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The American Journal of Bioethics
Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/uajb20

Evaluating the Capacity of Theories of Justice to Serve as a Justice Framework for International Clinical Research

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Version of record first published: 16 Oct 2012.

To cite this article: Bridget Pratt, Deborah Zion & Bebe Loff (2012): Evaluating the Capacity of Theories of Justice to Serve as a Justice Framework for International Clinical Research, The American Journal of Bioethics, 12:11, 30-41

To link to this article: http://dx.doi.org/10.1080/15265161.2012.719261

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The American Journal of Bioethics, 12(11): 30–41, 2012
Copyright © Taylor & Francis Group, LLC
ISSN: 1526-5161 print / 1536-0075 online
DOI: 10.1080/15265161.2012.719261

The American Journal of Bioethics 2012.12:30-41. downloaded from www.tandfonline.com

Target Article

Evaluating the Capacity of Theories of Justice to Serve as a Justice Framework for International Clinical Research

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This article investigates whether or not theories of justice from political philosophy, first, support the position that health research should contribute to justice in global health, and second, provide guidance about what is owed by international clinical research (ICR) actors to parties in low- and middle-income countries. Four theories—John Rawls's theory of justice, the rights-based cosmopolitan theories of Thomas Pogge and Henry Shue, and Jennifer Ruger's health capability paradigm—are evaluated. The article shows that three of the four theories require the conduct of health research for justice in global health. The theories help identify the ends of justice to which ICR is to contribute, but they cannot tell us how to organize ICR to promote these ends. Aside from Ruger's health capability paradigm, the theories also lack an allocative principle for assigning specific duties to specific actors. This creates difficulties for establishing obligations for certain types of ICR actors.

Keywords: cosmopolitanism, global health, health capability paradigm, justice, international clinical research, Rawls

Redressing the inequities in health experienced by impoverished populations is not the primary function of most international health research. Dominant objectives of such research include identifying interventions to improve health in the affluent nations sponsoring the research, serving as a tool of foreign diplomacy for sponsoring nations, and boosting their economic growth (Institute of Medicine 1997). In contrast, the Commission on Health Research for Development, the World Health Organization (WHO), and bioethicists have stated that international health research partnerships should promote justice in global health (Benatar and Shapiro 2005; Commission on Health Research for Development 1990; London 2005; World Health Assembly 2010). It has been said that "advancing scientific knowledge should not be given a higher priority than reversing gross injustices in global health that exist within the [international] research setting" (Benatar and Shapiro 2005, 46). International health research ought to be a vehicle for reducing the health inequities experienced by individuals in low- and middle-income countries (LMICs).

These pronouncements, however, fail to adequately identify a basis for the contention that international research should contribute to justice. There is no clear articulation of why international research actors have obligations of justice to individuals in LMICs or what the nature of their obligations should be.[1]

This article investigates whether or not theories of justice derived from political philosophy, first, support the position that health research should contribute to justice in global health, and second, provide guidance about what is

1. Solomon Benatar and Peter Singer (2010, 196) have argued that linking international research to promoting social justice is based on the "overarching value of solidarity." However, they do not try to connect international research to broader theories of global justice or even social justice within the domestic realm. Alex London (2005) has briefly discussed international research in relation to Thomas Pogge's human rights cosmopolitanism. London argues that sponsors and researchers have a duty to aid owed as a result of their complicity in upholding the TRIPS Agreement. Medical researchers incur such obligations insofar as they are citizens of countries who uphold TRIPS or are funded by entities with such obligations. London further asserts that the duty to aid consists of advancing human development, where human development is "the project of establishing and fostering basic social structures that guarantee to community members the fair value of their most basic human capacities" (London 2005, 32). International health research constitutes one element of a larger societal system whose aim is to advance human development and so improve health. Research is then only permissible when it expands the capacity of host community health structures to meet the priority health needs of community members. Accordingly, London's human development approach holds that international clinical research is permissible if it focuses on the health priorities of the host community; integrates successful interventions into its health-related social structures; and provides other benefits that are responsive to the wider health priorities of the host community (London 2005).

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owed by external research actors from high-income countries to parties in LMICs. The focus on international clinical research (ICR) reflects the fact that it composes the largest proportion of externally sponsored health research currently conducted in LMICs (Bennett et al. 2008).

Four theories are evaluated—John Rawls's theory of justice, the rights-based cosmopolitan theories of Thomas Pogge and Henry Shue, and Jennifer Ruger's health capability paradigm. Each is assessed for the following components: the presence of principles that require the conduct of health research, health-related obligations of justice that apply to parties that perform ICR, a second-tier mechanism that allocates specific duties (toward the fulfillment of the health-related obligations) to specific ICR actors, and additional direction that can substantively guide the model and program of ICR undertaken in resource-poor settings.

In order to make the implications of each theory clear, its prescriptions are applied to the Microbicides Development Programme partnership and its recently completed Phase III PRO-2000 microbicide trial in Mwanza, Tanzania (see Box 1). The PRO-2000 trial was selected as a case study for three reasons. First, this trial was "explicitly driven by the core principles of equity, beneficence and social justice," so it was of particular interest to evaluate how it aligned with guidance derived from theories of justice (Benatar and Singer 2010, 195). Second, enough information has been published on the trial to enable analysis. Finally, it was conducted as part of a product development public–private partnership. Such partnerships have become the preferred way of public and philanthropic funders of health research to promote health in LMIC populations.[2,3]

We recognize that theories of justice are not devised to address ICR or give comprehensive guidance about its conduct. Thus, not surprisingly, aside from Ruger's health capability paradigm, such theories lack allocative principles that designate specific duties to specific ICR actors. As might also be expected, these theories do not adequately define what sort of health problems should be prioritized or give sufficient instruction from which a preferred model of ICR might be determined. Even so, it is useful to assess what guidance theories of justice are capable of providing since, at present, there is limited direction about *how* ICR can contribute to justice in global health. The article shows that three of the four theories of justice discussed support the conduct of health research to advance justice in global health. Each theory, however, nominates different relationships as being central (state–person, institution–person, and/or person–person), and this can exclude relevant ICR actors.

