What is the Standard of Care in Development Economics?

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Abstract: Central to the experimental approach to development economics is the use of randomized controlled trials (RCTs) to evaluate the effectiveness of prospective socioeconomic interventions. The use of RCTs in development economics raise a host of ethical issues which are just beginning to be explored. In this paper I address one ethical issue in particular: the routine uses of the status quo as a control when designing and conducting a development RCT. Drawing on the literature on the principle of standard care in clinical ethics as well as considerations of distributive justice in non-ideal circumstances, I argue the practice of using the status quo as a control is largely justified. In closing, however, I add an important qualification to address the concern my assessment is overly permissive.

Keywords: development economics, randomized controlled trials, standard of care, distributive justice, non-ideal theory

1. Introduction

The use of randomized controlled trials (RCTs) to evaluate the effectiveness of prospective therapeutic interventions is a well-known scientific practice. More recently, there has been an ever-growing increase in the use of RCTs to assess the effectiveness of prospective socioeconomic interventions.[1] The findings from these RCTs can provide valuable information to local, state or federal governments, intergovernmental organizations (IGOs), international charitable non-government organizations (INGOs), and even private for-profit firms interested in effectively achieving various social and political ends.[2] Like with RCTs in clinical research, the use of RCTs to evaluate prospective socioeconomic interventions raise a host of ethical questions—many of which are just beginning to be explored.[3] In this paper, I focus on the RCTs conducted by development economists in low-income countries (henceforth, development RCTs). More specifically, I focus on the common practice of using the status quo as a control when designing and conducting a development RCT.

Examples of this practice are not hard to come by. In a landmark study on microfinance, development economists evaluated a group-lending microcredit program in the city Hyderabad, India (Banerjee et. al. 2015). 104 neighborhoods were selected for the experiment, half of which were randomly assigned to receive the treatment, which in this case was access to the services of a private microfinance institution. The other half served as a control group and did not have access to the microcredit program. In another important study on the effects of subsidizing

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[1] Abhijit Banerjee and Esther Duflo's (2011) best-selling book, *Poor Economics*: *A Radical Rethinking of the Way to Fight Global Poverty*, provides an accessible overview.

[2] However, see Cartwright and Hardie (2012) for an important discussion of the dangers of using evidence from RCTs unreflectively. Note that I make no commitments to evidence from RCTs being on the top of some evidence-ranking scheme. I only suggest that RCTs *can* provide valuable evidence of the effectiveness of some intervention. A more critical discussion on the use of RCTs can be found in Deaton and Cartwright (2018).

[3] Some recent contributions to this growing area of research from both philosophers and social scientists includes Abramowicz and Szafarz (2020); Asiedu et al. (2021); Baele (2013); MacKay (2018; 2020); MacKay and Chakrabarti (2019).

healthcare products, development economists selected twenty prenatal clinics in Kenya and randomized the price at which they could sell insecticide-treated bed nets (ITNs) to pregnant women (Cohen and Dupas 2010). ITNs are known to prevent malaria infection and are also highly effective in reducing maternal anemia and infant mortality; their widespread use also generates considerable health benefits to nonusers. In the experiment, sixteen of the clinics were assigned to four different groupings corresponding to different subsidy levels ranging from a full subsidy (free) to a 90% subsidy; the remaining four were used as a control group and did not have access to subsidized bed nets.

Using the status quo as a control unsurprisingly causes ethical uneasiness in outside observers. The residents of low-income countries in which development economists conduct RCTs live in conditions of extreme poverty.[4] Of course, the motivation behind conducting development RCTs is often to identify effective poverty-alleviating interventions, but matters are complicated by the fact that past and present injustices are at least partially to blame for the predicament of the global poor. This raises the possibility that development economists are doing something wrong in using the status quo as a control—an ethical complaint worth taking seriously.

The uneasiness many may feel about this aspect of the *experimental approach to development economics* (Banerjee and Duflo 2009) raises an important ethical question: What level of socioeconomic resources and opportunities are owed to research participants by development economists in the first place? At its core, this is a question about distributive justice, and in particular, distributive justice in *non-ideal circumstances.* To assist with the inquiry at hand, I will be drawing on helpful principles and concepts from the well-established

[4] See Banerjee and Duflo (2007) for a detailed analysis of the economic lives of the global poor.

literature on the ethics of clinical research. In particular, I will focus on the influential *principle of standard care* and its application in the context of international clinical research—a topic of considerable controversy. As will become clear, the debate surrounding the correct interpretation of the principle of standard care in international clinical research has yielded concepts and distinctions that are of relevant to the question of what is owed to research participants in development RCTs. A key objective of this paper is to determine what exactly the standard of care is in development RCTs. In brief, I will argue that development economists are typically justified in using the status quo as a control when conducting a development RCT.

