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Health Researchers' Ancillary Care Obligations in Low-Resource Settings How Can We Tell What Is Morally Required?

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Abstract

Health researchers working in low-resource settings often encounter serious unmet health needs among participants. What is the nature and extent of researchers' obligations to respond to such needs? Competing accounts have been proposed, but there is no independent standard by which to assess them or to guide future inquiry. I propose an independent standard and demonstrate its use. In conclusion I recommend two areas of focus for future inquiry: what makes an account of researchers' obligations reasonable from the standpoint of both participants and researchers and how general duties of rescue apply to researchers' resource-allocation decision making in low-resource settings.

INTRODUCTION

Health researchers working in low-resource settings routinely encounter serious unmet health needs for which research participants have, at best, limited treatment options through the local health system (Taylor, Merritt, and Mullany 2011). A recent case discussion features a study conducted in Bamako, Mali (Dickert and Wendler 2009). The study objective was to see whether children with severe malaria develop pulmonary hypertension in order to improve the general understanding of morbidity and mortality associated with malaria. In the study team's interactions with participating children, they encountered not only malaria but also "eye infections, upper respiratory tract illnesses, rashes, pericardial effusions," and a heart defect calling for surgical correction (Dickert and Wendler 2009, pp. 428, 424). Another recent case discussion features the Nepal Newborn Washing Study (NNWS), a community-based efficacy trial of a one-time chlorhexidine skin cleansing for promoting newborn survival in a district of Nepal where most people are impoverished, over 95 percent of mothers give birth at home, and access to antenatal, obstetric, postnatal, and neonatal care is limited at best (Merritt, Taylor, and Mullany 2010; Tielsch et al. 2007). The trial enrolled 17,306 mother-infant pairs. Unmet needs encountered by the study team included poor nutritional status and a high prevalence of hookworm among pregnant women, or "less than completely" hygienic home birth environments, and common treatable morbidities among newborns (Merritt, Taylor, and Mullany 2010, p. 213).

Ancillary care (AC) is defined as health care that research participants need but that is not necessary to ensure the safety or scientific validity of the research, to redress injuries caused by research participation, or to fulfill morally optional promises (Richardson and Belsky 2004, p. 26). Do researchers have any moral obligation to provide or facilitate AC, and if so, for what reasons, for which kinds of needs, and to what extent? A 2008 peer-reviewed consensus paper by the Georgetown University Workshop on the Ancillary-Care Obligations of Medical Researchers Working in Developing Countries found existing AC guidelines and policies to be of little use. The authors of the consensus paper recommend several basic parameters for any adequate AC guidance (Participants 2008, pp. 0711–12):

four guidance points for researchers and sponsors to follow in developing their AC responses (the "four Ps"—positive duty, planning, partnership, and practical provisions [p. 0712]) and a set of questions in three categories (AC needs, available alternatives for care, and the strength of researchers' and sponsors' responsibilities [p. 0711]) to help research ethics committees (RECs), including institutional review boards, evaluate the quality of AC planning in protocols under review. Whether we accept these basic parameters as given or continue to reflect critically on them, they represent at most a starting point. Beyond establishing a starting point, a central goal of efforts to develop more robust AC guidance is to assist researchers and sponsors with the task of discerning their AC obligations in particular cases (where "case" might mean either the case of a particular protocol under design or review or the case of a particular individual or group encountered under field conditions in the implementation of an approved protocol).

In the spirit of *practical provisions*, the fourth of the consensus paper's "four Ps" (2008, p. 0712), effective AC responses will sometimes call for dedicated financial commitments on the part of the study team. Research sponsors have significant power and discretion, both at the level of across-the-board policies and at the level of budgetary considerations specific to individual research protocols, to control the financial resources available to researchers in support of AC responses. Thus, in principle, it may be fitting to regard sponsors as cobearers of researchers' AC obligations. In practice, nonetheless, the better part of the deliberative heavy lifting about AC will typically fall to researchers. It is researchers who assume ultimate responsibility for the design and day-to-day conduct of study operations during which AC needs will be encountered and any AC responses offered. Whether or not sponsors' programmatic requirements or permissions overtly encourage researchers to undertake AC responses, and whether or not RECs direct them to do so, researchers will typically be in a position to have the most complete acquaintance with AC needs and with the options for possible responses relative to their own protocols. For this reason, the discussion in the present paper regards researchers as the decision makers most in need of fuller AC guidance. Where the questions at issue closely implicate the moral responsibilities of sponsors as such, the discussion will briefly touch on these. On the whole, the moral reasoning offered here will also be of interest to regulators, RECs, research participants, community advisory boards, and others who make AC-related decisions or have a stake in them.

In order to develop more robust AC guidance, we need an adequate normative model of the AC obligation. By "normative model" I mean a systematic, critically reflective, and practically useful account of a moral obligation. Two candidate normative models have emerged in the literature on AC to date: the partial-entrustment model and the whole-person model (Belsky and Richardson 2004; Dickert and Wendler 2009). What is missing is an independent standard by which to assess how well a normative model can do its job, namely, to guide moral deliberation about whether to provide or facilitate AC. The aim of this paper is to construct the missing independent standard in the form of a set of performance criteria. In what follows, I first articulate the performance criteria with a rationale for each. I then demonstrate the use of these criteria through critical examination of existing models. I conclude by recommending directions for future inquiry to support improved performance by existing or new normative models.

WHAT DO WE WANT FROM A NORMATIVE MODEL?

Principal investigators and senior study personnel who conduct health research with human participants are authorized by sponsors and RECs to deploy significant resources in pursuit of agreed-on scientific objectives. As de facto professional executives and managers, they exercise broad discretion over resource allocation at the level of study operations. Moreover,

they may be informally empowered to leverage additional resource capacity through professional networks encompassing other actors such as locally active NGOs or private-sector organizations. When researchers anticipate or encounter AC needs among study participants, their power to influence the use of resources together with their possession of relevant technical knowledge poses the pragmatic question of how to proceed in the awareness of those needs, as in the Mali and Nepal cases.

Pragmatically available responses to particular AC needs can range all the way from "do nothing about it" to "make it your highest and most urgent priority to meet the need." In resolving the pragmatic question, the role of moral deliberation is to identify from among the pragmatically available options those courses of action, if any, that researchers are morally required to take. A successful normative model should be able to serve this deliberative purpose in particular cases by doing three things: (1) it should provide a *principled basis* for determining whether, for what reasons, and under what conditions researchers have any AC obligation; (2) it should nonarbitrarily specify the *content* of any such obligation, that is, what kinds of AC needs (if any) researchers have an obligation to address; and (3) it should nonarbitrarily locate lower and upper limits on the *extent* of any such obligation. Accordingly, I propose a set of three performance criteria.

Two overarching background concerns inform the following articulation and use of the performance criteria. One background concern is *reasonableness*, both from the standpoint of researchers as the primary bearers of any AC obligation and from the standpoint of research participants as the primary parties whose interests the idea of an AC obligation is intended (by its proponents) to serve. Part of the point of scholarship in research ethics is to challenge, refine, or modify elements of the moral reasoning operative in the international system of ethical oversight for research with human participants. The current discussion about health researchers' AC obligations is a case in point. The moral raison d'être of the ethical oversight system is to protect the rights and welfare of human research participants by enforcing constraints on the pursuit of generalizable knowledge. By entertaining an obligation to respond to participants' unmet health needs beyond what is necessary for scientific validity, safety, the redress of injury, and the fulfillment of morally optional promises, the AC discussion represents a possible expansion of the set of moral demands to be pressed on researchers on participants' behalf by agents of the ethical oversight system such as regulators and RECs. It also represents a possible selection of certain interests of research participants (or certain aspects of their interests) as morally more salient, in effect privileging these interests rather than other interests they may have as particularly worthy of the system's heightened attention. The widespread formal recognition of AC obligations would thereby alter the moral economy of the researcher-participant relation on both sides. This being the case, it is a virtue in a normative model that its account of the basis, content, and extent of any AC obligation be reasonable from the standpoint of both researchers and participants.