2. Of the more than 60 existing drug projects for neglected diseases, three-quarters are being performed by product development public-private partnerships (Moran 2005).

3. We recognize that the theories of justice may offer different guidance for other ICR partnerships, particularly ones that are not part of product development public-private partnerships. However, the process of analysis described in this article can be applied to other ICR projects and partnerships to identify what is owed and by whom.

Box 1
The Microbicides Development Programme's PRO 2000 Trial (Mwanza, Tanzania Site)

The Microbicides Development Programme is a not-for-profit, product development public–private partnership that was created to develop a vaginal microbicide for the prevention of HIV transmission. The program is funded by the Department for International Development (DFID) and the United Kingdom (UK) Medical Research Council and is coordinated by the Medical Research Council Clinical Trials Unit and Imperial College London.

The Microbicides Development Programme is comprised of 14 research institutions, of which five are located in Europe and nine are in Africa (MDP 2010). After a decade, the Microbicides Development Programme has completed a Phase III trial testing the efficacy of the microbicide gel PRO-2000 at preventing HIV infection in women. The PRO-2000 trial began in July 2002 and was completed in August 2009. It was carried out at six sites, all located in Africa (MDP 2010). If effective, the PRO-2000 gel was intended to meet the health needs of women who are "less sexually active," such as married women and women in long-term relationships (Nunn et al. 2009).

At the Mwanza, Tanzania site, the PRO-2000 trial was conducted as a collaboration between Tanzania's National Institute of Medical Research and the London School of Hygiene and Tropical Medicine. Together, these institutions have implemented a variety of research and health development projects since the late 1980s. As part of the PRO-2000 trial, some social science research was done early on, investigating the acceptability of microbicides and the barriers to their effective use in the host community (Lees et al. 2009).

The host community at the Mwanza site consisted of women aged 16 years or older who were working or had recently worked in a restaurant, guesthouse, hotel, grocery, or bar in Mwanza and were known to supplement their income through transactional sex (Shagi et al. 2008). This occupational cohort had an HIV prevalence of 25%, which was higher than the wider Tanzanian population average of 6.5% (Vallely et al. 2007). Even though a highly effective method of HIV prevention—the male condom—already exists, regular condom use was difficult for women in the host community to negotiate with their casual and/or regular sex partners (Vallely et al. 2007).

The social science research conducted as part of the trial showed that transactional sex in Mwanza is typically not performed in a private place and is often alcohol-fueled and hurried (Lees et al. 2009). Where women have sex with a regular partner, condoms have long been associated with infidelity and a lack of trust. Effective use of microbicides by women in long-term relationships will likely require covert use, and this may

deter use because if discovered it will raise doubts about their trust in their partner's fidelity (Lees et al. 2009).

Should PRO-2000 have proven a successful intervention, the endpoint of the research process would have been its licensing for distribution at a price just above its cost in Tanzania and other host countries (MDP 2010). In late 2009, however, the results of the study showed that PRO-2000 was not effective at preventing HIV transmission.

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RAWLSIAN JUSTICE

The Principle of Fair Equality of Normal Opportunity

Social-contract cosmopolitan accounts establish grounds for the global application of Rawlsian principles of justice—namely, the principle of equal liberty, the principle of fair equality of opportunity, and the difference principle (Beitz 1979; Caney 2006; Moellendorf 2002; Pogge 1989). These accounts generally do not discuss what is required by justice with respect to health. Norman Daniels has proposed a modified version of Rawls's second principle—the fair equality of normal opportunity principle, which extends Rawls's original theory to deal with disease. It clarifies what is owed by the state to individuals within that state with regard to health as a matter of justice. Daniels does not endorse the global application of his fair equality of normal opportunity principle (Daniels 2008).[4] As his work constitutes the most comprehensive account of the application of Rawlsian justice to health, this article considers the implications of upholding fair equality of normal opportunity with respect to the kind of externally funded health research a government should allow to operate within its borders.

Upholding the fair equality of normal opportunity principle requires just societies to maintain the normal functioning (an absence of pathology) of their citizens. According to Daniels, maintaining citizens' normal functioning entails meeting the following health needs: adequate nutrition; sanitary, safe living and working conditions; exercise and rest; preventative and curative health care and services; social support services; and the social determinants of health (primary social goods distributed according to Rawlsian principles) (Daniels 2008). As states are obligated to protect their citizens' health needs, this requires that institutions: (1) provide universal access to preventative and curative medical services, (2) provide universal access to traditional preventative public health measures, and (3) enact social policies that reduce inequalities in health risks (Daniels 2008).

Daniels's theory presupposes the existence of a health system and has implications for the design of health care institutions (Daniels 2001; Daniels 2008). Although Daniels does not discuss health research systems, it is asserted here that if societies are to provide access to adequate preventative and curative health care and services, his theory must assume the existence of research institutions. If health care is to be optimal rather than static, health research systems are necessary. Clinical research will comprise one component of such systems, as it provides a means to evaluate existing and new medical devices and therapies.

Maintaining citizens' normal functioning obliges states to organize their national health research systems to be consistent with the fair equality of normal opportunity principle. In part, this entails only permitting certain sorts of health research to occur within their borders—namely, research that contributes to their citizens having access to preventative and curative health care and services for health conditions present in society. If a state chooses to host ICR, it is suggested that an obligation exists to host only those ICR projects that create and evaluate preventative and curative treatments for diseases experienced in the host country and that develop interventions that are appropriate for integration into the host country's health system.