Before proceeding, a word of caution: while I will be arguing that the standard of care in development RCTs very often is the status quo, this by no means should by no means be taken to suggest that there are no other ethical considerations that bear on the permissibility of conducting development RCTs. This paper primarily focuses on a specific kind of ethical concern, namely, a concern about distributive justice. In closing, I will discuss an important qualification, not based in considerations of distributive justice, that is meant to address the concern that my account is overly permissive when it comes to the standard of care in development RCTs.

2. Background Concepts and Distinctions

In this section I want to briefly identify key concepts and distinctions from general ethical theory that will play an important role throughout this paper. To start, I take justice to designate an ethical concern with what is owed to persons. What is owed to someone is fundamentally linked to their *claim rights* or *claims* more simply. When someone is owed X, or has a claim to X, they have grounds to demand X be provided to them, and if X is not provided to them, they are wronged. Questions of distributive justice are a subclass of questions about justice which

specifically deal with the level of socioeconomic resources and opportunities that persons have a claim to. As mentioned at the outset, my concern in this paper is with distributive justice and not justice broadly construed.

Next, consider John Rawls's (1971, pp. 108-117) distinction between *natural duties* and *obligations.* Natural duties "apply to us without regard to our voluntary acts" and "have no necessary connection with institutions or social practices" (Rawls 1971, p. 114). More simply, these are duties everyone has in virtue of being persons; they would apply to us in a (hypothetical) state of nature in which institutional arrangements do not exist. Natural duties can be both positive and negative; the former require us to perform certain actions while the latter requires us to refrain from performing certain actions. Perhaps the least controversial example of a negative natural duty is the duty of non-maleficence, which requires persons to not deliberately harm or injure others. Examples of positive duties include the duty of beneficence (or charity or humanity), the duty of rescue (or mutual aid), and the duty of justice, which requires us to either (i) comply with the demands of just institutions when they exist or (ii) further just arrangements when they do not exist.

Natural duties can be contrasted with obligations, which "arise as a result of our voluntary acts; these acts may be the giving of express or tacit undertakings, such as promises and agreements, but they need not be, as in the case of accepting benefits (Rawls 1971, p. 113). Two classes of obligations are relevant to the inquiry at hand. First, there are *professional obligations*; these obligations persons incur in virtue of occupying a particular professional role in society. The obligations of physicians (to be discussed more below) are an example of professional obligations. Note that these ethical requirements are obligations in virtue of the fact that physicians (or lawyers, or teachers) could have chosen another profession, hence why they

are said to arise out of voluntary acts. A second class of obligations that will play an important role are *institutional obligations;* these are obligations that one incurs because of one's institutional role or affiliation, e.g., by being employee of a government agency.[5] As we will see below, while development economists do not have professional obligations as traditionally conceived, they may have institutional obligations worth taking seriously.

Notice that, often, duties and obligations are correlated with claims. If someone has a natural duty to not harm or injure others as the duty of non-maleficence posits, that corresponds to everyone else's claim to not be subject to injury or harm. In many cases, if *s* has a claim to X, some entity has a correlate duty or obligation to provide *s* with X. For our purposes X is some socioeconomic resource or opportunity, though X could be taken to be mutual respect or assistance in the case of an emergency. The natural duty of beneficence is a noteworthy example of a duty that is not correlated with any particular individual's claims. While we may have a natural duty to promote the good of others (within reasonable limits), no particular person has a claim to our charity. This is what differentiates duties of beneficence from duties and obligations of justice—to repeat, the latter are fundamentally linked to claims.

Lastly, there is an important to distinction between ideal and non-ideal theory, which is also attributable to Rawls (1971, pp. 245-246; 1999, pp. 4-6). For Rawls, ideal theory operates under two assumptions: (i) all relevant individuals and institutions fully comply with the demands of justice placed on them; (ii) favorable historical conditions obtain, i.e., "society is sufficiently and economically and socially developed to realize justice" (Valentini 2012, p. 655). This suggests at least two ways in which circumstances may fail to be ideal and two respective approaches to non-ideal theory. *Partial compliance* theory corresponds to (i) and deals with how

[5] The link between institutional obligations and the principle of standard care in the context of international clinical research has most recently been developed in MacKay (2015).

individuals and institutions should respond to the non-compliance of others. *Transitional* theory corresponds to (ii) and deals with how individuals and institutions should bring about favorable conditions. Both approaches often overlap with one another, and this paper is no exception. First, I assume that individuals as well as institutions (be they domestic or global—and if they exist) do not fully comply with the demands of distributive justice. This means that the residents of low-income countries are not being fully granted what they are owed as a matter of distributive justice, and further, will not be granted what they are fully owed in the foreseeable future. The link to transitional theory may not be immediately apparent but like Rawls, I take a certain level of economic and social development to be a necessary precondition for just arrangements to be brought about (Rawls 1999, pp. 106-111). This links the elimination of global poverty to the demands of justice and makes the work of development economists a vital empirical component of transitional theory.

