Human Rights and the Ethic of Care: A Framework for Health Research and Practice

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Wide gaps in health status, access to health care, quality of care, and provision of health-related services are increasingly evident in the context of globalization. In the face of glaring disparities between the health status of the "Haves" and that of the "Have Nots," health professionals in wealthier countries must consider the impact of such disparities on the ethical conduct of health research. Unfortunately, currently established codes of moral conduct fail to provide adequate guidance for ethical decision-making in health research. Formal codes include the U.S. Department of Health and Human Services (DHHS) regulations for protection of human subjects, the Nuremberg Code, the Helsinki Declaration, and the guidelines of the Council for International Organizations of Medical Sciences.[1] Taken together, these documents constitute a body of important standards for protecting research subjects from harm and regulating the balance between potential risks to subjects and potential benefits. Yet, these standards fail to resolve ethical conflicts between upholding human rights and producing more information for medical benefit. Such conflicts are increasingly apparent as economic globalization reveals the depth of international disparities in resources and knowledge.

In this Article, we examine how an ethics based on caring and responsibility can guide clinical research in a manner that is consistent with human rights and justice in the face of global disparities. We review two paradigms for moral reasoning—the morality of rights and the morality of care—with respect to applying the principles of human rights to health. The morality of rights relies on the abstract concept of justice to guide behavior. The morality of care, as the name suggests, seeks to guide decision-making in a way that *takes care of* others, examining real-world conflicts and contexts to resolve moral dilemmas. As such, it can

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supplement the abstractions of justice, protection, and benefit to provide ethical guidance in a wide variety of circumstances. We examine how the two moral paradigms play out in a contemporary bioethical challenge—the case of research related to Human Immunodeficiency Virus (HIV) and AIDS in the developing world. Finally, we propose an approach to ethical decision-making for clinical research that we apply to the HIV/AIDS experience, but which we believe has wider applicability.

We suggest that incorporation of a morality of care into the approach to health research can deepen the ethical discussion, produce more nuanced strategies for research planning, and identify and reinforce a professional stance that is more responsive to both health disparities and changing needs. A more versatile and caring ethical framework will offer better guidance to researchers and health care providers when faced with complex situations and ever-present disparities in an era of globalized health research.

I. HUMAN RIGHTS AND HEALTH

The recognition that protection of human research subjects is a proper public concern and the modern human rights movement are both relatively young ideas. Medical experiments conducted in concentration camps during World War II prompted military judges to promulgate the standard of informed consent.[2] The Nuremberg decisions framed medical research as a social-justice issue, as Robert Levine has noted.[3] Wording in the recent revision of the Helsinki Declaration on ethical principles for human-subjects research captures social-justice concerns both explicitly, with language about "appropriate caution...in the conduct of research which may affect the environment,"[4] and implicitly, in a controversial standard regarding controlled trials.[5]

Beginning with the formation of the United Nations (U.N.) in 1945, the principles of human rights have been codified in a series of international declarations and treaties. The U.N. Charter was followed by the International Bill of Human Rights (1948),[6] the International Covenant on Civil and Political Rights (1966, revised 1994),[7] the International Covenant on Economic, Social, and Cultural Rights (1966),[8] the Convention on the Elimination of All Forms of Discrimination Against Women (1981),[9] and the Convention on the Rights of the Child (1989).[10]

Human rights, as set out in these declarations, are primarily individual rights in relation to governments. The human rights framework insists that there are some things governments should not do, such as promote slavery or allow torture, and there are other things governments should do, such as protect freedom of expression and religion.[11] The goal of the human

rights movement is to ensure that people around the world survive and have the opportunity to achieve their full potential. Clean water, adequate nutrition, education, health care, and basic freedoms are prerequisites for individuals and communities to flourish. Health care providers and other health professionals should be involved in securing these benefits as rights.