Allocating Responsibility for Upholding Fair Equality of Normal Opportunity

In Daniels's account, states may permit ICR projects that advance their citizens' normal functioning to be carried out within their borders, though these projects are not required by his theory. The relationship between state and citizen is the focus. Daniels's theory does not create obligations of justice for individuals, institutions, or governments to individuals in other countries, let alone a specific duty for them to carry out ICR in such countries. Returning to the PRO-2000 trial, Daniels's theory establishes no obligations for the external funders (DFID and the Medical Research Council), research organization (London School of Hygiene and Tropical Medicine), and the investigators from the UK and Australia involved in the PRO-2000 trial to conduct ICR in Tanzania.

Specific Duties for ICR Actors

Daniels's theory does not identify a mechanism for allocating specific duties to specific individuals within the state. It cannot tell us what specific duties of justice are held by host country parties involved in ICR, such as those involved in the PRO-20000 trial, like researchers at the National Medical Research Institute in Tanzania. Rawlsian justice, on this account, offers minimal guidance as to what is owed by a variety of ICR actors.

4. Daniels adopts a middle-ground position that, while obligations of justice exist at the global level, they are not equivalent to those that exist at the state level (Daniels 2008). In *Just Health*, he briefly describes the starting premise of what he calls the "relational" approach to global justice. In its current form, however, the "relational" approach lacks too many of the features necessary for a justice framework for ICR for an evaluation of its capacity to serve as such a framework to be useful. Since the principles of inclusion and equal concern that apply globally are vague, it is difficult to ascertain whether they require the conduct of health research in order to be upheld and to identify what health-related obligations the approach supports. As a result, we feel it is more fruitful to consider the implications of upholding the fair equality of normal opportunity principle.

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Nature of ICR

Daniels's work gives limited guidance with respect to what ICR should be permitted. His extension of Rawls's theory suggests a procedural mechanism could be relied upon to set research agendas in the context of limited resources. Clinical research priorities, including types of ICR to allow, could be identified by a fair process, where a diverse range of stakeholders determine a set of criteria for inclusion on the agenda. Daniels (2008, 118) specifies the requirements of this fair process in his accountability for reasonableness framework:

- The publicity condition (all decisions and their rationales must be publically accessible).
- The relevance condition (rationales for decisions must provide a reasonable explanation of how a [research funder or institute][5] seeks to meet the varied health needs of "a defined population fairly").
- The appeals and revisions condition (there must be mechanisms for challenge and dispute resolution regarding decisions).
- The regulative condition (there is public regulation to ensure the latter three requirements are met).

Returning to the case study, for Tanzania to set its health research priorities according to the accountability for reasonableness framework, the criteria used to make the decision to focus on specific research targets and the parties responsible for that decision must be publicly identified. Publicly accessible documents should then describe on what basis HIV microbicides are included on the agenda and who was responsible for making this choice.

To meet the relevance condition, research to develop microbicides must meet a health need of a defined population. The Microbicides Development Programme website emphasizes the need for a female-controlled HIV prevention tool, particularly in low-income countries. Social factors in Mwanza make condoms efficacious rather than effective, creating a need for alternative HIV prevention tools. Microbicides do meet a health need in Tanzania, albeit a socially constructed one.

Requiring clinical research to target "a defined population" and create outputs that meet that population's health needs "fairly" is an indeterminate criterion. In large part, this is because "a defined population" is an open-ended term. If, for example, Tanzanian stakeholders decide that the defined population is women in Tanzania, a microbicide will not meet their health need for an HIV prevention tool fairly. Microbicides are likely to be more effective for women who are less sexually active, which limits their usefulness for sex workers (Nunn et al. 2009). This means that the health need of a large proportion of poor women in Tanzania will not be met by a microbicide, resulting in inequity.

Ultimately, the accountability for reasonableness framework's relevance condition is not determinate enough to give much direction as to whether microbicides might be identified as a research target that contributes to citizens' normal functioning. Inclusion criteria, therefore, become critical. Depending on what inclusion criteria stakeholders select, the ICR that is identified as permissible in Tanzania may vary widely. Stakeholders could well identify criteria that support doing research on an HIV prevention tool for women who are less sexually active in Tanzania, or they may not. It may be reasonably decided that the preferable approach is a marketing effort supporting the use of condoms.

Setting inclusion criteria via a fair process is then very important. Unfortunately, the accountability for reasonableness framework, in its present form, does not offer enough instruction on how to implement this fair process (Rid 2009). Thus, a major shortcoming of relying on Daniels's extension of Rawls's theory as a justice framework for ICR is that it offers insufficient guidance, at present, to facilitate setting national governments' clinical research agendas.

It also provides no guidance on how ICR is to be organized or what the balance of different actors' roles is to be in it. As a product development public–private partnership, the Microbicides Development Programme is a single entity set up to develop one type of product for a single disease. Daniels's theory is silent on whether this ICR model has the features needed to promote Tanzanian citizens' normal functioning. While it may be argued that it is unfair to expect this degree of detail, it is nonetheless true to say that decision making with respect to the conduct of ICR is not greatly advanced by applying this theory.

HUMAN RIGHTS COSMOPOLITANISM: THOMAS POGGE'S INSTITUTIONAL HUMAN RIGHTS THEORY

Identifying Health-Related Obligations of Justice

Pogge's institutional human rights theory grounds obligations of justice in parties' contribution to a certain form of harm. Parties that impose an institutional scheme that foreseeably and avoidably creates human rights deficits have a duty to reform the institutional order or mitigate the particular deprivations to which they have contributed. Pogge further identifies the imposition of severe poverty, which creates deficits in access to food, water, shelter, and basic medical care, as one case of international harming that can provide a foundation for parties having obligations of rectification to individuals outside of their nation-state.

Parties that uphold international resource and borrowing privileges[6] encourage and sustain bad government and the corruption of the rulers and elites in LMICs. This, in

5. Daniels's discussion of the relevance condition refers to health care providers, not research funders or research institutes.