Lastly, it is worth mentioning a third approach to non-ideal theory this paper incorporates, which is a departure from Rawls's conception of non-ideal theory. For Rawls, non-ideal theory presupposes that an ideal theory has been worked out. On non-ideal theory understood as *anticipatory* theory, "non-ideal theory has to make assumptions about the minimum requirements that any *plausible* and *complete* ideal theory of justice will include (Sreenivasan 2007, p. 221), Throughout, I remain agnostic on what the *exactly* correct theory of domestic or global distributive justice requires but maintain that the global poor's share of socioeconomic resources and opportunities is well-below what any plausible theory would specify.

3. The Principle of Standard Care

In contexts entirely divorced of medical research, physicians have ethical obligations to their patients. Following Don Marquis, I refer to the following well-recognized obligation as the physician's *therapeutic obligation*: "A physician should not recommend for a patient therapy such that, given present medical knowledge, the hypothesis that the particular therapy is inferior to some other therapy is more probable than the opposite hypothesis" (Marquis 1983, p. 42). The therapeutic obligation of physicians is what has traditionally provided the basis the principle of standard care.[6] A succinct and influential statement of the principle first appeared in the World Medical Association's (WMA) 1975 Declaration of Helsinki. Paragraph II.3 reads: "In any medical study, every patient – including those in the control group, if any – should be assured of the best proven diagnostic and therapeutic method" (WMA 1975). The motivation for the principle should be clear: clinical researchers cannot withhold therapy from research subjects, and thereby knowingly make them worse-off than they would have otherwise been had they not partaken in a study, for the sake of obtaining clinically valuable knowledge. In other words, the principle of standard care specifies that clinical researchers *owe* research subjects some pre-specified level of medical resources and attention, i.e., the best proven diagnostic and therapeutic method. Providing research subjects with anything deemed *ex ante* inferior to the standard of care for some medical condition is therefore wrong.

3.1 PCTs vs. ACTs

Despite the attraction of the principle of standard care, its interpretation and application has not been uncontroversial. These controversies stem from the use of placebo-controlled trials (PCTs) instead of active-controlled trials (ACTs) in clinical research. Very quickly, the idea behind a

[6] This is not to say that all commentators agree that physician-researchers are bound by their therapeutic obligations. See, in particular, Brody and Miller (2002; 2003), who argue that the ethics of clinical practice and clinical research should be kept separate from one another.

PCT is that the control arm receives a placebo, i.e., some type of medically inert substance. In an ACT, the control arm receives a medical intervention of some sort. If the study is designed in line with the principle of standard care, then the intervention is the "best proven diagnostic and therapeutic method". It should be noted, however, that an ACT may violate the principle of standard care by providing subjects with substandard care for a treatable condition. Receiving the status quo in a development RCT is methodologically different than receiving a placebo in a PCT since research subjects will know which arm of the trial they belong to in the former case but not in the latter case. However, both practices raise similar ethical questions about what researchers owe their subjects, and so it is worth reviewing the controversies here.

The first point to note is that the principle of standard care cannot plausibly be interpreted as an absolute deontic constraint on clinical research. The debate over the use of PCTs in high-income countries illustrates this point. While PCTs may offer a higher degree of scientific validity (Temple and Ellenberg 2000) and scientific validity is itself an ethical consideration (Emmanuel, Wendler, and Grady 2000), it is quite clear that a PCT for a new treatment violates any straight-forward reading of the principle of standard care when an effective treatment already exists. Some commentators (e.g., Rothman and Michels 1994) argue that PCTs are unethical for this precise reason; they further argue that the only possible justification for a PCT is when no proven therapy exists. Giving a treatment group a promising experimental new therapy for a serious medical condition while withholding existing effective treatment for the control group seems like as clear a breach of medical ethics as one can imagine. Yet not all medical conditions are life threatening or could result in irreversible morbidity if untreated. It clearly would not be unethical, for example, to run a PCT of a new remedy for baldness, heartburn, or headaches if the subjects provided informed consent (Temple and Ellenberg 2000).

However, exposure to risk of death or irreversible morbidity should not be the only prohibition on running a PCT when an effective treatment exists. As Emmanuel and Miller (2001) point out, harm should not just be restricted to death and irreversible morbidity but also temporary suffering, severe discomfort, as well as psychological and social sources of harm that can be incurred to members of the control group in a PCT. It should go without saying that this expansive notion of harm should apply to development RCTs as well.

Due to these considerations, the section pertaining to the principle of standard care in most recent version of the Declaration of Helsinki now reads as follows:

> The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:
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> Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or
> Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.
>
> Extreme care must be taken to avoid abuse of this option (WMA 2013).