My understanding of "reasonableness" for the purposes of this article is, except where otherwise noted, specific to the context of research ethics. It responds primarily to a normative conception of research with human participants as a voluntary cooperative undertaking. A "reasonable" normative model of a novel moral responsibility such as the AC obligation should, when used in decision making, deliver results that could not be reasonably rejected, in the sense that they do not unduly interfere with participants' interests and researchers' otherwise morally permissible liberties (provided that the conditions already established as necessary and sufficient for the ethical conduct of human subjects research are satisfied).

A companion background concern is *precision in the assignment of moral responsibilities*. While the researcher-participant relation is the principal focus of thought about AC obligations, it does not exist in isolation from other professional and institutional spheres of moral responsibility. The interests of parties other than research participants can be relevantly set back or exposed to opportunity costs by researchers' decisions about the use of resources at their disposal for responding to AC needs. Among these other parties are, most notably, the prospective beneficiaries of researchers' scientific activities and nonparticipants in the populations from which participants are enrolled. At the same time, actors other than researchers, such as local health workers and health system agencies, may bear at least some measure of moral responsibility for responding to the needs in question. It would be a mistake to assign moral responsibility exclusively to researchers by default without canvassing the possibilities for assigning shared or full responsibility to others. For these reasons, any viable normative model of the AC obligation should take into account both the responsibilities of researchers with respect to parties other than participants and the responsibilities of parties other than researchers for responding to participants' AC needs.

THE PERFORMANCE CRITERIA

Principled Basis of AC Obligation

A successful normative model provides a principled basis for determining whether researchers have any AC obligation and for identifying the reasons why and under what conditions they might.

Do Researchers Have Any AC Obligation?—To deny that researchers ever have any AC obligations is to deny, specifically, "that there are fundamental reasons for providing care [to research participants] apart from science, safety, promise, and injury" (Richardson and Belsky 2004, p. 27). Denial of this proposition is inconsistent with a moral commitment foundational to the ethics of research with human participants: the prohibition against treating any person as a mere means (Emanuel, Wendler, and Grady 2000; Richardson 2008, p. 263). There will be at least some cases in which that commitment presents researchers with moral demands, however minimal, to provide care beyond what would be required strictly by reasons of science, safety, promise, and injury. Leah Belsky and Henry Richardson (2004, p. 1494; see also Richardson and Belsky 2004, p. 27) offer a paradigmatic hypothetical example: a study monitoring toxicity and effectiveness of an experimental drug for a rare disease in which the prohibition against treating any person as a mere means clearly requires researchers to offer at least some palliative care for a participant's underlying disease condition (assuming such care would be otherwise unavailable), even though the researchers have made no prior promise to do so, the discomfort is not caused by research procedures, and palliative care is not necessary to ensure scientific validity or safety.

Such minimal AC obligations should not be open to protocol-by-protocol deliberation but rather should just be included in the basic moral standards to be met by all protocols for research in low-resource settings.[1] The prohibition against treating any person as a mere means suffices to confirm both that some researchers sometimes have an obligation to provide AC and that in certain cases sponsors have a corresponding obligation to support the provision of AC. I assume henceforth that any viable normative model endorses this view, settling the question of *whether* researchers have any AC obligations at all.

[1]The author is grateful to Hilary Bok for comments and discussion related to this point.

The question then remains how to determine, in particular cases, whether researchers have any AC obligation in addition to what is required by the prohibition against treating any person as a mere means. Because making this determination involves examining additional possible reasons in support of AC obligations, a normative model should help its users to identify those reasons. Next, depending on the circumstances of the case, the identified set of reasons might or might not yield an AC obligation. A normative model should help its users to ascertain the conditions under which researchers have an AC obligation by relating the identified reasons, together with any countervailing considerations, systematically to the circumstances of the case at hand.

For What Reasons Might Researchers Have an AC Obligation?—It is helpful to distinguish between two types of moral duties—general and special—that can be identified as *reasons* in satisfaction of the principled basis criterion. Samuel Scheffler sets out this distinction as follows:

> According to a familiar distinction, *general duties* are duties that we have to people as such, whereas *special duties* are duties that we have only to those particular people with whom we have had certain significant sorts of interactions or to whom we stand in certain significant sorts of relations. (2001, p. 49)

A general duty is one that any moral agent has toward any other person simply in virtue of the moral status of persons. Thus, anyone who recognizes the moral status of persons will a fortiori recognize that some general duties obtain: at the very least, some form of duty not to harm. Room for controversy remains in characterizing the moral status of persons and determining more precisely what general duties derive from it. By contrast with general duties, special duties do not derive from moral status alone. Each alleged kind of special duty must be argued for in terms of the specific moral significance of the interaction or relation from which it is said to derive. This additional step in the argument adds a further layer of potential controversy. It is possible in principle to recognize the moral status of persons without recognizing any special duties. It is also possible to allow that some special duties might obtain while rejecting any given alleged kind of special duty. The possibility that there are no special AC duties remains a live option.

A prominent general duty relevant to AC is the duty of rescue: the duty to help persons in serious need whom nobody else can help, or whom one can predict that nobody else will help, when one is able to help them without serious sacrifice or risk (Richardson and Belsky 2004, p. 26). In cases in which the general duty of rescue obtains, it belongs to anyone able to help; when researchers are the only agents able to help, the duty of rescue is theirs. While it is possible to deny that anyone ever has a general duty of rescue, it is beyond the scope of the present paper to undertake a critical examination of the relevant arguments, and there are no parties to the existing AC discussion who reject duties of rescue. Proponents of existing normative models assert that researchers sometimes bear general duties of rescue toward participants (Richardson and Belsky 2004, p. 26; Dickert and Wendler 2009, p. 427). Richardson and Belsky (2004, p. 26) offer as a hypothetical example the provision of deworming drugs to children at risk of malnutrition in a remote developing-country locale. Researchers could have a rescue-based obligation to plan and implement this AC intervention “just because there may be no other doctors or hospitals in the area, or none who will help one’s subjects” (Richardson and Belsky 2004, p. 26) and because the intervention in question is cheap, simple, and urgently needed under the circumstances. In the similar real-life example of NNWS, the neonatal survival trial, the study team provided deworming drugs to pregnant women in a population with a high prevalence of hookworm (Merritt, Taylor, and Mullany 2010; Tielsch et al. 2007).

To endorse the general duty of rescue is to regard it, in virtue of its generality, as a preexisting feature of the moral baseline in the context of which researchers come to interact with participants, so that it should be considered systematically in every case as a possible reason why researchers might have an AC obligation. Normative models that endorse the general duty of rescue, whether they argue for it afresh or refer (as existing models do) to independent arguments elsewhere in the philosophical literature (McIntyre 1994; Scanlon 1998, pp. 224–28; Smith 1990), will be of limited usefulness without a duty-of-rescue component that enables users to identify applicable duties of rescue and consider them under the terms of the relevant argument(s). At the end of section 2 I discuss as a version of the duty-of-rescue component a proposal that my colleagues and I have put forward (2010).

Any argument for special duties to provide or facilitate AC will depend on some account of the specific moral significance of the fact that researchers engage in researcher-participant interactions with participants or stand in a researcher-participant relation to them (Richardson and Belsky 2004; Miller et al. 2008; Dickert and Wendler 2009). The contrast suggested by the idea of special AC duties cuts in two directions. In one direction, the contrast is with general duties. Only researchers, as contrasted with just any moral agent, engage in the relevant kinds of interactions with, or stand in the relevant kind of relation to, persons who are research participants. In a second direction, the contrast is with other kinds of special duties, such as those that derive specifically from the fact that clinicians engage in clinician-patient interactions with patients or stand in a clinician-patient relation to them. Only researchers working with human participants are authorized specifically to undertake health-related interventions and interactions with and to collect identifiable private information from living individuals in the service of a social good (i.e., generalizable knowledge) other than the health of those individuals (HHS 2009, 45 CFR 46.102[d]; 45 CFR 46.102[f]). If there are any special AC duties, they belong specifically to agents who occupy the researcher role thus understood.[2]

Proponents of existing normative models conceive of special AC duties as supplemental to baseline duties of rescue (Richardson and Belsky 2004, p. 26; Richardson 2007, p. 1957; Richardson 2008, p. 261; Dickert and Wendler 2009, p. 425). A successful argument for special AC duties would enhance precision in the assignment of moral responsibilities by sharply distinguishing the duties of researchers (as such) to participants (as such) from other duties (whether general or special) that either researchers or nonresearchers might also bear.