6. The international resource privilege is the right of regimes to sell off their countries' resources. It is indifferent to how regimes acquire their power. The right accrues to anyone holding sovereign power, irrespective of whether or not they have any sort of democratic legitimacy, and entitles them to "effect legally valid transfers of ownership rights" to their country's resources (Pogge 2007, 48). The international borrowing privilege is the right of legitimate and illegitimate regimes to borrow money in the name of their country. These privileges or rules foster bad government and corruption

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turn, engenders severe poverty. Bad government and corruption refer to regimes that have come to power by force and exercise their power through repression of the populace and violence, enacting few policies to advance their citizens' well-being (Pogge 2008). Where parties (states, institutions, companies, individuals) uphold these privileges in countries with corrupt governments, they acquire obligations to (1) reform the deprivation-generating rules and (2) mitigate their effects.

Given that deprivations in basic health care are often experienced as a direct result of poverty, mitigating the effects of impoverishment can be said to entail an obligation to alleviate poverty-related morbidity and mortality. This can be achieved by dealing with the social determinants of health and by providing (improved) access to effective and appropriate public health and medical interventions and services for poverty-related illnesses (Pogge 2008). The latter assumes the conduct of health research to develop and test the capacity of health-related goods and services. As the majority of poverty-related illnesses have effective treatments (Stevens 2007), what is required is substantial investigation into how to make existing interventions accessible—namely, health policy and systems research. In effect, Pogge's theory supports a small role for clinical research that consists of developing interventions for poverty-related illnesses that lack effective interventions.

The obligation to alleviate poverty-related illnesses can apply to public and private entities. The obligations are owed to individuals in corrupt LMICs, whose human rights deficits are largely the result of the exercise of the international resource and borrowing privileges (Pogge 2003; Ashford 2007). Consequently, such obligations may not extend to all LMICs, irrespective of the health status of their populations.

Allocating Health-Related Obligations of Justice

Pogge allocates the obligations that flow from international harming to the actors that are directly and indirectly responsible for causing the specific harm (Ashford 2007). Those agents who have a central role in supporting the international resource or borrowing privileges can be said to have direct responsibility for imposing severe poverty. In today's world, we suggest that such actors primarily consist of transnational businesses (in extractive industries), banks, and the governments of many countries.

This article is concerned with identifying grounds for obligations between existing ICR actors and individuals in LMICs. While banks and firms in extractive industries are rarely, if ever, involved in international research, high-income country governments are major funders of international health research (Global Forum for Health Research 2004). Although Pogge may argue that all high-income country governments have health-related obligations to individuals in LMICS, we argue that a stronger obligation exists if a high-income country government can be shown to have upheld the international resource and/or borrowing privilege of corrupt leaders in a specific low-income country. This will establish robust health-related obligations of justice for that government to individuals living in that low-income country.

To demonstrate the difficulty inherent in establishing this connection, evidence is next presented to attempt to show that the UK government has sustained the international resource and borrowing privileges in Tanzania over the past decade. This analysis must assume that Tanzania's leaders are corrupt, but this is also hard to prove.[7] To establish that the UK government has an obligation to alleviate poverty-related illnesses in Tanzania, either the first two or the last of the following conditions must be met:

1. The UK government has made it permissible for, sanctioned, and/or incentivized UK firms to buy natural resources from Tanzania.
2. UK firms buy natural resources from Tanzania.
3. The UK government loans money to the government of Tanzania.

If conditions 1 and 2 are met, the UK government upholds the international resource privilege of Tanzania. If condition 3 is met, it sustains the international borrowing privilege of Tanzania.

Britain is one of Tanzania's leading trading partners and one of the country's largest foreign direct investors, particularly in the agriculture, tourism, and mining sectors. Gold mining is the fastest growing sector of Tanzania's economy. The two major multinational mining companies in Tanzania—Barrick and AGA—are Canadian and South African respectively. One of AGA's major shareholders is the British company Anglo American (Melby 2008). Additionally, British mining companies such as African Eagle Ltd. operate within Tanzania. But does this state of affairs constitute strong evidence that the UK upholds the international resource privilege of Tanzania's leaders?

Clearly, the UK government permits its mining companies to operate in Tanzania, but the incentive for com-

by giving repressive rulers sources of revenue and providing incentives for parties to try to seize political power by force (Pogge 2008).

7. If we were to use Pogge's criteria for bad government and corruption (i.e., power acquired by force and used to the benefit of the ruling elite rather than the majority of citizens), it is not clear that Tanzania exemplifies those traits. Multiparty elections have been held in both 2005 and 2010 and have been overwhelmingly won by the Chama Cha Mapinduzi party. There is debate over whether these elections were free or fair, with allegations that local elections were marred by intimidation and vote buying (Geoghegan 2010; also see http://www.business-anti-corruption.com/country-profiles/sub-saharan-africa/tanzania/general-information). The elections, however, were not obvious cases of rule being taken by force. There is also no clear evidence that the Kikwete government uses its power to benefit itself rather than the people of Tanzania. The economy has grown under its leadership, but there have been corruption scandals involving ministers and leading Chama Cha Mapinduzi members. President Kikwete has been criticized for failing to effectively combat corruption and reduce citizens' poverty (Geoghegan 2010; also see http://www.business-anti-corruption.com/country-profiles/sub-saharan-africa/tanzania/general-information and http://news.bbc.co.uk/2/hi/africa/country_profiles/1072330.stm#leaders).

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panies to do so is not British law but rather Tanzanian tax and investment laws. These laws, including the Mining Act of 1998, are the product of World Bank economic reforms, which do implicate Britain, as it funds the World Bank along with other Organization for Economic Cooperation and Development (OECD) countries. Nonetheless, the United States and Japan commit more funds to the World Bank than Britain does (four and two times as much, respectively, in 2009/2010) and, in effect, have much greater voting power than the UK (World Bank 2010).