What this suggests is that the principle of standard care is nowadays taken to be defeasible. This opens two possible lines of argument for development economists trying to justify the routine use of the status quo as a control. First, they may appeal to the "no proven intervention" exemption and argue that development RCTs routinely meet it. This argument would presumably rest on epistemological premises so controversial that it is hard to take seriously.[7] Second,

[7] To advance this argument, one would have to maintain, with a straight face, that RCTs are the *only* source of evidence when it comes to evaluating the effectiveness of some socioeconomic intervention This is clearly false as there are other means of obtaining evidence on the effectiveness of some socioeconomic interventions, e.g., Bayes nets, econometric methods, and process tracing (Cartwright and Hardie 2012, pp. 36-40).

development economists may argue that development RCTs are like uncontroversial PCTs in that they do not expose the control arm to risks of serious or irreversible harm. However, as stated at the outset, development RCTs raise questions about what is *owed* to research subjects. Point out that research subjects are not harmed does not allay concerns about distributive justice; research subjects may be wronged even if they are not made worse-off by an RCT.[8] This is, of course, not to suggest that development economists should be unconcerned with potential harms to research subjects. Development economists are clearly bound by the natural duty of non-maleficence and RCT design should reflect this. Going forward, I will set aside concerns about potential harms to research subjects to focus on the main issue at hand, namely, concerns about distributive justice.

3.2 Local vs. Global Standard of Care

The principle of standard care has become linked to questions of distributive justice in light of the controversy surrounding AZT trials of the 1990s. This controversy arose in the context of international rather than domestic clinical research and is more analogous to the kind of research done by development economists. The goal of discussing the AZT trials is not to render an ethical verdict on the case, which many have attempted. Rather, it is important to review the details of the case because, as we will see, a host of helpful concepts and distinctions emerged from the debate over whether the AZT trials were ethically justifiable or not.[9]

The details of the case are as follows. In the 1990s, sixteen RCTs were designed and conducted in eleven developing countries: Burkina Faso, the Dominican Republic, Ethiopia,

[8] This is not to suggest that questions about what is owed to research subjects have no bearing on the whether they are harmed or not. Jennifer Hawkins (2008) argues that certain cases of *positive obligation flouting* count as harms. If development economists are failing to comply with certain positive duties and obligations to their research subjects, then there is perhaps a basis to say they are harming them. This view is worth taking seriously. For example, if a physician fails to provide her patient with effective treatment for a serious medical condition, the patient has a plausible ethical (and legal) basis for claiming she was harmed.

[9] See Hawkins and Emmanuel (2008) for a more detailed overview of the AZT trials.

Ivory Coast, Kenya, Malawi, South Africa, Tanzania, Thailand, Uganda, and Zimbabwe. The motivation behind these trials was to address the problem of maternal-fetal HIV transmission in developing countries. However, as early as 1994, a standard of care treatment for maternal-fetal HIV transmission had been established in the developed world. This treatment plan, known as the 076 regimen, was expensive, lengthy, and difficult to administer. At the time, the 076 regimen cost $1,000 per woman and involved large quantities of AZT (the trade name of the drug ziovudine) to be administered in an elaborate schedule over a minimum of 12 weeks starting in the second trimester of pregnancy. The goal of AZT trials was to determine whether a simpler, less expensive version of the 076 regimen would be effective in reducing maternal-fetal HIV transmission.

The controversy surrounding the AZT trials stemmed from the fact that fifteen of the trials used a placebo-control when a proven treatment already existed, i.e., the 076 regimen. The most well-known critics of the AZT trials were Marcia Angell (1997) and Peter Lurie and Sidney Wolfe (1997), who argued that the use of a placebo-control in the AZT trials invoked an ethically unacceptable ethical double standard. According to these critics, the placebo-controlled AZT trials would have clearly been unethical if they had been conducted in a high-income country, where the 076 regimen had been established as the standard of care, and therefore the same trial should be deemed unethical in the developing world. One way to understand the basis of this complaint is a disagreement about the *relevant reference point* for the principle of standard care (London 2000). Angell stressed that the "best proven" clause of paragraph II.3 of the Declaration of Helsinki should never be interpreted locally; she warned that doing so "could result in widespread exploitation of the vulnerable in the Third World for research programs that could not be carried out in sponsoring countries" (Angell 1997, p. 848). Similarly, Lurie and

Wolfe called for "a single international standard of ethical research" and also warned that "the abominable state of health care in [developing] countries can be used to justify studies that could never pass the muster in the sponsoring country" (Lurie and Wolfe 1997, p. 855). Both critics could ultimately be seen as advocating for a *global* interpretation of the principle of standard care.

In defense of the local interpretation of the standard of care, commentators such as Crouch and Arras (1998) argue that the "best proven treatment" should incorporate factors such as ease of administration and cost in addition to therapeutic benefit. This inevitably requires clinical researchers to consider the capacities and resources of a country's health system when determining the standard of care. It also requires researchers pay attention to variations in the local population that could affect factors such as therapeutic benefit and ease of administration. These are unquestionably *practical* considerations that shape research contexts and make applying a global standard of care inappropriate. As Crouch and Arras point out with respect to the AZT trials:

> In these studies, therefore, the question is not merely whether short course AZT is better than nothing. Rather, the study question is whether the shorter AZT regimen is safe in these populations, and, if so, whether the demonstrated efficacy is large enough, as compared to the placebo group, to make it affordable to the government in question (Crouch and Arras 1998, p. 2).