Under What Conditions Might Researchers Have an AC Obligation?—A normative model should provide a principled basis for determining the *conditions under which* the moral reasons in favor of providing or facilitating AC (whether general duties or special duties or both in some combination) indicate an AC obligation. Decision makers should be able to use the model to relate the identified pro-AC reasons, together with countervailing considerations, systematically to the circumstances of the case at hand.

Attention to the background concerns of reasonableness and precision in the assignment of moral responsibilities will help to organize common countervailing considerations. Under the heading of reasonableness from the standpoint of participants, an example of a countervailing consideration is the possibility of undue inducement (Emanuel, Currie, and

[2]The understanding of the researcher role outlined here refers to the definitions of “research” and “human subject” found in the Common Rule (HHS 2009). This understanding is consistent with the definition of research involving human subjects found in the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS 2002, preamble), except that the CIOMS definition more broadly allows for obtaining information about individuals “who may or may not be identifiable.” I do not pursue variations among national and international classifications of human subjects research in this article. We should concern ourselves in the first instance with the type of case that centrally raises questions about the AC obligation. I take it that the Common Rule definitions of “research” and “human subject” together delimit that type of case.

Herman 2005). Reasonableness from the standpoint of researchers will flag considerations such as the possible impact of a particular kind of AC response on scientific outcome measures in the case at hand. Under the heading of precision in the assignment of moral responsibilities, the interests of prospective beneficiaries of scientific research will reinforce considerations of scientific validity. The interests of nonparticipants in the local population will introduce considerations such as the risk of supplanting or undermining the local health system by setting up parallel health service delivery for AC. The possibility of assigning moral responsibility for addressing certain unmet needs to other actors, in whole or in part, will open up the consideration of available alternatives to courses of action in which the study team would assume sole responsibility (Participants 2008, p. 0711, box 1).

Content of AC Obligation

A successful normative model nonarbitrarily specifies which kinds of AC needs (if any) researchers have an obligation to address. In low-resource settings, researchers may anticipate or encounter a vast array of unmet health needs, including not only needs for preventive and therapeutic biomedical interventions but also needs for food, water, sanitation, education, and infrastructure. Such needs are especially salient in public health studies where researchers' interactions with individual participants occur in the midst of community living spaces or where the main unit of research interest is a community, population, or geographical district (Merritt, Taylor, and Mullany 2010; Hyder and Merritt 2009). Researchers conducting a public health study of chronic disease could encounter a need for infrastructure development such as ramps for people with disabilities, and researchers conducting a public health study of infectious diseases could encounter a need for training community health workers and building soak pits for households (Hyder and Merritt 2009). The variety and multiplicity of AC needs broadens the range of pragmatically available responses that might be morally required.

A successful normative model will function as a guide to moral deliberation for cases in which there are many kinds of AC needs that researchers might opt to address but no viable means of addressing them all, so that they must decide either to address no AC needs (a pragmatically available option in any case) or to address some kinds of AC needs rather than others. For cases in which a normative model grants researchers moral permission to do nothing about some or all of the AC needs at issue, it should provide a justification that is reasonable from the standpoint of participants. For cases in which a normative model places moral demands on researchers to address AC needs and to prioritize certain kinds of AC needs over others, the model should provide a justification that is reasonable from the standpoint of both participants and researchers.

Extent of AC Obligation

A successful normative model nonarbitrarily locates a lower and upper limit on the extent of any AC obligation. Any assertion of duties to aid others will raise worries about demandingness. Such worries underlie a philosophical tradition of greater skepticism about duties to aid than about duties not to harm. As Lichtenberg notes, "A critical concern is that once we admit duties to aid into the moral realm they threaten to take over and invade our lives: it is hard to draw a line that will prevent them from becoming relentlessly demanding" (2010, p. 557). The most thoroughly worked-over territory concerning philosophical debate about duties to aid is the realm of choices open to affluent individuals in relation to the needy. The AC discussion brings a different perspective to these debates. With respect to the AC obligation, the most pointed worry about demandingness is that duties to aid participants might overwhelm health researchers' scientific projects when these are themselves undertaken as contributions to the promotion of health for people in need.

Normative models that endorse general duties of rescue will locate a lower limit for the AC obligation that is to be set by applying to the case at hand the arguments they use to justify such duties. Models that assert special AC duties in addition to general duties will locate a more demanding lower limit for relevant cases.

Next, in keeping with the background concern for precision in the assignment of moral responsibilities, the interests of the prospective beneficiaries of scientific results help to establish, in principle, an upper limit on the extent of what any AC obligation can demand of researchers. The authors of the 2008 consensus paper address this issue in one of their objections to the "expansive position," which they portray as making the following claim (Participants 2008, p. 0710): "The world being pervasively unjust, medical researchers from the developed world and their sponsors have a duty to do all they can to address all of the ancillary-care needs they encounter." The relevant objection to the expansive position runs as follows:

> Medical research in general, and in particular much of the medical research conducted in developing countries, is directed towards easing people's health burden, which, in the developing world, is severe. Meeting all encountered ancillary-care needs would strain budgets and monopolize the scarce time of trained personnel. Unlimited ancillary-care demands would impose heavy costs on medical research and would very likely have an inhibitory effect. Therefore, imposing this level of cost on the research enterprise is ethically unreasonable. (2008, p. 0710)[3]

As this objection is framed, the conclusion (that "imposing this level of cost on the research enterprise is ethically unreasonable") appears to rest on an empirical claim that unlimited AC demands would be likely to discourage just the sort of health research that is needed in order to alleviate global health disparities. As compared with a scenario in which AC demands are limited, less research of the needed sort would be done and less benefit would accrue to people in need as a result.

However that may be, a conceptual claim to support the same conclusion is also available. First, let us make the plausible factual assumption that global health disparities cannot be alleviated without undertaking some research with human participants, under whatever research agenda is indicated by relevant parameters of health science and policy (World Health Organization, forthcoming). Next, let us stipulate that we are concerned only with the set of particular research protocols whose scientific results are reasonably expected to help alleviate global health disparities (a stipulation already implicit in the framing of the 2008 consensus paper's objection to the expansive position). This is to say that populations suffering from global health disparities are strongly represented among prospective beneficiaries of the expected scientific results. Let us stipulate further that within this set of protocols, we are concerned only with those that are, in all other relevant respects, morally permissible to carry out, on the grounds that they satisfy the ethical principles that are necessary and sufficient to justify research with human participants (Emanuel, Wendler, and Grady 2000). The resulting subset, far from being empty, contains countless actual and possible research protocols. Any given protocol in this subset will pursue via morally permissible procedures some scientific objective(s) that, if met, will contribute to improved

[3]In the same passage, the authors of the consensus paper mention three other objections against the expansive position. Of these, two express the background concern for precision in the assignment of moral responsibilities: one to say that researchers as such, provided that their research activities are nonexploitative, should not be assigned greater responsibility than any other affluent individual for the alleviation of global injustice; another to say that if researchers were to comply with the moral demands of the expansive position, they would often trespass on the domain of local actors' preexisting responsibilities to address the health needs in question. A further objection expresses the background concern for reasonableness, invoking research participants' interest in not being subjected to undue inducement.

health status for some of the neediest people on earth. Under any such protocol, it is necessary to dedicate some minimum amount of resources to ensuring the timely production of high-quality, scientifically valid results, and it would be incoherent to undertake the research effort while simultaneously conceiving of these same resources as freely available to meet participants' AC needs. Thus it is not only counterproductive but self-contradictory, from the standpoint of whatever commitment to global justice is supposed to require the production of the scientific results at issue, to construe the AC obligation as so extensive that it undercuts the minimum amount of resources needed to produce those very results. By this reasoning (and setting aside the possibility of gaming the system by adding in scientific objectives that are unduly costly in proportion to the expected global health benefit), it is possible in principle to locate an upper limit on the extent of what any AC obligation can demand of researchers with reference to any protocol in the stipulated subset.