The Universal Declaration of Human Rights (UDHR), adopted by the U.N. General Assembly shortly after the U.N. was formed, established a common standard to which all peoples and nations may aspire.[12] Article 25, the key section on health, states that everyone has the right to a standard of living adequate to the health and well being of himself and his family, including food, clothing, housing, medical care, and necessary social services. The adoption of the UDHR by forty-eight member states reflects the commitment of the international community to a minimal standard of health care for all people. Subsequent, related covenants and treaties underscore the responsibility of governments to provide the social, political, and economic circumstances in which people can flourish. This commitment is echoed in the World Health Organization's (WHO) constitution, which states "the enjoyment of the highest attainable standards of health is one of the fundamental rights of every human being."[13] Both failing to provide adequate opportunities for health and directly preventing access to health care impede the enjoyment of the highest attainable health standard.

While failing to guarantee universal access to clinical care is the most obvious such defect, barriers to the enjoyment-of-health right more often operate subtly at a social level. Since people are vulnerable to disease through membership in society (for example, the common cold acquired from one's neighbor), health cannot always be achieved by modifying individual behavior. Those who occupy a lower rung of the social ladder face a magnified problem, being both more likely to fall ill and less able to seek help for it.[14] By this token, creating and maintaining social and economic differences that prevent individuals from obtaining basic necessities also makes those people more prone to disease. Preventing people from achieving their healthiest potential denies them a human right. Such abuses of human rights, even though they may occur through the social organization structure and economic potential rather than overt punishment of individuals, demand that health care providers act to support the right to health.

Here, we are asserting that abuses of health rights can be overt, or subtly interwoven into economic structures. It is well established that the role and status of individuals in a society determines their health fate. The strongest predictor of health over the long run is neither heredity nor

individual behavior, but social status.[15] For an examination of disease distribution (who becomes ill) and disease outcome (who most often dies or is disabled), the HIV/AIDS epidemic is revealing. In each country the epidemic initially affects specific groups, depending on how and where the virus enters that society. However, over time it concentrates among those parts of the population who hold the least power and who live on the edges of society.[16]

Fifteen to twenty years ago, the highest incidence rates of AIDS were seen in America's large coastal cities. For instance, in the first thirteen months of the AIDS epidemic (i.e., between June 1981 and July 1982), 48% of cases came from New York City (217 of 452).[17] Today, the highest incidences are in the rural South. In 1999, 41% of U.S. AIDS cases were diagnosed in the South, compared to 29% in the Northeast, and even smaller proportions in other regions.[18]

The pattern of downward social mobility of epidemic disease is not new; other illnesses have followed a similar pattern. For example, tuberculosis, once the emblem of an elitist and delicate lifestyle in the West,[19] is now almost exclusively a disease of the poor.[20] Asthma, an allergy-like condition to which innate susceptibility is probably universal, is now so common among the urban poor that it has become a *cause célèbre* to advocates for improved housing and health care in northeastern cities.[21]

Yet, advances in political and economic rights have not necessarily been accompanied by improvements in health. For instance, the collapse of an oppressive political apparatus in the former Soviet Union was followed by economic disruption and social chaos with major health consequences. Increases in crime and disparities in resources led to serious disease in overcrowded prisons, epidemics in many communities, and a decline in life expectancy. In some Asian countries (e.g., China and Vietnam), economic reforms and the opening of society to Western influence has increased drug abuse and commercial sex, and the diseases that travel with them. The Chinese remind us to consider the potential untoward consequences of beneficial innovations, saying that "it is good to open the window and let in fresh air, but flies may enter as well."

The human rights framework highlights the dynamic nature of the relationship between fundamental human rights and health. It provides language to describe the common experience of oppression among people around the world and facilitates communication across disciplines, including health care workers, politicians, lawyers, community activists, and others. The nature of the work they do requires that health professionals practice in relationship with others, either individuals or populations. Human rights abuses—including lack of resources—obstruct

professional practice in that they compromise these relationships through limiting the ability to provide care. The difference between care that is unaffordable or inaccessible, and care that is inadequate or intermittent, is no real difference at all. Health professionals who care for those on both sides of the divide—the impoverished and the privileged—are thus held hostage by such abuses.