Defenders of a local interpretation of the principle of standard care can be seen as advocating that international clinical research should address the unique health needs of communities in the developing world and that, due to conditions of fiscal scarcity, applying a global standard of care would hamper this ethically important objective.[10]

[10] Crouch and Arras (1998) conclude that the AZT trials were ultimately still unethical because the short-course AZT regimen would still have been too expensive to implement.

Development economists will likely be sympathetic to the considerations advanced by commentators such as Crouch and Arras. After all, the RCTs designed by development economists are typically meant to address problems that are unique to the developing world, most notably extreme poverty. There would be little point to conducting an RCT on a prospective socioeconomic intervention if local governments could, given present circumstances, provide research subjects with the "standard of care" for education, healthcare, and finance found in high-income countries. Yet the worries highlighted by the critics of the AZT trials should not be disregarded by development economists. When it comes to the standard of care in international clinical research, there is an important distinction between the *de facto* and *de jure* standard of care emphasized by A.J. London (2000) that development economists eager to embrace local interpretations of the principle of standard care should bear in mind. The distinction better tracks the concern about distributive justice motivating the present inquiry, so it is important to turn to it now.

3.3 *De facto* vs. *de jure*

According to a *de facto* interpretation of the concept of standard of care, the "best proven treatment" is determined by *actual* medical practice. The *de facto* interpretation can then be combined with a local or global reference point. Applied to the AZT trials, proponents of a "global standard" could be seen as arguing that the use of placebo-controls was wrong because the actual clinical practice for preventing maternal-infant HIV transmissions in high-income countries was the 076 regimen; this would be a global *de facto* interpretation of the concept of standard care. On a local *de facto* interpretation, the use of placebo-controls was permissible because there was effectively no established clinical practice for dealing with maternal-infant

HIV transmission in the countries in which the AZT trials took place. Hence, administering a placebo did not place the control group below the standard of care.

The local *de facto* interpretation is presumably the interpretation critics of the AZT trials caution against adopting. But instead of focusing on actual medical practice, a *de jure* interpretation of the concept of the standard of care looks to what established medical practice *should* be. Like before, the *de jure* interpretation can be combined with a local or global reference point, though as we see below, this is less important when the *de jure* interpretation is grounded in the therapeutic obligations of physicians. According to London (2000), critics of the AZT trials such as Angell (1997) could more charitably be interpreted as advancing a *de jure* interpretation of the concept of standard of care. Even if the local *de facto* standard of care for some medical condition is virtually non-existent in the developing world, research subjects in low-income countries may still be entitled to more than the local *de facto* standard of care by clinical researchers *in virtue of* their roles as physicians. As London notes, "the *de jure* standard is founded upon the researcher's obligation to ensure that subjects of clinical trials are not knowingly exposed to foreseeable and preventable harms" (London 2000, p. 389). Since the medical researchers involved in the AZT trials *knew* that the best proven treatment for reducing maternal-fetal HIV transmission was the 076 regimen, they violated the principle of standard of care *because* they violated their therapeutic obligation; they therefore acted wrongly regardless of whether they were members of the relevant host communities or the larger global medical community. In the AZT trials, the purported wrongness of the experiments was therefore a failure by clinical researchers to provide research subjects what they are owed.

Not all commentators agree with the characterization of the *de jure* interpretation of the principle of standard care presented above. The motivation behind Crouch and Arras (1998)

defense of a local standard of care can still be given a *de jure* spin if the standard of care incorporates broader, practical considerations instead of narrowly focusing on therapeutic benefits. As Rebecca Kukla (2007) argues, whether an intervention *should* be made accessible to a population "depends on a complex combination of factors including economic factors, narrowly medical facts, social support systems, local preferences and values, and much more" (Kukla 2007, p. 178). But for the principle of standard of care to consider these broader, practical considerations one then needs to give up the traditional basis for the principle of standard care, i.e., the physician's therapeutic obligation, and find a new basis. On this broader interpretation of the principle of standard care, physician-researchers will perhaps routinely violate their therapeutic obligation by conducting a PCT in the developing world, but they would not necessarily be violating the principle of standard care—and it's the latter which is ultimately the more important ethical consideration.

For the purposes of the present inquiry, settling the debate over the correct interpretation of the principle of standard care in international clinical research is not the main concern. It is, however, possible to quickly rule out any global interpretation of principle of standard care as a viable ethical principle in the context of development economics. For one, it is not clear what the global *de facto* standard is given inequities in access to healthcare, education, and finance in high income countries (Kukla 2007). Further, to insist on a global *de jure* interpretation would be a paradigm example of the best being the enemy of the good.

This leaves the local *de facto* and local *de jure* interpretations as the two viable candidates. In the next section I turn to the question of whether the local *de jure* standard of care—understood in the context of development economics as an unspecified level of resources and opportunities owed to research subjects—is anything over and above the status quo, i.e., the

local *de facto* standard of care. The key obstacle to establishing a non-trivial local *de jure* interpretation is that professionally trained economists are not regarded as having the analogue of the physician's therapeutic obligation. Still, there are other avenues worth taking seriously by recent commentators on the ethics of RCTs. Ultimately, I will argue that in development economics, the local *de jure* standard of care is the status quo, i.e., the local *de facto* standard of care.