With respect to lending to Tanzania, the UK again does so indirectly through the World Bank (along with other OECD countries). Ninety-five percent of debt to the UK government by LMICs is export credit debt (Hawley 2003). Given that Tanzania does not appear to have export credit debt owing to the UK at present, it is unlikely that the UK has provided a direct loan to Tanzania's government recently (Export Credit Guarantees Department [ECGD] 2005; 2006; 2007; 2008; 2009; 2010).

As shown by this example, the fact that specific high-income countries uphold the international resource and borrowing privileges of authoritarian regimes is not necessarily easy to establish. Investigating the matter can also show that other countries—such as Canada and South Africa—have a stronger tendency to uphold the privileges.

At most, the UK government meets the minimal requirements (conditions 1 and 2) for upholding the international resource privilege. But what about other UK ICR actors involved in the PRO-2000 trial? Do they have obligations of justice to individuals in Tanzania?

Those agents who are complicit in supporting or benefiting from the international resource or borrowing privileges are indirectly responsible for imposing severe poverty. Under Pogge's theory, any institution, company, foundation, or individual that receives money from a high-income-country government that upholds the privileges, invests in multinational firms in the extractive industries, or relies on products such as computers, mobile phones, or natural-energy products derived from oil has an obligation to alleviate poverty-related illnesses.

The first requirement sufficient to establish indirect responsibility (i.e., accepting UK government funding) generates an obligation to improve poverty-related ill health in Tanzania for some British individuals, institutions, universities, and companies. This would include certain ICR actors, including DFID, the UK Medical Research Council, universities like the London School of Hygiene and Tropical Medicine, pharmaceutical companies (that accept government subsidies), and publicly funded clinical researchers, but not all.

Specific Duties for ICR Actors

Problematically, Pogge's theory does not detail a mechanism for allocating specific duties to specific actors. Although DFID, the Medical Research Council, and the London School of Hygiene and Tropical Medicine have the same general obligation of justice, it is not evident how they ought to behave in order to promote its fulfillment. The process by which obligation bearers are to fulfill their obligation to alleviate poverty-related illnesses is not addressed at present. It could involve performing ICR, other forms of research, or something else entirely.

Nature of ICR

Under Pogge's theory, the purpose of ICR is to enhance the prevention and treatment of poverty-related health conditions. The main research target of ICR is then to adapt and develop interventions for poverty-related illnesses, particularly those experienced in low-income countries. It contributes to making a basic level of health care available so that all individuals worldwide can survive and have a decent life.

To make the recommendations of Pogge's theory clearer, whether or not conducting the PRO-2000 trial (partly) fulfills (publicly funded) UK ICR actors' obligation of justice to the people of Tanzania will be considered. If we accept that HIV is a poverty-related illness for the host "community" of the PRO-2000 trial, then DFID, the Medical Research Council, and the London School of Hygiene and Tropical Medicine may have a duty to develop prevention tools appropriate for use by the host community and other individuals in Tanzania.

However, it is not clear that developing microbicides constitutes a way of meeting that obligation. Microbicides are specifically not intended for women who engage in sex work because they are thought to make women more susceptible to HIV infection if used at a high frequency (Nunn et al. 2010). Published work indicates that the social norms of transactional sex and sex in committed relationships in Mwanza do not favor the use of microbicides (Lees et al. 2009). The appropriateness of developing microbicides as a prevention tool for the host "community" of the PRO-2000 trial (women who engage in transactional sex) and for women in general in Tanzania is questionable. Thus, by carrying out the trial, DFID, the UK Medical Research Council, the London School of Hygiene and Tropical Medicine, and the principal investigators may not be fulfilling their duties of justice to the Tanzanian people.

The problem lies, in part, in the fact that the research target (microbicides) was chosen first and the host community second. Had the host community been selected first, the researchers might have been more able to develop or adapt an intervention that was more appropriate.

A notable difficulty in applying Pogge's theory to ICR is that funders, research institutes, and researchers may only owe obligations to those countries with corrupt governments with which their nation does business or lends money. Given that much of ICR is conducted collaboratively between funders and research institutes from multiple countries, this framework may be restrictive. Funders from different countries will potentially owe ICR to different LMICs. Additionally, Pogge's theory does not provide any guidance on the nature of ICR in LMICs where

the international resource and borrowing privileges are not upheld.

HUMAN RIGHTS COSMOPOLITANISM: HENRY SHUE'S INTERACTIONAL HUMAN RIGHTS THEORY

Identifying Health-Related Obligations of Justice

The central premise of Henry Shue's human rights cosmopolitan theory is that every individual worldwide is entitled to the objects of their basic rights. Basic rights are a category of moral rights and constitute individuals' minimum reasonable demands on society. They are universal and their fulfillment has the highest priority because they are essential to the enjoyment of all other rights. They consist of security rights and subsistence rights, including the right to minimal economic security, which entails unpolluted air and water; adequate food, clothing, and shelter; and a minimum of "elementary health care" (Shue 1996, 25).

Shue argues that three types of correlative duties must be performed if basic rights are to be fulfilled for individuals worldwide. They include duties to avoid depriving individuals of their only available means of security and subsistence, to protect individuals against such deprivation, and to aid the deprived (Shue 1996). In part, these duties require protecting individuals worldwide from being deprived of access to basic public health care and aiding those individuals who have been deprived of access to such care.

While the content of the duties to protect and aid could be specified in a number of ways, Shue's theory emphasizes the creation of mediating institutions (i.e., institutions established for the purpose of coordinating individual responses). Institutional implementation of the duties offers greater efficiency than individual agents' isolated and uncoordinated efforts (Shue 1988). Shue does not specify whether these institutions should be public institutions, private institutions, or both. Accordingly, it would seem that fulfilling the duty to protect, in part, entails either establishing a (branch of a) new international institution or working through existing institutions to strengthen states' capacity to make basic public health care accessible to their citizens. Fulfilling the duty to aid, in part, demands either creating a (branch of a) new international institution or working through existing institutions to make basic public health care accessible to people worldwide.