A complete formulation of the conceptual claim, however, needs to address directly the AC obligations of research sponsors as such. For any given set of scientific objectives in a research protocol, a sponsor could have an obligation to make additional resources available so as to support researchers' provision of AC in association with that protocol while protecting the minimum amount of resources needed to produce the intended scientific results. This possibility raises questions about opportunity costs at the level of sponsors' decision making about resource allocation. Relevant opportunity costs include reductions in funds available to support research protocols of comparable promise. Continuing with the same line of objection against the "expansive position" as just articulated, there is no reason to think that considerations of *global justice* generate stronger moral obligations for research sponsors to support AC over additional research needed to alleviate global health disparities. If a particular sponsor could more effectively serve the ends of global justice by shifting some portion of its resources into support for the provision of health care, it would normally be more efficient to do so via direct health care programming rather than by piggybacking on research activities.

Sponsors' obligations to support AC (in addition to what is required by the prohibition against treating any person as a mere means) derive primarily from whatever reasons independently ground researchers' obligations. Whenever researchers have AC obligations for those reasons, the financial burden of meeting them is reasonably assigned to sponsors. While it is not possible to set a precise upper limit on the extent of the moral demands that thereby apply to sponsors, the demands are limited in principle by sponsors' competing moral responsibilities. The onus to demonstrate otherwise is on the advocate of more expansive AC obligations for sponsors.

In sum, a normative model of the AC obligation can satisfy the extent criterion simply by being consistent with the foregoing accounts (or some comparably plausible accounts) of lower and upper limits on what the obligation demands.

USING THE PERFORMANCE CRITERIA

Proponents of existing normative models have introduced them in the spirit of beginning and continuing the conversation about AC. The constructive aim of the following critical discussion is to advance that conversation by demonstrating the value of the performance criteria I have proposed, as illuminated by the background concerns of reasonableness and precision, for directing future inquiry about AC obligations. For each of the two existing normative models currently on offer, the partial-entrustment model and the whole-person model, I describe the model, briefly assess its satisfaction of the performance criteria, and offer a critique of its performance with an eye to reasonableness and precision. I then describe a proposed version of the duty-of-rescue component and assess its potential to

enhance the performance of these normative models or others into which it could be incorporated.

THE PARTIAL-ENTRUSTMENT MODEL

Description

Belsky and Richardson's partial-entrustment model was the earliest normative model proposed (Belsky and Richardson 2004; Richardson and Belsky 2004). Richardson has since continued to develop it (Richardson 2007; Richardson 2008; Richardson, forthcoming). The partial-entrustment model's distinctive contribution is its argument for the existence of special AC duties over and above the baseline duties of rescue. This argument employs an innovative philosophical conception of the informed consent process and its moral significance as follows (Richardson 2011; see also Richardson 2008, p. 264).

Suppose that A, a researcher, and B, a prospective participant to be recruited for A's study, are complete strangers to one another. Regarding actions that A might take in response to B's unmet needs, the baseline state of affairs between them is that B bears by default certain responsibilities for looking after his or her own needs and A bears at most only general obligations, such as those based on duties of rescue, toward B.

When A (or a study worker acting as A's agent) seeks B's voluntary informed consent to participate in A's study, A is soliciting for his or her own research purposes B's waiver of certain rights to privacy regarding some scientifically circumscribed set of facts about B: typically B's body, B's health conditions, B's behavior, B's personal experiences, opinions, or attitudes or identifiable private information about B recorded elsewhere (HHS 2009, 45 CFR 46.102[f]).[4] Suppose that B voluntarily agrees to the privacy waiver that A has solicited, whereupon A voluntarily accepts B's agreement. B is now enrolled as a participant in A's study. Richardson (forthcoming) argues that B's agreement to the privacy waiver constitutes a "transfer or delegation" to A of some of the responsibilities that belonged by default to B before B consented to participate in A's study. That is, B's granting of permission to A to collect and use a set of private facts about B "temporarily entrusts the permittee [A] with the carrying out of some of these responsibilities" (Richardson, forthcoming). Richardson (forthcoming) argues further that such entrustment can (depending on how other factors play out) generate special obligations of beneficence, namely, "special ancillary-care obligations," which A now bears toward B in addition to whatever general obligations A bore toward B under the pretransaction baseline circumstances. The scope of these special ancillary-care obligations is limited to precisely the set of facts regarding which B has agreed to the privacy waiver solicited by A, for the reason that precisely these facts are the focus of the responsibilities that B temporarily entrusts to A via the privacy waiver.

In locating particular AC needs inside or outside the scope of partial entrustment, the model makes no empirical suppositions about what (if anything) participants actually take themselves to be "entrusting," in the more colloquial sense, to researchers by consenting to participate. Nor does it make any empirical suppositions about what (if anything) researchers take themselves to be accepting in trust from consenting participants. In the case

[4]To be clear: the privacy rights that A can permissibly even ask B to waive are themselves tightly constrained by the ethical requirements of research with human participants. Whereas at baseline, B has a right to protect the facts at issue from A's scrutiny as from everyone else's, A is seeking B's permission to learn these facts about A and to use them for the stated scientific purposes (as A is morally required to describe to B), all under strict conditions that are subject to prospective and continuing independent ethical review. For instance, the moral permissibility of A's soliciting the requested waiver of B's privacy rights would normally be conditional on A's assumption of full responsibility for protecting the confidentiality of information about the facts that B, by consenting to participate, would agree to disclose to A.

of any particular research protocol, the scope limitation identifies the needs that are eligible for special AC duties solely by applying the theoretical construct of partial entrustment to the content of the privacy waivers to be solicited in the protocol's informed consent process (Richardson and Belsky 2004, pp. 27–28, p. 30).

Thus, under Richardson's conception of informed consent, when participants consent to specific research procedures such as blood draws or radiological imaging, they implicitly entrust to researchers part, but only part, of their health: those aspects of their health about which precisely the research procedures to which they have consented might reveal, to the researcher's expert eye, clinically significant information indicating the presence of AC needs. For example, when researchers perform pelvic exams to which participants have consented for purposes of data collection in a trial of antimicrobials to prevent sexually transmitted infections (STIs), they might learn that some participants have vaginal candidiasis, a treatable fungal infection (Belsky and Richardson 2004). The contrast is with needs that would be evident anyway, such as a treatable dental condition that is readily apparent when someone smiles. In this hypothetical example, conditions of reproductive health that can be diagnosed only through the research-related pelvic exam are implicitly entrusted and are therefore located inside the scope of partial entrustment, whereas casually observable dental conditions are excluded (Belsky and Richardson 2004).

Being located inside the scope of partial entrustment is necessary but not sufficient for a given AC need to generate an AC obligation based on the associated special duty. Once the scope limitation is established, the second step in using the partial-entrustment model is to focus selectively on the AC needs inside that scope, assessing the strength of participants' moral claims on researchers to respond to those needs under the circumstances of the case at hand. A moral claim is supposed to be stronger the higher the degree of participants' vulnerability, the greater the extent of participants' uncompensated research-related risks or burdens, the greater the intensity and the longer the duration of the researcher-participant relationship, and the higher the degree of participants' dependence on researchers as agents who may be, under local circumstances, uniquely able to respond. A moral claim is supposed to be weaker the more limits there are on resources available to researchers and the greater the likelihood of confounding study results or undercutting study power. Any of these factors alone or several together might affect the strength of a moral claim (Belsky and Richardson 2004; Richardson 2007).

In the hypothetical trial of antimicrobials to prevent STIs, the final decision reached by the use of the partial-entrustment model is that the researchers have an AC obligation, based on special AC duties, to treat vaginal candidiasis. To recap, the first step in using the model locates this condition—but not, by contrast, a readily apparent dental condition—inside the scope of partial entrustment with respect to the STI protocol. In the second step, application of the strength-assessment framework concentrates attention on participants' high degree of vulnerability, in the sense that if the researchers chose not to treat vaginal candidiasis it would "greatly affect" participants' well-being for the worse, and on the researchers' ability to treat the condition easily and at low cost (Belsky and Richardson 2004, pp. 1495–96). The fact that the participants are highly vulnerable strengthens their moral claim on the researchers and the fact that the condition is easily treatable shows that this moral claim is not weakened by any constraints on the researchers' available resources. Richardson further illustrates how the partial-entrustment model can be used across varying cases at the protocol-by-protocol level without resorting to "intuitive weighing" on the one hand or, on the other hand, purporting to calibrate incommensurable factors "along a single metric" (2007 p. 1959).