4. Grounding the Principle of Standard Care

In what follows, I proceed by making an argument by elimination to determine whether development economists owe their research subjects more than the status quo, i.e., the local *de facto* standard of care. As already mentioned, development economists do not have obligations in virtue of being members of the class of professionally trained economists. Whether a professional code of ethics would be recognized by all members of the economics profession can be developed is a question I leave open for others to explore. Given the heterogeneity of the discipline, the prospects seem dim. It is hard to imagine what professional ethical obligations a microeconomist constructing and exploring theoretical models could come to be bound by. And it would puzzling to insist that the microeconomic theorist, working in the confines of her office, has *professional* obligations to distant strangers. Philosophical interest in the ethics of development RCTs is motivated precisely by the intuition that development economists are bound by *some* ethical considerations despite not having professional obligations as traditionally conceived.

4.1 Natural Duties

As should be clear, I am not suggesting that non-physician researchers conducting RCTs (which includes development economists) are not bound by any principles of ethical research design. As Kukla (2007) has pointed out, an ethically problematic clinical trial is not automatically rendered permissible by substituting the physician-researchers with non-physicians. Using this insight, Kukla has attempted to ground principles of ethical research design in general moral requirements of justice and respect for persons, or natural duties more simply. Kukla introduces a "Minimum Standard" Principle (MSP) which is meant to extend the principle of standard care beyond the clinical context. On MSP, "researchers should not run studies unless, *to the best of their knowledge*, every trial arm receives care that is at least as good as the local *de jure* standard of care" (Kukla 2007, p. 178). Kukla is extending the notion of care to include more than just healthcare, and by invoking the concept of a *de jure* standard of care, Kukla is suggesting that there is a level of resources and opportunities that research subjects are entitled to as a matter of justice *given* the cultural and material context in which the research takes place. Going forward, the concept of "standard of care" will take on this broader meaning.

Kukla is right that research subjects are owed at least some minimum level of resources or opportunities; such a claim is consistent with most (if not all) plausible theories of distributive justice. But while Kukla's proposal is promising in that it bypasses the traditional grounding of research ethics in professional obligations, it rests on a highly controversial premise. As Douglas MacKay points out, "most political philosophers claim that it is the responsibility of *institutions*—not individuals—to provide citizens with what they are owed, whether access to health care, income, opportunities etc." (MacKay 2015, p. 8).[11] Of course, as MacKay further points out, researchers have negative duties to not interfere with research subjects' access to

[11] Two notable exceptions are Cohen (1997) and Murphy (1998). Both defend the view that individuals have positive duties of distributive justice.

what they are currently given as a matter of distributive justice, but this is uncontroversial and ultimately consistent with using the status quo as a control.

In Kukla's defense, however, it is worth pointing out that MSP is a principle that is meant to apply in non-ideal circumstances, i.e., circumstances where institutions do not comply with the demands of justice or simply do not exist. What MSP can perhaps be taken to suggest is that in non-ideal circumstances researchers have positive duties to provide research subjects with at least the local *de jure* standard of care—whatever it may be. This is still a controversial position to maintain as there is also no settled account of what positive duties persons have in non-ideal circumstances. Rawls (1971) introduces the notion of a natural duty to bring about just arrangements where they do not exist, but the exact demands of this duty are unclear given societal variations in non-compliance and favorable historical conditions (Valentini 2021). This is the chief concern of non-ideal theory understood as partial compliance theory.[12] Three types of answers are typically offered: do your fair share and nothing more; do more than your fair share by picking up the slack of others; and do less than your fair share so long as you reasonably expect non-compliance from others (Miller 2011). While I do not mean to suggest that development economists are moral saints, it does not seem like a stretch to maintain that, even by running RCTs in which the status quo is used as a control, development economists are doing more than their fair share of the duty to bring about just arrangements. Not only are they directing large amounts of resources and opportunities to low-income countries, they are also devoting their talents and abilities—which could be put to other uses—towards figuring out how to bring about just arrangements most effectively. Consequently, it is hard to maintain that

[12] Partial compliance with respect to duties of justice is only one approach to partial compliance theory. Another approach is partial compliance with respect to promoting good outcomes. This approach is taken up in Murphy (2000).

development economists would owe the control arm more than the status quo even granting that there are substantive positive duties in non-ideal circumstances. Despite this, MSP is motivated by a serious ethical concern. In the closing, I revisit the idea of a minimum standard of care by appealing to the natural duty of rescue.