Although Shue's theory does not go further in its consideration of health, we argue that fulfilling the two health-related obligations means that the international community must perform international health research and research capacity strengthening. International health research is necessary for global justice because achieving access to basic health care for all requires testing interventions for diseases found in low-income countries for which no effective intervention exists and identifying the best strategies for the delivery of existing interventions within low-income countries. The international community must also help strengthen health research systems in low-income countries so that they can carry out health research independently.

Allocating Health-Related Obligations of Justice

All agents (individuals and organizations) have a duty to avoid depriving individuals of their basic rights. According to Shue, external agents from high-income countries acquire the primary duty to protect the basic rights of individuals in LMICs when LMIC governments are unable to fulfill it on their own. Affluent individuals have a duty to provide the substance of basic rights to people who lack them (i.e., a duty to aid) (Shue 1996).

External agents, which could include high-income country governments, nongovernmental organizations (NGOs), and transnational corporations (Shue does not specify), then have a duty to set up institutions to strengthen states' capacity to make basic public health care accessible. This includes their capacity to conduct their own health research. Once these specialized institutions are created and resourced to carry out this task, they and the individuals who work within them acquire the duty to protect basic rights.

At present, there exist global and national institutions, such as the World Bank and the U.S. Agency for International Development (USAID), with departments dedicated to improving access to basic public health care in LMICs. Returning to the PRO-2000 trial case study, of the parties involved, only DFID was created (by the UK government) to carry out health development work. It is not clear that the other collaborative partners from the UK—the Medical Research Council and London School of Hygiene and Tropical Medicine—would acquire duties to perform research capacity strengthening in Tanzania, as they were not established for development purposes.

Shue's theory allocates the duty to aid solely based upon individuals' ability to pay (Shue 1996). This is insufficient, particularly when discharging the duty involves reforming existing organizations. While the wealth criterion might identify individuals such as Bill Gates, who *is* in a position to shift the focus of a global health organization toward health care accessibility in LMICs, it also might identify Roger Federer or Gwyneth Paltrow. "Ability to pay" is an inadequate measure of the capacity to assist.[8] Given the content of the duty to aid, choosing individuals with the best capacity to fulfill this duty necessitates selecting them based on criteria such as the ability to coordinate and perform collective action, working in an organization in a field related to an aspect of subsistence or security rights such as health care provision, working in an organization that has activities in international settings, and having a relatively high-level position.

Provided that the duty to aid is allocated according to these four criteria, ICR actors (among others) may

8. Shue's allocative criterion is fairly nonspecific. While it identifies the entire range of ICR actors as bearers of health-related obligations, it also identifies a range of actors outside the health sector who are unlikely to be able to meet the obligations. In contrast, Pogge's allocative criteria can exclude relevant ICR actors. Obligations are assigned on the basis of complex relationships involving international harming, creating complex webs of obligation bearers and recipients.

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be regarded as having this duty. Individuals working in mid- to senior-level positions at DFID, the Medical Research Council, and the London School of Hygiene and Tropical Medicine then acquire a duty to aid based on their role at research institutions.[9] To some extent, individuals in these organizations may be seen to have discharged their duty by setting up the Microbicides Development Programme, a single product partnership. However, the term "elementary health care" is not defined by Shue, and, as a result, access to microbicides may or may not be part of a minimum level of care.

It is also important to note that Shue's theory works best to assist individuals in countries that are *unable* to meet their citizens' basic needs (Shue 1996). The theory may not ground as strong a duty to protect or aid citizens of states that are able but unwilling to provide basic public health care, which (somewhat like the application of sanctions) could punish populations in LMICs for the actions of corrupt dictators. Shue's theory may then not support the Microbicides Development Programme's selection of Tanzania as a host country because its leaders are plagued by corruption (Muga 2010). The duty to aid may not be owed to Tanzania.

Nature of ICR

Under Shue's framework, the purpose of health research is to enable people to meet their basic health needs. Accordingly, it would call for a large role for health policy and systems research. While it is true that clinical research is a necessary component of health care, the drugs and devices needed to provide basic public health care, for the most part, already exist (Stevens 2007). Clinical research-related innovation gaps in the provision of basic health care will likely only lie in the following areas:

1. Developing prevention interventions and treatments for diseases (found in LMICs) where none exist.
2. Developing treatments for diseases where emerging resistance or other factors have significantly reduced the effectiveness of existing treatments in a specific population.
3. Adapting and optimising existing prevention interventions and treatments so that they are accessible and affordable in resource-poor settings (e.g., vaccines that don't require refrigeration).

Provided that the criteria proposed for locating specific duty-bearers are adopted, mid-level to senior-level individuals employed at health research funding agencies and research institutes with international health departments might discharge their duty to aid by ensuring that all three of these areas of study are on their employers' research agendas.

Returning to the case study, it is debatable as to whether the Microbicides Development Programme's goal of developing microbicides constitutes a research priority under Shue's theory. An effective prevention tool for HIV already exists (condoms), though social factors compromise its effectiveness in LMICs like Tanzania. This may mean that the Microbicides Development Programme's research target qualifies under the second research area or it may not.

9. These actors may also be identified to have other duties to aid based on other roles that they occupy.

HEALTH CAPABILITY PARADIGM

Identifying Health-Related Obligations of Justice

Jennifer Ruger's health capability paradigm is a theory of justice that addresses health. The paradigm is premised on the idea that the principle of human flourishing supports a universal obligation to maintain and improve health capabilities. The principle grounds a universal duty to (efficiently) reduce shortfall inequalities in central health capabilities. Here, central health capabilities refer to individual ability and freedom to achieve certain health functionings (e.g., escaping preventable morbidity and avoidable mortality). Reducing shortfall inequalities in an individual's or population's health status refers to diminishing the gap in actual health status from the optimal level (the highest achieved worldwide). The paradigm envisions a *shared health governance* model where individuals, health goods and services providers, and health-related institutions work together to reduce shortfalls from the optimal level of health functioning (in terms of life expectancy, disease prevalence and incidence, maternal mortality rates, infant mortality rates, and other variables) (Ruger 2010).