While health professionals might be unable to change political systems or engrained economic structures in ways that grossly eliminate underlying disparities and impediments to health, their sense of professionalism or humanitarian responsibility moves them, and often leads them to feel obligated to take action against such abuses. It is in this way that the actions of individual professionals who provide health service or conduct research are linked to human rights.

II. SPECIFIC ISSUES

We begin our consideration of the link between human rights and health-research ethics by turning to specific issues. The following six themes arise often when patients and health care providers make decisions about research participation. Naturally, we are especially interested in the choices available when research is done in the context of health disparities and/or where complex motivations obscure definitions of right and wrong.

A. Medical Progress

The desire to acquire more information motivates virtually every clinical trial (along with all health research in general). Researchers and supporters of research hope that ways of improving health can be devised if better information is available. Clearly, the health care provider's desire to gain more knowledge that could help patients aligns with the researcher's motivation to advance medical science and contribute to progress.

But progress for whom? "Medical progress" is for the common good; it has no meaning at the individual level, and we should not pretend that it does. If a research protocol helps one person, but only one, to survive, it has benefited that person, even if it fails to further medical knowledge, and even if it fails to help large numbers of people. Will a research protocol that is beneficial to one or a small number of individuals be abandoned because it fails to rise to the "progress" standard?

Researchers, potential research participants, and health care providers must recognize the disjunction between contributing to collective progress and alleviating an individual's suffering. The researcher seeks to benefit

humankind, an abstract notion of good. The individual participant experiences direct effects of research participation, and finds empirically that his or her decision to participate was either good or bad. It is the health care provider who is most directly challenged by the disjunction between collective and individual benefit. Allied with the researcher by discipline and training, the health care provider values the abstract benefit of research, but at the same time is allied with the patient by predisposition and consent to offer services. Therefore, the provider must also attend to the individual effects of participating in the research. Which choice between the two is right is likely to be uncertain. Which choice supports caring is clearer.

A deeper problem emerges when there is a material disparity in resources between where the research is devised and funded, and where it is carried out. Progress is highly valued in the technology-heavy economies of the western industrialized nations; here, the potential for progress is an accepted rationale for running the risks of research. In the developing world, progress is different—more pressing wants, differing world views, and less dependence on technical advance give progress in the abstract a more equivocal valuation. The fact that progress arising from the fruits of medical research is more likely to benefit the people of the country that funds the research than those of the country where it is carried out magnifies the divergent weighing of "progress." Researchers from wealthy nations cannot assume that medical progress is a good reason for any individual to participate in research, and even less so when the individual lives in a developing country.

B. Altruism

Linked to the multiple disparities that energize "medical progress" as an ethical problem is altruism. We suggest that altruism is largely constructed by researchers or research funders who seek to justify plans that are at best paternalistic.

The word altruism itself reveals the purely positivist roots of the concept. "Altruism" was introduced into English in the mid-1800s by the translators of Comte, who gave it its present meaning.[22] To believe in altruism implies a belief that social good is measurable, and preferable to good for the individual. When researchers suggest that an individual will enroll in their study for what they term "altruistic reasons," they are saying that while participating in research could be harmful to the individual, the study could be beneficial to people in general. The ethical choice has been made by the researchers. To them, it is a choice between abstractions. By deciding to go forward with research, however, they pile moral freight onto

the decision of prospective participants.

To the individuals who must decide to participate or not, the choice is different. The prospective participants must choose between choices. First, they have to decide at the level of their own comfort and security whether to enter the personally non-ideal state of research participation. Next, they must decide on the basis of their own beliefs whether to consider the potential benefit of the research to the community at large. The fact that the research has been approved by some recognized authority and is going forward—that is, that the decision has been made by the researchers—alters the valence of the prospective participant's decision-making. Being told that the research might benefit everyone, the prospective participant's decision to enter a study or not becomes a question of selfishness or selflessness. The individual's moral equipoise is lost. The situation is liable to become even further determined if the health care provider, particularly a trusted health care provider, endorses the research.