4.2 Domestic Institutional Obligations

MacKay (2018; 2020) offers a much less contentious foundation for a principle of standard care in his work on *policy* RCTs, i.e., RCTs on prospective socioeconomic interventions authorized or conducted by local, state, and federal governments or their respective agencies. While some development RCTs are also policy RCTs, not all development RCTs are—a point I return to briefly. MacKay's approach rests on a key insight: governments are the kind of institutions that have positive duties to pursue justice-related outcomes for their citizens. Consequently, governments have duties to provide citizens with access to healthcare, education, and finance so that they may achieve these target outcomes. An analogue of the principle of standard care can as a result be grounded in the duty that governments have to residents within their territory. MacKay argues that for any target outcome a government has a duty to realize, governments possess a duty to implement the policy that is (i) known to be most effective in realizing that particular outcome; and (ii) consistent with the realization of other justice outcomes (MacKay 2018, p. 62). MacKay calls this the best proven, morally and practically attainable and sustainable (BPA) policy. The BPA policy is (a) consistent with residents' rights; and (b) government could implement it long-term, given a just system of resource procurement and allocation.

The BPA policy can be seen as an analogue of the local *de jure* standard of care for policy RCTs (MacKay 2018, p. 62 fn. 28). This raises the question: Do development economists

have an obligation to provide the control arm with the BPA policy? One possible way of establishing this result is by appealing to the institutional obligations development economists incur in virtue their status as *government-authorized investigators* (GAIs) (MacKay 2018, p. 64). The rationale behind this approach is that GAIs have an institutional obligation to act only in ways that a government *may* permissibly authorize. This is crucially different from saying that GAIs have institutional obligations to act only in ways that a government *actually* authorizes. The latter has clear counterexamples (e.g., the Tuskegee syphilis experiments). Yet the former offers an institutional answer to the question of what development economists owe their research subjects. Since a government may not permissibly deny its citizens what is owed to them, it follows that GAIs are not allowed to do so either. It would further follow that GAIs are required to provide research subjects with the BPA policy or local *de jure* standard of care.

Unfortunately, this proposal has serious difficulties in the context of research in development economics. First, not all development RCTs are government-authorized by a host country. Some are conducted by INGOs (discussed below) and even for-profit organizations such as development banks and private utility companies.[13] Still, it is worth considering the extent to which development economists may have institutional obligations to provide the control arm with more than the status quo. The concept of a BPA policy will likely strike development economists as extravagant due to the non-ideal circumstances in which their research takes place. This complaint is not entirely misguided; MacKay's framework is best suited for RCTs run or sponsored by the governments of high and middle-income countries. And while it would be inappropriate to characterize the circumstances of present high and middle-

[13] In one study, development economists collaborated with an international private utility company to evaluate a social program designed to increase direct household access to piped water in Tangiers, Morocco (Devoto et al. 2012).

income countries as *ideal*, the circumstances are certainly *less* non-ideal in that historical circumstances are favorable and, as a result, some institutions and policies meant to promote justice-related outcomes are in place.

Ultimately, the problem with adopting the BPA policy as the standard of care in development economics is that it would effectively render all past and future RCTs conducted by development economists unethical. It is worth repeating that part of what makes the developing world non-ideal, and what motivates the need for the kind of research done by development economists, is that governments (and perhaps other global institutions) are not providing citizens with what they are owed as a matter of distributive justice even if we adopt local standards. One does not need to identify BPA policies to know this when one considers the routine mismanagement of public resources due to elite capture and other forms of corruption that are commonplace in low-income countries. By imposing institutional obligations to provide research subjects with the BPA policy, development economists are as a result too overburdened with picking up the slack of institutional non-compliers to ever conduct an RCT permissibly.

MacKay fully acknowledges the point above and offers one way of reconciling his account of institutional obligations with non-ideal circumstances. When conducting an RCT in the developing world in which participants are exposed to policies inferior to the BPA (which I am suggesting is routine practice), MacKay suggests that "GAIs commit a *pro tanto* wrong against participants, but this wrong is outweighed by competing considerations, namely, the value of the research" (MacKay 2018, p. 65). This response is not unreasonable. Here, it is helpful to recall that in clinical research the principle of standard care is defeasible, so MacKay's proposal for non-ideal circumstances is not simply an *ad hoc* maneuver. And while perhaps it is worrisome to conclude that development economists who operate as GAIs wrong research

participants, MacKay's account is, to date, the most plausible way to reconcile actual research practices with non-ideal circumstances. Yet this only shows that development economists do something *pro tanto* wrong when they conduct a development RCT. Crucially, it does not show that they are typically unjustified, *all things considered*, in exposing research subjects to the status quo or policies inferior to the BPA policy, whatever it may be.

4.3 Global Institutional Obligations

Appealing to *global* rather than domestic institutional obligations does not offer much help either. Here, the thought would be that INGOs such as the United Nations (U.N.) or the World Bank have duties of distributive justice, and affiliation with such institutions would confer positive obligations on development economists. Similar considerations apply with the appeal to global institutional obligations as with the appeal to domestic institutional obligations. Like with domestic institutional obligations, one can maintain that development economists associated with, for example, the U.N. *pro tanto* wrong research subjects by exposing them to the status quo when the RCT is sufficiently socially valuable. But there is a more fundamental problem with this proposal: there are currently no currently existing global institutions with the coercive powers necessary to have obligations of distributive justice (Nagel 2005). Consequently, it implausible to suggest that individuals could incur global institutional obligations of distributive justice.