Reaching an optimal level of central health capabilities requires a broad evidence base on the effectiveness of *appropriate* public health, health care, and social support services and on the social determinants of health in countries worldwide (Ruger 2010). This demands the conduct of a wide range of health research, including ICR.

Allocating Health-Related Obligations of Justice

Unlike the majority of cosmopolitan theories of justice, Ruger's paradigm does not stop with grounding a general obligation among actors and institutions worldwide. The health capability paradigm identifies two principles for allocating specific duties among institutions and actors—voluntary commitment and functional requirements.

Voluntary commitment means that individuals and groups must "voluntarily embrace sharing resources and relinquish some autonomy through collective action to address health problems" (Ruger 2009, 270). The functional requirements principle demands that institutions and actors have the roles, abilities, and, we suggest, the resources necessary to carry out their specific duties to remedy global health inequalities. Specific duties are distributed to institutions or actors because the functions they assume make them particularly capable of performing the duties (Ruger 2009).

Given these two principles, the primary responsibility for reducing shortfalls in health capabilities is allocated to states. Global actors and institutions are identified as having a secondary role in achieving just health outcomes. This

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is because they carry out global health functions beyond those of states. Global institutions and actors must, therefore, *support and facilitate* countries' efforts to develop and promote the health of their citizens, particularly those countries where the shortfall between its health status and the optimal level is large. Global actors and institutions can be public or private entities and include governments, international institutions, NGOs, businesses, foundations, families, and individuals (Ruger 2009).

A shared health governance model means that, where states are unable to reduce shortfalls in their citizens' health capabilities, global actors and institutions have an obligation to assist them to do so, though states—referred to here as weak states—retain the primary responsibility. Actors over a wide range then have an obligation to weak states (corrupt and noncorrupt).

Specific Duties for ICR Actors

Global institutions and actors' specific duties are determined by the nature of the global health functions that they perform (Ruger 2009). Global health actors and institutions are charged with, among other duties, *generating and disseminating knowledge and information*. As part of this duty, they must "help create new technologies; transfer, adapt and apply existing knowledge; and help countries develop information and research capacity" (Ruger 2006, 1001). Based on their expertise in conducting randomized controlled trials and research capacity strengthening in LMICs, ICR actors' functions identify them as being specifically charged with working with weak states to (1) create new health interventions, (2) adapt existing health interventions for use, and (3) strengthen their clinical research capacity.

The health capability paradigm's voluntary commitment principle further demands that actors who are allocated specific duties be willing to carry them out without being coerced. The voluntariness requirement identifies specific ICR actors, within the broader category of ICR actors, who, through their mandates and activities, have demonstrated a commitment to fulfilling the duty to generate and disseminate knowledge in order to reduce global health disparities. Examples of ICR funders whose strategy documents and practices express this commitment include the Wellcome Trust, USAID's Health Research Program, the UK Medical Research Council, WHO, DFID, the Swedish International Development Cooperation Agency, and the Novartis Vaccines Institute for Global Health (Department for Research Cooperation 2006; DFID 2008; Medical Research Council 2009; Novartis 2008; USAID 2008; Wellcome Trust 2005; WHO Special Programme for Research & Training in Tropical Diseases 2007). Failing to demonstrate voluntary commitment, however, does not absolve ICR actors from having the duty to generate and disseminate knowledge.

The Microbicides Development Programme PRO-2000 trial will be used to examine the implications of the health capability paradigm in practice. According to Ruger's criteria, Tanzania is a weak state. Life expectancy is just above 50 years for women and men (as compared with the optimal level of 82 years in Japan) (WHO 2009). DFID, the UK Medical Research Council, and the London School of Hygiene and Tropical Medicine are global institutions that fund and conduct ICR in many countries. These institutions display voluntary commitment to supporting activities that narrow the health status gap between LMICs and high-income countries. The voluntary commitment and functional requirement principles then identify DFID, the UK Medical Research Council, and the London School of Hygiene and Tropical Medicine as having specific duties to (1) create new interventions and adapt existing interventions with Tanzanian partners, and (2) build clinical research capacity in Tanzania.

The specific content of these institutions' duties varies according to their function. Accordingly, DFID and the Medical Research Council are obliged to (1) fund ICR partnerships with Tanzania to create and adapt interventions that target those health conditions that are major contributors to its citizens' shortfall health inequalities, and (2) fund clinical research capacity-building as part of these partnerships. In funding the Microbicides Development Programme, the two institutions have largely fulfilled their duty. HIV is a major contributor to the health gap between Tanzania's population and high-income country populations. In 2004, burden-of-disease estimates attributed the greatest number of deaths and disability-adjusted life years (DALYs) in Tanzania to HIV/AIDS (WHO 2008b).

The London School of Hygiene and Tropical Medicine is obliged to (1) create ICR partnerships with Tanzania to develop interventions that target the major contributors to its citizens' shortfall health inequalities, and (2) undertake clinical research capacity-building as part of these partnerships. By conducting the PRO-2000 trial with Tanzania's National Institute of Medical Research, the London School of Hygiene and Tropical Medicine meets the first part of this duty. Beyond the trial and the Microbicides Development Programme, the London School of Hygiene and Tropical Medicine and the National Institute of Medical Research have been research partners since the late 1980s. Through this partnership, the development of the latter institution's clinical trial capacity related to HIV and sexually transmitted illnesses has been supported. In doing so, the London School of Hygiene and Tropical Medicine has met the second part of its duty to Tanzania, though not necessarily through the Microbicides Development Programme partnership.

Nature of ICR

According to the health capability paradigm, the purpose of international health research is to help weak states reach optimal levels of central health capabilities at the individual and population levels. This demands the conduct of many forms of international health research, including ICR, *with* LMIC partners. When resources are limited, low-income country health needs should be the focus of international research investment because low-income countries (rather than middle-income countries) generally (though not

always) exhibit a larger gap in health status relative to the optimal level.