The term "altruism" is thus a tip-off to an ethical squeeze play. Health care providers who sign on with a research project change the weighting of the choices their patients are faced with. The researcher who proffers altruism as a legitimate reason for people to submit to the imperfect state of research participation ignores the dual-level nature of the actual decision to participate, and subtly injects a moral suasion into that decision. An individual's decision, especially if the research participation has been presented by the individual's own care provider, is complexly freighted, far from simple, and worthy of careful and not rule-bound attention.

C. Equipoise

Equipoise is the state of not knowing which of two claims is true. In the context of health research, equipoise refers to the investigator's honest ignorance as to which of two interventions is more beneficial. Many writers have emphasized the central importance of this state of not knowing in the ethics of health research. If one treatment regimen is clearly more effective than others, subjecting patients to the less-effective approach(es) violates the consensus standard expressed in the Helsinki Declaration—that everyone is entitled to the highest current standard of care. Only if the researcher is genuinely undecided about which approach is better is it justifiable to conduct a clinical trial. Benjamin Freedman rejected individual equipoise on the part of the investigator, the true absence of what he called "treatment preference," as an impediment to carrying out clinical trials. Charles Weijer and others have joined Freedman in advocating community equipoise as a hedge against disingenuous

contentions on the part of researchers that they were truly uncertain of whether there was a difference between treatments A and B. Not just the investigator, but the medical community, these authors claim, must be genuinely uncertain as to whether treatment A is preferable to treatment B, or the reverse.[23] Equipoise, by these claims, makes it permissible to expose some individuals to a new treatment that is (or later turns out to be) less effective than the best treatment.

Levine has argued that equipoise motivates research in two ways.[24] Not knowing which approach is better generates a need to find out. The research (with its attendant risks and discomforts) is therefore justifiable if it serves to relieve equipoise in a way that helps to decide which approach is better. If the results suggest that one treatment is better than others, equipoise is lost, and the researcher is obligated to stop the study even if the full protocol has not been completed. Today, standards for stopping are normally incorporated into clinical trial protocols, an acknowledgment of the necessary equipoise principle.

If equipoise is the principle on which ethical enrollment in clinical trials is based, then the point where equipoise vanishes is an ethical fulcrum. Clearly, the exact point at which evidence makes a new treatment look better than placebo can be different for one health care provider than for another. Clinical trials attempt to standardize that point, so that all health professionals will agree that it is not yet proven that treatment is preferable to placebo. The clinical trial thus obviates decision-making on the part of the individual health care provider and researcher and justifies its own continuation—or the inception of another trial. But appeals to the medical community to decide when treatment A is better than B invite the certainty of consensus, but do not necessarily produce truth (that would be true even if the nature of "community" in medicine were not so elusive). Codifying how to draw inferences from clinical trials does not entirely work. Part of the discomfort health care providers experience when enrolling patients into some clinical trials comes from their own sense that the placebo and treatment options are not really equivalent, no matter what the medical community says. The health care provider is again hostage.

Justifying research through consensus or community equipoise—as clinical trials invoke—lifts from the shoulders of both the researcher and health care provider the responsibility to decide whether they believe the study treatments to be equipoised. It also eliminates the prospective participant's belief from the ethical equation. A more versatile approach would embrace the varied, and potentially conflicting, beliefs of all parties involved. But then equipoise could not be the sole motivation for research,

and relieving equipoise could not be the primary justification for entertaining its risks. Like medical progress, equipoise would have to be demoted from its major role in ethical decision-making if the ethics of health research were based on the complexities of caring for individuals acting individually.

D. Placebo Control

Results of a randomized, placebo-controlled trial are the *sine qua non* of evidence in an increasingly evidence bound, health science establishment. Investigators who seek to find a good prophylactic or treatment regimen are essentially required to mount a placebo-controlled trial. Even if researchers are concerned that patients given placebo are not receiving adequate care, they might find no alternative to the placebo-controlled trial. If the treatment's efficacy is to be believed and the treatment used so that people can be helped, some people—the participants who are randomized to the placebo arm—will have to receive no treatment at all. Of course, occasionally a treatment is harmful, and placebo recipients are the lucky ones. Still, the randomized, placebo-controlled trial often, albeit not always, stakes adequate care for some patients today against the hope of better care for many patients tomorrow.