Another option is to appeal to what Rawls (1999) identifies as the duty of assistance to what he calls *burdened societies*. The duty of assistance is meant to apply to states,[14] but it is possible that development economists from high-income countries incur an institutional obligation to execute the duty of assistance on behalf of the high-income state in which they

[14] Rawls (1999) uses the moralized concept of *peoples* instead of states in his theory of global justice. For simplicity, I introduce the duty of assistance as a duty of high-income states.

reside. The details of this proposal need to be further worked out, but some of the considerations from the discussion of the natural duty to advance just arrangements apply here as well. Even if such of a duty of assistance were to apply to residents of high-income countries, which I take to include many development economists, it seems development economists would already complying with this requirement.

5. The Natural Duty of Rescue & Concluding Remarks

I have taken steps to establish the difficulties in maintaining that the standard of care in development economics is anything above the local *de facto* standard. My argument has been negative; I have ruled out natural duties, professional obligations, and institutional obligations as providing the basis for a *de jure* conception of the standard of care in development research. In closing, I try to provide some basis for the idea of a minimum standard of care in development economics by appealing to the natural duty of rescue.[15] The natural duty of rescue is a positive duty but not one I link to questions of distributive justice. Here, I only offer a conventional understanding of the natural duty of rescue and distance myself from attempts by some commentators, most notably Peter Singer (1972), to give the natural duty of rescue a more global, demanding interpretation.

On what I am calling a conventional understanding of the natural duty of rescue, physical proximity to an emergency is morally relevant. To use a worn-out example, if while walking to work I notice someone drowning that I can save without significant risk to myself (say I can throw them a lifesaver), the natural duty of rescue requires that I provide this stranger with my

[15] This approach similar in some ways to Hawkins' (2008) reliance on Good Samaritan obligations in her analysis of the use of PCTs in international clinical research. Besides a difference in terminology, I am using the duty of rescue to establish a minimum, whereas Hawkins combines the duty of rescue with the duties of distress avoidance and gratitude to establish something like a local *de jure* standard of care.

assistance, and the stranger in question presumably has a claim to my assistance as well. Someone on the other side of town, or in another country all together, does not have a duty to rescue this stranger because they lack either proximity to the emergency, knowledge of the emergency, or some combination of both.

The idea here is that by conducting their research in low-income countries, development economists place themselves in a special position to act on the natural duty of rescue. Their non-experimental colleagues working in the confines of their offices are not in this special position, at least not frequently. What this suggest is that by designing and conducting an RCT in which the control group is left in an emergency, development economists would be failing to act on their natural duty of rescue, and the experiment would therefore be ethically wrong to carry out. To date, I do not know of any development RCT in which researchers failed to act on their natural duty of rescue. But one can imagine, for example, a development RCT designed and conducted during a famine or some other type of emergency. In such a case, it would be wrong for development economists to not do everything in their power to address the gravity of the situation because they are bound by their natural duty of rescue.[16] Similar considerations apply to situations where an emergency develops over the course of an experiment. In such a case, development economists would have a duty to halt the experiment and direct their resources and attention to helping participants in all trial arms. While I believe what I am suggesting is relatively uncontroversial, it is important to establish a firm philosophical basis for such a minimum going forward.

[16] One can conceive of an emergency scenario where the importance of evaluating a life-saving intervention is necessary because it could help persons in similar emergency situations in the future. In such a case, perhaps the natural duty of rescue is outweighed by other ethical considerations. However, trying to figure out how to act on the duty of rescue most effectively may ultimately be consistent with the duty of rescue.

To close, I will reiterate once again that I have not set out to provide a wholesale ethical defense of the experimental approach to development economics. I have only argued here that development economists are typically justified in using the status quo as a control. There are clearly other ethical requirements that need to be met for a development RCTs to go forward. In addition to securing informed consent and demonstrating social value, development economists may also have a positive duty or obligation to meet the analogue of the *principle of clinical equipoise* (Freedman 1987), which requires the medical community to be in a collective state of uncertainty with respect to the therapeutic benefits of each trial arm of an RCT. Like with the principle of standard care, the principle of clinical equipoise is grounded in the therapeutic obligations of physicians. This suggests that an extension of this well-known ethical requirement in clinical research will not be so straightforwardly carried over to development economics. [17]

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[17] This project has already begun, and many of the papers cited in this paper have primarily concerned themselves with the task of extending equipoise beyond the clinical context. Kukla (2007) is an early first attempt and MacKay's (2018; 2020) work on policy RCTs has focused on extending equipoise to the realm of policymaking. See also Abromowicz and Szafarz (2020) for an early first discussion of equipoise in the context of development economics.

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