The international research agenda should focus on efficiently reducing shortfall inequalities in health capabilities in LMICs. Resource allocation should favor research on the health needs that are most responsible for creating the gap between specific countries' health status and the optimal level. It should prioritize the development of cost-effective interventions and services to combat (1) the health conditions that contribute the most to specific LMICs' premature mortality and escapable morbidity (disease, dysfunction, disability, etc.), and (2) the risk factors that are major contributors to people's vulnerability to those health conditions.

The paradigm endorses reducing "shortfall inequalities based on an indicator of length of life related to the central health capability of avoiding premature mortality" (Ruger 2010, 200). Mortality is one indicator. However, the health capability paradigm does not endorse using one indicator over all others. There is flexibility to rely on different measures. This is because many current measures have shortcomings. For example, there is significant debate as to whether the DALY and the age and disability weights it uses are appropriate (King and Bertino 2008). Ruger has expressed similar concerns, but the health capability paradigm does not entirely reject the DALY. High-priority interventions could then be those with the potential for high impact on reducing the mortality and/or DALY burden.

To shed more light on what such a prioritization process might mean (though at the overall low-income country level, not within a specific country) for ICR, we can look to WHO's 2004 update on the global burden of disease (WHO 2008a). The report shows that the diseases that cause the most death in low-income countries are (1) lower respiratory infections, (2) ischemic heart disease, (3) diarrheal diseases, (4) HIV/AIDS, (5) cerebrovascular disease, (6) chronic obstructive pulmonary disease, (7) tuberculosis (TB), (8) neonatal infections, (9) malaria, and (10) prematurity and low birth weight (WHO 2008a). In light of this data, the health capability paradigm would prioritize global actors funding ICR on interventions and services that target these diseases. Toward the aim of efficiency, the paradigm would further support the development of interventions for the 10 high-burden diseases that are likely to be cost-effective in LMICs. It might also direct clinical research toward filling gaps where prevention, diagnostic, and/or treatment strategies do not exist. For example, the problem of drug resistance has generated a need for new treatments for diseases like TB and malaria.

In terms of endorsing microbicide studies such as the PRO-2000 trial as a priority, the health capability paradigm's guidance is nuanced. HIV is a disease that is a major contributor to the gap in health status of both the host community and the Tanzanian population compared to populations in high-income countries. Burden-of-disease considerations aside, the health capability paradigm also emphasizes efficiency and intervention appropriateness. Although HIV is a major contributor to shortfall health inequalities in Tanzania, research on prevention technologies may not be the most efficient way of reducing the gap in health status. As shown by social science research in Mwanza, the social barriers that reduce condoms' effectiveness in Tanzania are also likely to affect microbicide effectiveness. Developing this new technology may not be the most efficient or appropriate way to prevent HIV infection in women in Mwanza or Tanzania as a whole.

Ultimately, the health capability paradigm (in its current form) does not unequivocally endorse or reject certain aspects of the Microbicides Development Programme research agenda as a priority. This creates some doubt as to whether it can offer specific guidance for the ICR agenda.

CONCLUSIONS

While what comprises justice in global health varies from theory to theory, three of the four theories of justice analyzed in this article require the conduct of ICR. These theories of global justice identify a basis for grounding the contention that ICR should contribute to justice in health.

The theories also establish that parties, including ICR actors, have health-related obligations of justice to individuals in LMICs. However, these theories can exclude relevant ICR actors and LMICs with poor population health. Daniels's theory limits obligations to the state–citizen relationship. ICR actors external to a host country are not allocated obligations of justice. Pogge's theory grounds obligations for governments, institutions, and individuals to individuals in corrupt LMICs. Obligations may not be owed to individuals in noncorrupt LMICs. Shue's theory does the opposite. Only Ruger's health capability paradigm considers the entire range of ICR actors and gives all of them obligations to any LMIC with poor population health.

Although this may create difficulty in establishing obligations for certain types of ICR actors to individuals in corrupt or noncorrupt LMICs, an even bigger problem is that, aside from Ruger's theory, the theories of justice analyzed in this article go no further than affirming that (affluent) parties worldwide owe health-related obligations to individuals in LMICs. Without additional principles for distributing responsibilities, these theories of justice offer little argument for why specific actors ought to act in specific ways. A general obligation is spread across millions of actors, leaving the majority with no idea of what they ought to be doing and why they, in particular, ought to be doing it.

None of the theories establish obligations (let alone specific duties) that necessarily require questioning either the distribution of power that underlies the system of international research for "global health" or its present organization.[10] For example, Shue's theory calls for building and reforming institutions to promote access to basic health care. This might entail setting up institutions that conduct ICR on diseases in low-income countries where no treatments exist. However, institutions are currently funding and conducting international research on treatments for neglected diseases.

10. Ruger is in the process of addressing the issue of global health governance and the organization of the global institutional system (Ruger forthcoming).

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What more does this theory then require us to do? If institutional reform is necessary, how do we identify when this is the case and how ought institutions be reformed? The present system, where the research agenda is controlled by parties from high-income countries, does not seem particularly fair or demonstrably effective at improving health in the host communities and countries of research. While we do not deal comprehensively with the matter here, it is important to note that the theories of justice investigated do not create duties that would necessarily address power imbalances at the institutional level. It has been argued that how power is distributed and exercised falls within the purview of theories of justice (London 2005). Nonetheless, frameworks derived from the four discussed theories do not have the capacity to respond to justice at the institutional level and were probably not intended to do so.

The theories of justice also do not tell us enough about the shape of an ICR enterprise that advances global justice. In making this critique, we recognize that the theories were not necessarily devised to consider ICR and prescribe rules for its conduct. The theories can help identify the ends to which ICR is to contribute, but cannot tell us how to organize ICR projects to promote these ends or what roles different ICR actors should play. These matters require further investigation. ■

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