That wager presents caring researchers everywhere with a dilemma. But health care providers in resource-poor regions must face this problem on a magnified scale. Where there is too little money to pay for treatment for all, the availability of a placebo-controlled research protocol moves health care providers to a Hobson's choice. They must decide between two situations that compromise care: Either no or inadequate treatment for all of their patients, or potentially effective treatment for some. Those who enter the trial and are randomized to the active-treatment arm will receive treatment that might be effective; those randomized to the placebo arm are certain to receive no treatment.

The World Medical Association chose to address the placebo dilemma directly in the recent revision of its statement on ethical principles for research involving human subjects. It stated unequivocally that new treatments must be tested against the best current treatment, not a placebo.[25] Placebo trials are to be undertaken only when there is no proven treatment. Although this seems straightforward, in many real world situations, the ethics of a placebo arm are not immediately obvious. As the case of HIV/AIDS drugs will show, conducting placebo-controlled trials of inexpensive regimens in poor nations when the effectiveness of more expensive regimens has been demonstrated is a Solomon's dilemma. If a trial goes forward, some people will not do as well as others, because some

will receive placebo. If no trial is carried out, nobody will be treated. Thus, no matter which choice is made, research perpetuates inequality in access to health. The morality of care and human rights would recognize that social injustice lies at the root of the dilemma, and then indicate that action to correct larger social disparities be linked to furthering research agendas.

E. Informed Consent

The right to informed consent established a new standard of justice in health research when it was agreed on as part of the Nuremberg Code. However, even informed consent cannot transform offering a treatment regimen that is less than optimally beneficial into good care. Getting people to agree to receive a lesser standard of care does not make offering inadequate care acceptable. In this light, informed consent assists the pursuit of justice in research, but it does not by itself guarantee that the obligations of caring have been discharged.

As practiced in the United States today, research participants have the right not only to be informed about the procedures entailed in research and their potential risks and benefits, but also the right to understand. The current interpretation of informed consent thus closes the gap between researchers' discharging their obligation to inform, and the patients' needs to know and understand what is going to happen—a divide that emerges readily when research procedures are described in technical jargon. By observing the informed-consent standard, justice is done in that all prospective subjects are equally aware and, therefore, equally able to choose.

But is that the only gap? The assertion that awareness creates choice seems problematic. Certainly, lack of awareness of possible risks and benefits diminishes the range of choices available to the subject. But full awareness, as the modern informed consent standard seeks to achieve, might still leave many choices unavailable—precluded by the patient's economic resources, class, sex, or race, or by a desire to please his or her family or health care provider.

Neither is the dilemma of the placebo alleviated by informed consent. That patients know, or are told, that they might receive placebo does satisfy an abstract concept of justice (e.g., that awareness creates choice), but it does not relieve the caring researcher's or the caring provider's burden of choosing between two unwanted situations. Consider the situation in which the person who normally provides care to a patient also acts as collaborator on a professional colleague's research project. As part of informed consent, the provider explains the research project to the

patient, offers all the information required under informed-consent guidelines, and asks for consent to participate. Should health care providers make clear to the patient their opinion about the wisdom of participating? If so, on what criteria should that be based?

The ethical conundrum is highlighted here: If health care providers discuss the choice about participation because of their concern for the patient's personal situation, must the providers acknowledge their own interest in the research project's success—even though that acknowledgment reveals that they are not interested solely in the patient's welfare? If the providers do not discuss their own role, are they offering the patient full enough disclosure about the situation, and in particular about how their own alliance with the researchers might alter their presumed alliance with the patient for whom they care? Informed consent elicits an ethical challenge about care, even as it resolves one about justice.