Satisfaction of Performance Criteria

The partial-entrustment model satisfies the principled basis criterion by entertaining both general duties of rescue and special AC duties as reasons why researchers might have AC obligations. As for the conditions under which researchers have any AC obligation in a particular case, the model focuses its strength-assessment framework primarily on the subset of AC needs that are located inside the scope of partial entrustment, namely, those needs regarding which researchers have implicitly assumed the responsibilities transferred or delegated to them through their solicitation and acceptance of participants' research-related privacy waivers. The partial-entrustment scope limitation, by purporting to determine precisely which kinds of needs are eligible for special AC duties in any particular case, satisfies the content criterion with respect to special duties. The partial-entrustment model in its current form leaves open to its users the choice of some reasonable way to identify applicable duties of rescue and to assess their strength (i.e., a duty-of-rescue component).

Regarding the extent of moral demands placed on researchers by any AC obligation, consider first the lower limit: is there a morally required minimum response to AC needs? As the partial-entrustment model endorses baseline duties of rescue, it locates in principle a lower limit accordingly. Moreover, in asserting that researchers can also have additional AC obligations based on special AC duties depending on the circumstances of the case, Richardson and Belsky thus maintain that in certain cases the morally required minimum response to AC needs is some significant level above what duties of rescue alone would require. Consider next the upper limit: at what level does a possible AC response become so demanding that it cannot be morally required? The consistency of the partial-entrustment model with the account of the upper limit that I have provided could be assured by incorporating into its strength-assessment framework the moral importance of producing scientific results reasonably expected to alleviate global health disparities. This modification would be continuous with the existing moral reasoning implicit in the strength-assessment framework, according to which the possible confounding of study results or undercutting of study power is a countervailing consideration that can legitimately weaken moral claims associated with special AC duties.

Critique

The partial-entrustment model excels at precision in the assignment of moral responsibilities to researchers as such for addressing certain needs of participants as such. But it does not yet explicitly address precision regarding researchers' moral responsibilities toward parties *outside* the researcher-participant relation, such as otherwise similarly situated non-participants, and it faces challenges with respect to reasonableness from the standpoint of each party *within* the researcher-participant relation.

Researchers' Moral Responsibilities toward Outside Parties—The very use of any normative model that asserts special AC duties potentially exposes the interests of parties outside the researcher-participant relation to the opportunity costs of researchers' resource-allocation decisions involving AC. As a representative example, let us consider a hypothetical case in which researchers have at their disposal some discretionary resources that would suffice to provide some needed and otherwise unavailable health interventions, either to research participants in the form of AC or to members of the local population at large in the form of interventions to be distributed without regard to a person's status as research participant or nonparticipant.[5]

[5]Examples approximating this type of case are documented by empirical findings of the author and colleagues in a manuscript currently under review.

Suppose that a team of researchers is conducting a study of associations between maternal oral health and newborn morbidity in a remote rural setting where advanced dental care is absent. The study will last two years and will enroll 10,000 mother-infant pairs. Suppose further that the study team is entertaining two options that are mutually exclusive under the circumstances. Option 1 is to hire and equip, for the duration of the study, a dedicated study dentist qualified to treat common varieties of acute dental conditions (tooth abscess and the like) for all and only research participants on an on-call basis. Option 2 is to hold a series of well-publicized dental camps at periodic intervals over the course of the study. For each camp event, the study team would bring in and equip several dentists to spend a weekend treating acute dental conditions among all comers from the population at large, including research participants if they happen to need such care at the times when the camps are held.

Based on epidemiologic data about the incidence of acute dental conditions in the population, the study team estimates that over the course of the study, approximately the same number of persons in total could be treated under each option. The chief difference between the two options lies in the interpersonal distribution of the ex ante prospect of access to care for acute dental conditions (table 1). Under option 1, research participants would have on-demand access to care at all times, while nonparticipants would have no access to care. Under option 2, all members of the population (participants and nonparticipants alike) would have access to care, but only at the times when the dental camps are held. In sum, option 1 distributes the ex ante prospect of uninterrupted access to care exclusively to research participants, while option 2 distributes the ex ante prospect of time-limited access to care equally across all members of the population.

In this case, a special AC duty would require the study team to give some priority at the outset to the interests of research participants in their deliberations about options 1 and 2 instead of giving equal consideration to the interests of all population members. To be sure, special AC duties do not necessitate giving absolute priority to participants' interests. It is compatible with the normal understanding of special duties to allow that a special AC duty can be defeated by a preponderance of competing moral considerations. Nonetheless, in any case where there is said to be a special AC duty, it is supposed to count in favor of prioritizing the interests of research participants in the allocation of discretionary resources, even if a competing option would produce a more equal interpersonal distribution of the prospect of benefit (Richardson, forthcoming).[6] This feature of special AC duties invites a form of objection that Scheffler labels "the distributive objection" (2001, pp. 56–64; see also Wertheimer 2011, p. 313). On the strength of a fundamental moral commitment to the "equal value and importance" of all persons (Scheffler 2001, p. 64), the distributive objection, as directed against the idea of special AC duties, asks why researchers are morally required to give some priority to the interests of participants over the comparable interests of nonparticipants when deliberating about their pragmatically available options for allocating discretionary resources.

In anticipation of the distributive objection, the partial-entrustment model in effect makes a positive case for the moral requirement in question through its substantive argument for partial entrustment as the principled basis for special AC duties. It is incumbent on critics who seek to deny the very possibility of special AC duties to identify relevant faults in that substantive argument. The partial-entrustment model can accommodate the moral importance of interpersonal equality by modifying the strength-assessment framework in a

[6]See Scheffler (2001, p. 82): "It may be conceded, of course, that the required priority is not unlimited and that the interests of non-associates cannot be completely disregarded. Within certain broad limits, however, we are duty bound to give priority to the interests of our associates [i.e., those to whom we owe certain sorts of special duties] when deciding how to allocate our time, energy, and resources."

manner compatible with the assertion of special AC duties. The costs of responding to AC needs relative to the resources at researchers' disposal can be construed in such a way as to give explicit consideration to opportunity costs affecting the interests of parties outside the researcher-participant relationship, such as nonparticipants in the local population. In some cases, equality in the interpersonal distribution of potential benefits among population members might defeat the moral claim associated with a special AC duty. Richardson (forthcoming) entertains something like this possibility in passing.

Reasonableness from the Standpoint of Participants and Researchers—What poses a challenge for reasonableness is the partial-entrustment model's distinctive reliance on the theoretical construct of partial entrustment to specify the content of special AC duties. Either from the standpoint of participants or from the standpoint of researchers, or both, it could be reasonable to reject key directives delivered by the prescribed use of the model.

Consider cases (see Dickert and Wendler 2009) in which participants have two or more kinds of AC needs that are all quite serious to a similar degree and that might each be addressed with similar degrees of feasibility through resources available to the researchers but that are not so pressing and easily addressed as to give rise to general duties of rescue (by whatever account of duties of rescue one accepts; or if one rejects duties of rescue, one will hold it trivially true of any AC need that it does not give rise to a duty of rescue). Let us stipulate that all else is equal, in the sense that no other moral demands are in the picture with regard to the needs at issue. The only question is whether the researchers have any special AC duties to address any of these needs. In such cases, the use of the partial-entrustment model to guide the decision-making process will deliver two potentially controversial directives.

The first directive is that it is morally permissible for the researchers to exclude from further deliberation, and thereby to do nothing about, any of the AC needs at issue that fall outside the scope of partial entrustment. But this directive could reasonably be rejected from the standpoint of participants. In some cases the participants' interests might be better served, without necessarily setting back the interests of other parties, by advancing all of the AC needs at issue to the strength-assessment stage of deliberation instead of cutting off deliberation about any of them. Why should participants (or others charged with representing their interests) accept the appeal to partial entrustment as an arbiter permitting researchers to do nothing about the needs that fall outside its scope? On the other hand, from the standpoint of researchers, the first directive appears reasonable enough, as it limits the moral demands to which they are subject. It also leaves open the moral permissibility of including in their further deliberations some of the needs that fall outside the scope of partial entrustment, should they wish to do so.

