and potential research participants can also guide researchers in determining sensible questions and how to test them in a way that protects the dignity and safety of participants, through focus groups, structured interviews, and pilot surveys.

Seek approval from institutional review boards (IRBs), including local boards

IRBs have the function of ensuring that research that involves “human subjects” (i.e., people) is carried out ethically. In high-income countries, most universities and many research institutes have an IRB. In many low- and middle-income countries, there is a local social science review board. Seeking approval for research locally—and if relevant, internationally—can be an important safeguard and can help researchers think through risks to research participants.

However, clearance from an IRB is not a substitute for engaging directly with ethical issues in RCTs and other research (O’Flynn, Barnett, and Camfield 2016). As Tony Watima wrote recently, “Being compliant does not mean it’s ethical” (Watima 2020). Some IRBs in high-income countries may have little familiarity with conditions in low-income environments, and social science review boards in lower income environments are heterogeneous in quality across countries (Cronin-Furman and Lake 2018). But engaging with IRBs still provides an essential layer of oversight for research that studies people and their actions.

Suggestions for Conducting RCTs

Ensure informed consent in data collection and engage the appropriate level of informed consent for the RCT

Almost all surveys incorporate the concept of informed consent, advising survey respondents that they are not obligated to respond to either the entire survey or to individual questions. Informed consent can be trickier with cluster randomised trials (Hoffmann 2020). For example, many education RCTs randomise at the community level, and while community leaders may be aware they are participating in a trial, individual community members may not. In some health trials, researchers have not sought consent from the control group if that might lead to observation and potential imitation of the treatment group (Glennister and Powers 2016; Lignou 2018). In government policy RCTs, informed consent may not be essential if two conditions are fulfilled. First, the government must have a “right to rule” in the sphere covered by the trial: a trial in a public school to which parents have willingly sent their children may meet this condition. (Obviously this cannot mean that governments can ethically do anything they please. This condition rests on a basic assumption of a broadly just government.) Second, data collection cannot infringe on individual rights. So data collection, particularly involving private information, would still require informed consent (MacKay and Chakrabarti 2019). When researchers are working to implement RCTs with non-government organizations, the “right to rule” is not present. Even in this case, some form of informed consent is often possible (McRae et al. 2011). This question should be reviewed by IRB and weighed against the risks to participants.

Consider providing direct benefits to your subjects, including those in the control group

Many surveys compensate respondents for their time in some way, often with an in-kind payment of some sort. There is debate about the ethics of compensating research participants, as highly vulnerable participants may be in such need that the payment acts as a disproportionately powerful incentive to participate in an RCT (or any data collection exercise). Still, some research teams adopt a principle of “no survey without service” (Osrin et al. 2009). In practice, that has taken the form of various kinds of training workshops or health information campaigns (on topics not related to the area of study) for control group participants in examples in Bangladesh, Côte d’Ivoire, India, Malawi, and Nepal (Davis 2020).

Suggestions for Writing Up RCTs

Include an explicit discussion of ethical issues

Empirical economics and some other social sciences do not have a norm of explicitly referencing ethical issues or even human subjects review in their publications (Alderman, Das, and Rao 2016). A recent query on Twitter solicited development economics papers with such a discussion and surfaced only two (Evans 2020). (Of course, there may be others, but this suggests that they are not abundant.) Asiedu et al. (2021) recently proposed a full set of questions that could be addressed in the ethics appendix of a social science paper.

To give two examples, in an RCT in Malawi examining the impact of providing “information about the true risk of HIV infection, which is much lower than people’s ex ante beliefs,” a five-page appendix section discusses a wide array of ethical issues and why the author believes that they are addressed in the study

(Kerwin 2018). In a study in the Philippines, which evaluated the randomly assigned removal of a religious values component from an ongoing skills training program, a shorter section is dedicated to discussion of ethical considerations (Bryan, Choi, and Karlan 2020). If you believe that your study poses no risks to participants and presents no ethical issues, then state that explicitly. This section can also explicitly reference the institutional review boards that cleared the project, which is common practice in medical journals.

Credit a wide range of contributions

Medical and public health journals often request that articles with multiple authors lay out the distinct contributions of each author. This is not the custom in social science studies, but it highlights the value of recognizing an array of contributions to the work. As social science RCTs write up their results, they can incorporate recognition of a range of essential roles in the project. Researchers can make sure they credit collaborators and subjects in ways that the latter feel comfortable with (Cronin-Furman and Lake 2018). One coordinated program of RCTs on the topic of cash transfers (The Transfer Project) recommends including “on behalf of the Programme X Evaluation Team” in addition to the names of the principal paper authors, with the evaluation team members elaborated in the paper (The Transfer Project 2018).

Conclusion

None of these suggestions are intended to dissuade the research community from actively engaging in careful evaluation of program and policy impacts, nor from using RCTs. Many policies and programs that consume resources go largely unevaluated (or are evaluated badly). Instead, researchers should do rigorous research in an ethical way.

Some may be skeptical of the voluntary nature of these proposals. But a recent example in economics gives hope. Not many years ago, the practice of pre-registering RCTs in economics or preparing pre-analysis plans was virtually unheard of. Now, referees at top economics journals commonly inquire whether reports of RCTs follow their pre-analysis plans. Cultural changes in how RCTs are implemented are also possible.

None of these actions (or perhaps, even all of them taken together) will form an impermeable shield against ethical criticism for a given study. There will always be debate about the ethics of RCTs in general and of particular RCTs. As Kwame Owino, CEO of Kenya’s Institute for Economic Affairs, has said, “Sometimes people study difficult things” (Green 2020), and studying difficult topics necessarily means engaging with thorny ethical issues.

However, I propose that—drawing on long experience in medicine and public health and more recent experience in the social sciences—it is possible to improve both on the ethics of RCTs and on transparency around those ethics, permitting more productive debate among both researchers and the potential beneficiaries of the research.

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