F. Medical Care for Research Participants

Marcia Angell asserts that when investigators enroll subjects in clinical trials, they assume a responsibility analogous to that of clinicians.[26] Are investigators, therefore, responsible for elevating the health status of participants in their studies, or are they entitled to leave unimproved the poor health standing of a population so long as the investigation meets the standard test of "doing no harm?" The revised Helsinki Declaration addresses a portion of this problem, recommending only the best proven therapy as the standard against which new treatments must be tested. But the Declaration also states that at the conclusion of the study, all subjects should be provided access to the best treatment demonstrated by the study.[27]

Some researchers contend that the gulf between rich countries and poor ones sanctions different standards of care on its two sides, and therefore what would be unacceptable study designs in the United States are appropriate in Africa or Asia. The power of this argument lies in its appeal to practicality and compassion. Its unarticulated assumption is that the economic gap is inevitable. However, the capacity of wealthy nations to ignore moral accounts that emphasize their own responsibility to alleviate suffering helps to generate and maintain that gap. While wealth might be produced in developed nations without impoverishing the less developed world, the burden of ensuring that the poor are well cared for is a costly one. Rich countries shoulder it only up to a point.

One way to elide their own moral complicity in perpetuating the economic gap is for policy makers in developed countries to pretend that the issue is an abstract one, resolvable by attending to standards of practice

or a disingenuous appeal for medical compassion. The responsibility to care enjoins us to provide the best possible health services and the best proven therapy. Indeed, to withdraw health care because of concerns about research ethics might prove even more invidious to the health rights of developed countries than to go forward with questionable research. Still, a full realization of the morality of care would dictate action to improve the material context, so that consent will not be coerced by social circumstance.

III. CURRENT PARADIGMS

How the individual health worker should act to preserve human rights and invigorate the quest for expanding human rights is the crux of health ethics. Most modern Western ethical systems are based on universal concepts of justice and equality. A significant alternative approach, explicated only in recent years, is based on caring and attentiveness to the complexity of human interrelationships. The two paradigms often lead to identical or similar ethical decisions, and the boundaries between them are controversial.[28] We begin by summarizing them separately.

A. Morality of Rights

The various codes governing biomedical ethics today are grounded in liberal theories of justice, human rights, and contract theory. Levine's discussion of the basis of medical ethical codes in deontological (duty-based) and utilitarian (pleasure-based or utility-based) theories brings out the dialectical relation between them. We see these codes as revealing also a melding of Kantian rationalism with the democratic liberalism introduced by John Rawls.[29]

Kant's categorical imperative offered the foundation for abstract morality.[30] It assumes that all humans have access to reason (even if we do not always use it). "True" moral principles therefore emerge as universal and could be derived not from perception, which might be shifting or faulty, but through the ubiquitous faculty of reasoning. Kantian moralism is necessarily abstract, since it rejects practice as grounds for moral decision-making. It also assumes that correct moral principles are impartial, because only impartial tenets can apply universally. Finally, because it requires that moral narratives be "read" through reason, it assumes that what is moral is correct or right. We see Kantian moralism in health care in the injunction to "do no harm." More tendentiously, we see it in the controversial contention that what is the highest standard of care for the wealthy ought also be the standard of care for the poor. Here,

justice and care can agree.

Rights-based morality draws also on the utilitarian underpinnings of Western liberalism. Utilitarian values offer a slightly different valence to moral decision-making. Jeremy Bentham and his follower, John Stuart Mill, distanced themselves from Kant, centering ethical decision-making on the principle of pleasure (Bentham) or happiness (Mill).[31] Bentham's "felicific calculus" sought to maximize *good*, rejecting the existence of any consistent natural law that could give rise to moral *right*. Utilitarian thought can accept moral accounts on a case-by-case basis. For instance, in modern liberal decision-making, an action such as killing might be sanctioned in one set of circumstances (e.g., war against fascism) and proscribed in another (e.g., genocide). Both choices about killing are moral, because in each case the decision helped to maximize good.