The second directive is that the researchers are morally required to bring forward to the strength-assessment stage of deliberation all of the AC needs at issue that fall inside the scope of partial entrustment and to prioritize these needs over those that fall outside the scope of partial entrustment (if they exercise the option of continuing to deliberate about the latter). This directive too could reasonably be rejected from the standpoint of participants. In certain cases, supposing that some of the AC needs at issue will in the end have to be prioritized to the exclusion of others, participants' interests might be better served by cutting off deliberation about one of more of the needs that happen to fall inside the scope of partial entrustment, so as to prioritize in further deliberation one or more of the needs that happen to fall outside the scope of partial entrustment. By similar reasoning, the second directive could reasonably be rejected from the standpoint of researchers as an undue restriction on their liberty to prioritize in further deliberations some AC needs that happen to fall outside

the scope of partial entrustment, which they might prefer to prioritize for their own legitimate reasons (possibly, inter alia, for reasons having to do with participants' interests).

The partial-entrustment model's high degree of precision in the assignment of researchers' moral responsibilities toward participants comes at a cost to reasonableness from the standpoint of both participants and researchers. It is this form of objection that motivates a rival normative model, which I call the whole-person model. I first discuss the whole-person model before considering a possible defense of the partial-entrustment model and making a constructive suggestion to reduce tensions between precision and reasonableness.

THE WHOLE-PERSON MODEL

Description

Neal Dickert and David Wendler have suggested the whole-person model as part of their critical response to the partial-entrustment model (2009; see also Dickert et al. 2006). Dickert and Wendler assert that in addition to baseline general duties of rescue, researchers have special AC duties based on the moral significance of their relationships with participants as "whole persons," regardless of how they come to know about various kinds of AC needs (2009, p. 427). In the hypothetical example of the STI protocol, the whole-person model would leave open the possibility that readily apparent tooth decay is on a par with vaginal candidiasis discovered only through study procedures as a need that researchers might have a special AC duty to address.

Dickert and Wendler argue by appeal to a form of example comparing two different kinds of AC needs, which might be either two needs that co-occur for the same participant or two needs that differ between participants: say, severe malaria and an infected leg wound (2009, pp. 426–27).[7] Although the authors do not explicitly say so, it is reasonable to assume that these needs are supposed to be, as in the preceding critique of the partial-entrustment model's reasonableness, ineligible for AC obligations under baseline duties of rescue, if only because each is said to call for a six-week hospitalization—not an easy fix. So, again, the only question is whether either or both of these needs can be the object of a special AC duty.

The two needs are similar in every morally relevant respect—for example, severity, urgency, cost of treatment, the degree of the participant's dependence on the researcher—except that under the protocol of a particular study one need is and the other need is not an aspect of health that participants implicitly entrust to the researchers through research-related permissions. In the case of the protocol studying pulmonary hypertension in children with severe malaria, severe malaria falls inside the partial-entrustment boundary and an infected leg wound falls outside it (2009, p. 426). Now, does the moral significance of "entrustment," in the sense intended by the partial-entrustment model, warrant the conclusion that the study team has a special AC duty to address severe malaria but not an infected leg wound? If the researcher-participant relationship (except for partial entrustment) is exactly the same with regard to both needs, then every morally relevant consideration (except partial entrustment) counts equally strongly in favor of a special duty to respond to both needs. It appears arbitrary for partial entrustment to claim pride of place, preempting every other relationship-based consideration however morally weighty. Dickert and Wendler, while firmly basing special AC duties on the moral significance of the researcher-participant relationship, recommend abandoning altogether any scope limitation—any systematic restriction on precisely which attributes of that relationship can generate special AC duties (2009, p. 427).

[7]Dickert and Wendler's example deals with three needs, but for the sake of simplicity I have condensed it into a similar example that deals with only two needs.

The whole-person model is otherwise much like the partial-entrustment model. Given a set of needs that initially qualify for special AC duties, both models recommend the same sort of framework to assess the strength of participants' moral claims to AC to address those needs.

Satisfaction of Performance Criteria

Regarding the principled basis criterion, the whole-person model, like the partial-entrustment model, entertains both general duties of rescue and special AC duties as reasons why researchers might have AC obligations. In its use of a strength-assessment framework to specify the conditions under which researchers have any AC obligation in a particular case, the whole-person model (also like its rival) deals primarily with the candidate needs for special AC duties, leaving open to its users the choice of a duty-of-rescue component. And it is virtually identical to the partial-entrustment model in its capacity, with only minor modifications, to satisfy the extent criterion.

By contrast with the partial-entrustment model, however, the whole-person model's argument for special AC duties proceeds entirely by appeal to the moral significance of the researcher-participant relationship per se. The mere occurrence of AC needs (focusing now on AC needs that do not already give rise to general duties of rescue) in the context of that relationship suffices to qualify them as eligible for special AC duties. As a result, the whole-person model differs radically from the partial-entrustment model in that it shifts to the strength-assessment framework the entire burden of satisfying the content criterion with respect to special AC duties (i.e., specifying which kinds of AC needs, if any, in a particular case will give rise to such duties).

Critique

In its very assertion of special AC duties, the whole-person model invites the distributive objection, in the same form and for the same reasons as the partial-entrustment model, vis-à-vis researchers' responsibilities toward outside parties. But, lacking any systematic account of what it is about the researcher-participant relationship that gives rise to special AC duties, the whole-person model is less able than the partial-entrustment model to make a robust positive case for such duties in answer to, or in anticipation of, the distributive objection. To be fair, Dickert and Wendler (2009) bracket the issue of researchers' responsibilities toward outside parties; yet the issue is relevant to any full accounting of the whole-person model.

The whole-person model's defining feature, in opposition to the partial-entrustment model, is its refusal to privilege any one attribute of the researcher-participant relationship as the singular basis for special AC duties. The effect of this refusal is to reverse the direction of the tension between precision and reasonableness that we noticed in the critique of the partial-entrustment model. That is, the whole-person model offers an improvement in reasonableness from the standpoint of both participants and researchers, but it does so at a cost to precision in the assignment of moral responsibilities to researchers (as such) for addressing certain needs of participants (as such).

What allows for the improvement in reasonableness is the whole-person model's substitution of silence for the two directives delivered by the partial-entrustment model. In lieu of a staged approach wherein deliberation may be cut off at the first stage for some of the AC needs at issue, the whole-person model prescribes strength assessment as the sole activity of deliberation, so that all of the AC needs at issue are included at the starting point. In lieu of any one moral consideration (such as partial entrustment) that demands deliberative prioritization for all of the AC needs to which it applies, the whole-person model treats the researcher-participant relationship as an amalgam of morally relevant

attributes (e.g., vulnerability, dependence, history of repeated interactions) that are all, in the abstract, approximately on a par in moral salience. Thus, from the standpoint of participants, the model refrains from even presenting as a target for reasonable rejection the appeal to any single moral consideration as an arbiter permitting researchers to do nothing about certain AC needs. The model recognizes no such arbiter. Similarly, from the standpoint of participants and researchers, the model presents no reasonably rejectable preference for any one moral consideration over others in determining which AC needs among those at issue researchers are morally required or permitted to prioritize in their deliberations.

The same silence that promotes this improvement in reasonableness, however, compromises precision in the assignment of moral responsibilities. Absent any specification of just what it is about the researcher-participant relationship that is supposed to give rise to special AC duties, the whole-person model is hard pressed to distinguish sharply between duties that researchers (as such) bear toward participants (as such) and other duties that researchers might come to bear through interpersonal circumstances with similar attributes such as a history of repeated interactions.[8]

Dickert and Wendler's objection against the partial-entrustment model is an instance of an important general insight. Any attempt to pinpoint a single attribute of the researcher-participant relationship as the unique basis for special AC duties will be open, in principle, to the objection that it wrongly excludes comparably important AC needs. But this insight does not compel a total abandonment of systematic restriction on the content of special AC duties, as Dickert and Wendler suggest (2009, p. 427). Rather than going immediately to that extreme, it is worth exploring intermediate positions that might better resolve the tension between reasonableness and precision.