In this sense, utilitarian morality moves away from the categorical nature of Kantian morality. But while utilitarianism changes the principle on which the moral code is based from truth to happiness, it shares some ideas with Kant's morality. Moral behavior is still guided by "do" and "don't." Even a resolution of an ethical dilemma that is situation specific will be based on an appeal to the abstract—good or happiness. The moral code is impartial, in the sense that the identity of the individual(s) helped by the decision is irrelevant.

In current health care ethics, we see utilitarian moralism at play in the debate about managed care, whether through private or socialized insurance. Management of health care costs allows for more efficient cost sharing and therefore minimizes payments overall. By making care provision less subject to patients' characteristics like knowledge or affluence, it provides the "happiness," or increase in community well being, of expanding the availability of adequate care. Utilitarian views also offer a justification for the State to detain and forcibly treat disease sufferers whose failure to comply with prescribed therapies makes them a threat to others. For instance, New York City has, at times, maintained locked isolation facilities at one or more municipal hospitals for the custody and treatment of tuberculosis patients who remain infectious because they failed to take anti-tuberculosis chemotherapy. While liberal justice would normally reject the incarceration of individuals who are guilty of no crime, the courts have supported detention of infectious tubercular people on the basis of protecting the public's health.

The last major influence on rights-based morality comes from democratized or populist pragmatism.[32] Rawls' theory of "reflective equilibrium"[33] and agreed-upon principles of justice, and the explicit contract approach that emerges from it,[34] guide important aspects of ethics

that are evident in codes like the Helsinki Declaration. The indispensability of informed consent reflects contract theory: It honors a subjective decision by the participant, forged in agreement with a researcher, to seek mutually what each wants individually.

Thus, the morality-of-rights approach is based on principles that at any one time could include some of the following: impartiality, equality, beneficence, and individual autonomy. These principles lead to rules that we see in the articles of the several codes of conduct (e.g., Helsinki). They seek to uphold specific attributes of *care* for people. The conjunction of care and rights here is notable. However, it remains abstract, as we discuss below.

Some of the attributes of rights-based ethics are privacy,[35] the right to information,[36] disclosure,[37] risk communication,[38] and avoidance of harm.[39] Privacy, associated with deontological morals, is also a tenet of contract theory. Individuals are assumed capable of reason and judicious choice, at least on their own behalf. Privacy gives rise to the right of confidentiality, particularly in American health ethics. Here, rights are abstract: Privacy and confidentiality support equality, and thus liberal justice, but they have no obvious link to care.

The right to information comes directly from a Rawlsian view of justice: People must know what is wrong with them and what might happen to them if they are to be able to seek freely just solutions to the problems of ill health and unequally distributed resources. The information right links with the privacy right to create an uneasy equality, or at least a leveling of the playing field. And it implies that holders of information must share it. For the individual that obligation generates a right of disclosure; for the group, it generates a right to know what its risks are.

The avoidance of harm is the old Hippocratic principle, embraced by both categorical and utilitarian models (reducing harm is a virtue in itself, and it is a measure of the optimization of good or happiness). In contract approaches to justice, avoiding harm can be an index of the success of liberalization, the quality of the dissemination of rights.[40] It is the most implicit element of the philosophies underlying rights and, as we discuss below, an explicit aspect of care-based ethics. Avoidance of harm provides an important interface between the abstract ethics of rights and the empirical ethics of care.

Indeed, the principles developed through philosophies of moral imperatives are abundantly evident to caregivers, either as intuited truths or received wisdom, or through training and practice. All of the privacy and information rights are tenets of caring. Often enough, practitioners derive these principles unconsciously, through the conscious practice of

care. The distinction, we argue, lies in whether these tenets remain principles for judgment or assessment only, or move the practitioner or researcher to act. Careful health care practitioners are aware of their need to balance patients' needs for privacy and confidentiality with a right to know about threats or risks. They also seek to avoid harm to the patient as it presents itself in a given clinical situation. And they reinforce the positioning of the patient in an idiosyncratic social support system, as well as in the larger society. We will return to this distinction after reviewing the basics of a morality of care.