For example, there could be hybrid models that assert plural possible bases for special AC duties (with or without partial entrustment as one of them). A hybrid model could retain the two-stage process of deliberation pioneered by the partial-entrustment model but adopt a disjunctive scope limitation. That is, an AC need could fall within the scope boundary *either* if it involved consideration x *or* if it involved consideration y or … and so on. In response to objections of the form that Dickert and Wendler make against the partial-entrustment model, a disjunctive scope limitation can bring more kinds of needs inside the scope boundary without going so far as to dissolve the boundary completely. The proliferation of disjuncts would be limited by the need for each disjunct to have its own justifying argument and by the need to provide a procedure for the adjudication of competing moral claims between or among differently based special AC duties. Like any model asserting special AC duties, a hybrid model would need a defense against the distributive objection. But a controlled expansion of the scope limitation would facilitate this defense by enriching the substantive rationale for prioritizing the interests of research participants over those of others.

Regarding reasonableness, the better a hybrid model manages to capture the specific moral considerations that are most important from the standpoint of participants and researchers, the less reasonable it will be to reject its deliberative directives. (Further conceptual work, ideally supplemented by systematic empirical inquiry, is needed to identify the relevant considerations.) Yet precision in the assignment of moral responsibilities to researchers (as such) for addressing certain needs of participants (as such) need not be hindered, and indeed could be enhanced, by a richer suite of justifying arguments for special AC duties.

[8]As Richardson puts it in making a similar point, "What medical researchers owe their research participants must be distinguished from what they owe (for example) the servers at the café where they regularly eat lunch" (2009, p. 2435).

A PROPOSED VERSION OF THE DUTY-TO-RESCUE COMPONENT

Description

My colleagues and I have proposed a two-step sequence of questions to help researchers identify candidate AC needs "for which it would make sense to recognize a duty of rescue" (Merritt, Taylor, and Mullany 2010, p. 215). This proposal is not offered as a stand-alone normative model of the AC obligation (Merritt, Taylor, and Mullany 2010, p. 215). Rather, it is a first attempt to fill in some deliberative details regarding the baseline duties of rescue that are recognized but not explicated by proponents of the partial-entrustment model and the whole-person model. Any normative model that recognizes baseline duties of rescue must either leave open to its users the choice of a duty-of-rescue component, as the partial-entrustment model and the whole-person model presently do, or build one in. The two-step sequence is explored here as one version of the requisite duty-of-rescue component; other versions are possible.

The two-step sequence is compatible with either the assertion or the denial of special AC duties. Given that its subject matter is a form of general duty, it makes no reference to moral commitments inherent in the researcher-participant interaction or relation as such. But it does make reference to researchers indexically, as it were, so far it presupposes by design that its users are researchers faced with a set of pragmatically available options about whether and how to respond to AC needs in low-resource settings.

Step 1 is to identify candidate AC needs for the duty of rescue by considering, for each AC need in the case at hand, the seriousness of the need (i.e., its severity or urgency or both) and whether it can be addressed by means clearly identifiable at the level of individual action (i.e., whether there is something that individual agents can do or be directed to do about the need in relation to individual beneficiaries). Once candidate AC needs are identified, step 2 is to identify those needs among them, if any, for which it is the researchers rather than other agents who bear a duty of rescue. Relevant factors include the researchers' possession of expertise sufficient to meet the need safely and effectively, the researchers' ability to apply that expertise without incurring inordinate costs, the inability of other individuals or organizations who might otherwise bear relevant duties to meet the need, and the researchers' freedom from competing obligations that would preclude taking the action otherwise called for.

My colleagues and I draw on NNWS (Tielsch et al. 2007) as an example to illustrate the use of the two-step sequence. For NNWS, step 1 identifies the following as candidate AC needs in the impoverished study population: among pregnant women, lack of secure access to a nutritious diet, a high prevalence of giving birth at home in not completely hygienic surroundings, and a high prevalence of hookworm, and among newborns, a variety of common severe morbidities. Step 1 would have excluded from eligibility for the duty of rescue various systemic needs of the NNWS study population, such as advanced obstetric facilities, the lack of which is remediable in this case only through long-term programmatic actions of government agencies and external donors.

Step 2 takes into account most prominently the operational context of NNWS as a community-based public health intervention trial enrolling over 17,000 mother-infant pairs and employing a cadre of more than 475 local workers to administer the study intervention and collect data in participants' households. In light of this operational context, the requirements of step 2 that researchers possess expertise sufficient to meet the need safely and effectively and that they be able to apply that expertise without incurring excessive costs together exclude the possibility that the NNWS team could have a duty of rescue to treat the anticipated cases of severe neonatal morbidity, as the workers were not qualified to do so

safely and effectively, nor could NNWS begin to finance the importation of skilled clinicians in sufficient numbers. Regarding viable options for the study team to respond to the remaining candidate AC needs, the consideration in step 2 about the inability of other individuals or organizations to meet the need leads decision makers to focus on interventions that the local health system has particular difficulty delivering. As to other obligations borne by the researchers that might preclude their taking certain actions to address AC needs, in the case of NNWS, the researchers' chief commitment is their prior obligation is to protect scientific validity, which happens not to be threatened by the interventions already selected as viable options for other reasons. The suggested conclusion is that the researchers have duties of rescue to train study workers to deliver simple interventions already "intermittently available through the local health system but unlikely to reach most of the population unless provided directly by the study team" (Merritt, Taylor, and Mullany 2010, p. 214). NNWS researchers acted consistently with this conclusion, offering to all pregnant women whom they approached for participation the following preventive interventions: vitamin A and iron-folic acid supplements; tetanus immunization if indicated; basic education on antenatal nutrition, hygienic delivery, and newborn care; and a clean-birthing kit containing such items as a plastic sheet, soap for the birth attendant to wash her hands, a clean blade to cut the umbilical cord, and cord ties (Merritt, Taylor, and Mullany 2010).

Satisfaction of Performance Criteria

The two-step sequence is proposed as a version of the duty-of-rescue component needed by any full normative model that recognizes baseline duties of rescue. As such, what does it contribute to any normative model's capacity to satisfy the performance criteria?

Regarding the principled basis criterion, the two-step sequence presupposes that duties of rescue constitute one reason why researchers might have AC obligations, referring for support to the independent philosophical arguments for duties of rescue that are already accepted by proponents of the partial-entrustment and whole-person models. In determining the conditions under which duties of rescue indicate an AC obligation in particular cases, the positive contribution of the two-step sequence is to organize selected practical implications of these arguments for use in the context of researchers' AC decision making.

Regarding the content criterion, proponents of both the partial-entrustment model and the whole-person model have mentioned duties of rescue only to set them aside, directing their sustained attention to the AC needs that are in question when it comes to special duties.[9] The two-step sequence can be plugged in as a complementary component of either model and used at an initial stage that precedes deliberation about special AC duties in any particular case. The NNWS illustration suggests that the two-step sequence is serviceable enough in this capacity, as far as it goes.

Finally, regarding the extent criterion, we have noted that for models that endorse the duty of rescue, applicable duties of rescue set a lower limit on the morally required AC response. The two-step sequence helps to make such a lower limit more concrete in particular cases, as illustrated by the NNWS example. While all elements of the sequence contribute to the process of identifying a concrete minimum obligation, the researchers' ability to apply the relevant expertise without incurring inordinate costs (a consideration in step 2) helps most directly to calibrate the extent of the moral demands arising from duties of rescue.

[9]The partial-entrustment model explicitly assigns a supporting role to general duties of rescue in its framework for assessing the strength of subjects' moral claims on researchers. Duties of rescue may "reinforce" relationship-based factors such as vulnerability and dependence and may "expand" researchers' AC responsibilities in severely resource-constrained settings where they have "rare abilities to provide urgently needed help" (Richardson and Belsky 2004, pp. 30, 32).

The notion of inordinate costs marks an important respect in which the two-step sequence stands in need of further development. Here is one avenue to explore. Consider particular episodes of deliberation in which all other elements of the two-step sequence are taken care of, such that several candidate needs have been identified, the study team has the requisite expertise to address each of them safely and effectively, no one else can meet the needs in question, and competing obligations are not an issue. Let us suppose further that all the remaining options have comparably tolerable monetary costs. But in addition to monetary costs, there are potential costs in effort and attention. Delivery of AC interventions might require locally based study personnel to work longer hours, cutting into the performance of their other, nonstudy-related social functions in the community. Finite study resources available for training personnel to deliver AC interventions might otherwise be directed toward the continuing development of their technical capacity to carry out research activities. Investigators and senior field directors might otherwise concentrate their relatively expensive attention on originating new scientific projects or adding scientific value to the current project. All told, there is potentially a significant loss of latitude for study team members to engage in their characteristic productive activities. This state of affairs instantiates a deep structural tension in morality: the more that agents are deontically obligated to do, the less they can freely pursue and promote other valuable ends.[10]

A fully developed duty-of-rescue component would ideally build in a conceptual resolution of this structural tension. Pending a conceptual resolution, an operational proxy is available. The more efficiently an AC response can be bundled into study team activities that are necessary anyway for carrying out the research protocol at hand, the more acceptable are the costs in effort and attention. Options can be ranked accordingly, from least to most costly. It will remain a matter of judgment, requiring principled interpretation of the parent argument for duty of rescue, to determine whether the cost of each option under consideration is acceptable or inordinate.

For cases in which duties of rescue alone are so demanding that they push up against the upper limit of the extent of the demand that any AC obligation can place on researchers, the two-step sequence accommodates the moral importance of producing needed scientific results under the competing obligations factor of step 2. This factor would rule out AC responses so demanding as to compromise the very capacity of the study team to produce the results concerned.

Critique

How will models incorporating the two-step sequence fare with respect to reasonableness and precision in the guidance they deliver about duties of rescue?

The reasonableness of any duty-of-rescue component will be largely inherited from its parent argument(s) for duties of rescue. For the two-step sequence, the most prominent parent is T. M. Scanlon’s argument, which Scanlon himself summarizes as follows:

> The cases in which it would most clearly be wrong not to give aid—and most clearly unreasonable to reject a principle requiring that aid be given—are cases in which those in need of aid are in dire straits: their lives are immediately threatened, for example, or they are starving, or in great pain, or living in conditions of bare subsistence. One principle stating our duties in such cases would hold that if you are presented with a situation in which you can prevent something very bad from happening, or alleviate someone’s dire plight, by making only a slight (or even moderate) sacrifice, then it would be wrong not to do so. (1998, p. 224)

[10]The author is grateful to Maggie Little for discussion of this point.

Scanlon's position is grounded in a contractualist theory of morality, according to which the mark of an authoritative moral principle is that no one (if "suitably motivated") could reasonably reject it (1998, p. 189). Here it is important to distinguish clearly between the context-specific understanding of "reasonableness" and "reasonable rejection" that I have been using up until now (as flagged in the introduction) and Scanlon's general theoretical account of "reasonableness" and "reasonable rejection" (1998, pp. 189–247). Implicit in the AC discussion to date is the thought that from the standpoint of both participants and researchers, it may be "reasonable," in the context-specific sense, to accept a contractualist account according to which certain duties of rescue cannot be "reasonably rejected" in the Scanlonian theoretical sense. This thought warrants more explicit examination in future discussion of AC.

Whether or not the two-step sequence in its present form is an adequate operational expression of a Scanlonian argument for duties of rescue and whether or not such an argument justifies the assertion of baseline duties of rescue, the deeper point to register is this: for any normative model of the AC obligation that accepts duties of rescue as a moral baseline, the (context-specific) reasonableness of the model as a whole will depend in part on how well its duty-of-rescue component enables users to put into practice some viable argument(s) justifying duties of rescue. Proponents of existing models and developers of new models may seek to improve upon the 2-step sequence in this respect or to develop alternative duty-of-rescue components emphasizing different parent arguments.

With respect to precision in the assignment of moral responsibilities, there are two dimensions of concern. One dimension is the reconciliation of researchers' responsibilities with the responsibilities of other agents. The two-step sequence considers this dimension in step 2. In practice, as illustrated in the NNWS example, a sensible approach is to look for the best fit between the expertise of the study team and any gaps in the local health system's capacity to meet the candidate needs that are identified in step 1 and not already ruled out by the expertise, cost, and competing obligations factors of step 2. In theory, numerous questions are under dispute in the philosophical literature about how best to allocate responsibilities when multiple agents are in a position to help (Miller 2001; Wenar 2007). Presumably, any duty-of-rescue component will offer better support to the normative models employing it the more fully it takes these questions into account; here the two-step sequence awaits further development.

The other dimension of concern for purposes of precision is the reconciliation of researchers' responsibilities toward participants with their responsibilities toward other parties, principally nonparticipants in the local population. The duty of rescue in itself, being a general duty, does not discriminate between the moral claims of research participants and those of nonparticipants among the prospective beneficiaries of needed interventions. So far as it is the duty of rescue that obligates researchers to provide or facilitate AC (by definition care that participants need), it may obligate them also to provide or facilitate the same interventions for similarly needy nonparticipants.

Under normal circumstances, members of the study team will necessarily and systematically interact with participants through their research activities. It is in the context of some such anticipated interactions that the 2008 consensus paper recommends that the planning of AC responses be treated as a basic parameter of adequate AC guidance (Participants 2008, p. 0712) and that researchers have the opportunity generally speaking to implement a planned AC response at a cost low enough for the targeted need to qualify for a duty of rescue. In every case that is normal in this respect, considerations of cost-effectiveness (see Wenar 2007) could direct researchers to meet the relevant needs (i.e., those that otherwise qualify for a duty of rescue on their part) for at least all participants and for similarly situated

nonparticipants for whom they can also meet the need safely, effectively, and at low cost. If a principled cutoff between acceptable and inordinate costs has been established (perhaps by a mechanism such as the one suggested in the discussion of the extent of the AC obligation), the cut-off will be approached as the cost of reaching less proximate nonparticipants increases. In other cases, however, considerations of cost-effectiveness might direct researchers from the outset simply to meet the relevant needs for members of the population at large, for example, by staffing a clinic that is open to one and all on demand.

What the two-step sequence does not offer is any guidance on how to deliberate about duties of rescue in conjunction with special AC duties when it is necessary to prioritize between them. For instance, assuming for the moment that there are special AC duties, consider the following sort of case: at least one need qualifies for a general duty of rescue on the part of the researchers and is common to both participants and nonparticipants in the local population; researchers are uniquely able to meet that need and actually could meet it safely, effectively, and at low cost for one and all; *and* in addition, participants have at least one AC need that is not serious enough to qualify for a duty of rescue but still qualifies for a special AC duty. Researchers might then face a choice between meeting the more serious need of nonparticipants (in concession to the distributive objection) or meeting the less serious need of participants (in keeping with the special AC duty).[11] In order to guide deliberation in such cases, a normative model that recognizes both general duties of rescue and special AC duties would have to build in a duty-of-rescue component through integration of the parent argument(s) for duty of rescue with the model's account of special duties.

Dealing with conflicts among potential duties that may apply is a generic problem for any moral view. It is not a defect of the partial-entrustment model, the whole-person model, or the two-step sequence that they have yet to reach the stage of development at which they could enable users to reconcile such conflicts. Rather, this capability represents an aspiration to guide future work on normative models of AC.

CONCLUSION

There may be no such thing as a normative model of the AC obligation that perfectly satisfies the performance criteria proposed here. The criteria are best used as a tool to guide the improvement of existing models or the development of a new, better-performing model. I hope to have demonstrated that the debate among proponents of rival models can proceed more productively by using these performance criteria as a common standard.

Regarding the prospects for models that feature special AC duties, the principal constructive suggestion to emerge from the foregoing discussion is the idea of a hybrid model with a disjunctive scope limitation. A hybrid model, in concept, can be well defended against the distributive objection and promises to resolve the tensions between reasonableness and precision to which the partial-entrustment model and the whole-person model are each exposed. Efforts to construct a successful hybrid model would benefit from conceptual and empirical inquiry into what makes an account of researchers' AC obligations reasonable from participants' and researchers' standpoints. With or without special AC duties, deeper inquiry into baseline duties of rescue, particularly as they apply in low-resource research settings, is needed to support the precise assignment of AC obligations in the context of researchers' and sponsors' concurrent responsibilities to parties other than research participants and in the context of other agents' responsibilities.

[11]See Scheffler (2001, p. 52): "I may sometimes be required [by the relevant sort of special duty] to help my brother even if his need is less urgent than [a] stranger's."

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TABLE 1

EX ANTE PROSPECT OF ACCESS TO CARE FOR ACUTE DENTAL CONDITIONS

	Option 1: study dentist	**Option 2: dental camps**
	Access to care	
Participants	On demand at all times	Time-limited
Nonparticipants		Time-limited