B. Morality of Care

The choices offered by, and decisions made from, a justice-based rights paradigm too often fail to answer the real-world concerns of individuals and populations who are the vulnerable subjects of health research. In contrast, in 1982, Carol Gilligan initially described an ethic of responsibility and care expressed by young women, which looks closely at context, including networks of relationships and power as a guide to the moral path.[41] The consequences of decisions are considered, along with whether the decisions are right and just. For example, a woman debating an abortion might consider not only her personal beliefs about when life begins, but also the impact of her decision on others to whom she feels responsibilities.

Among the health professions, nursing has evidenced a particular interest in the development of an ethic of care.[42] Because the practice of nursing in its purest form is essentially the act of caring for another human being, it is not surprising that nurse-philosophers find an ethic of care attractive. Nursing is largely a profession of women; and the fact that discussions of caring have been strongly influenced by the feminist perspective of its first theorists, Carol Gilligan and Nell Noddings,[43] is almost certainly responsible for some of its appeal to the profession.

There has been less formal discussion of the principles underlying an ethic of care in medicine. However, at least one philosopher-physician, Edmund Pellegrino, writes eloquently about the physician's duty to care for the patient by feeling compassion, doing for them what they cannot do for themselves, accepting responsibility, and acting competently.[44]

Some writers have proposed that there is no real distinction between an ethics of justice and an ethics of care. They hold that justice is based on caring, albeit implicitly, and argue that differentiating morality as based on either rights or caring is a response to a political calculus that has to do with class, sex, and sometimes race.[45] We agree that caring underlies justice, and that rights may be derived through the practice of care as

readily as they can be received as principles enunciated in response to a philosophical view of virtue or justice. But, we emphasize a distinction between ethics based on abstract principles of right and ethics arising from a caring willingness to adjust practice to the demands placed by real situations and social structures on individuals. We argue that this distinction is important in recognizing where existing codes of medical ethics are too rigid or insensitive, and pointing the way toward a more responsive and satisfying approach.

IV. CASE STUDY: HIV/AIDS RESEARCH IN THE DEVELOPING WORLD

In 1997 discord erupted in the pages of the venerable *New England Journal of Medicine* when physicians conducting clinical trials in Africa and Asia to investigate the efficacy of strategies to reduce maternal-fetal transmission of HIV were accused of unethically exploiting the desperation of poor countries hit hard by the HIV/AIDS epidemic.[46] The charge was that the trials of simple and inexpensive anti-retroviral regimens, which included placebo arms, would have been unacceptable in the sponsoring countries. Results of an earlier study conducted in the United States and France documented the effectiveness of a more complicated and expensive regimen in reducing maternal-fetal HIV transmission.[47] The AIDS Clinical Trials Group (ACTG) protocol 076 study demonstrated that zidovudine (AZT), administered for six months during pregnancy, intrapartum, and to the newborn, reduced the probability of transmission of HIV from mother to infant. That expensive regimen quickly became the standard of care for HIV-infected pregnant women in the sponsoring countries, but was deemed impractical for the developing world.

Studies in Africa and Asia sought a shorter, cheaper prophylactic regimen, by testing possible substitutes for the ACTG-076 regimen against placebo. These studies were sponsored by a number of U.S. institutions, including academic institutions and the National Institutes of Health (NIH),[48] in collaboration with foreign researchers. Concerns emerged about the acceptability of placebo use—given that six months of AZT therapy had already been shown to be efficacious, equipoise was obviously unattainable. Investigators countered, arguing that the ACTG regimen was neither affordable nor practicable in the developing world so that testing shorter, less expensive regimens against placebo was still acceptable.

Controversy ensued. A month later, a letter from the then-heads of the U.S. Centers for Disease Control and Prevention (CDC) and the NIH called for HIV/AIDS research to be developed in concert with local authorities, acknowledging that differences in resources created differing needs.[49] In February 1998, four agencies responsible for overseeing

placebo-controlled trials of HIV/AIDS therapies in developing countries issued a joint statement asking that placebo use be halted in such trials. The CDC, NIH, Joint United Nations Programme on AIDS (UNAIDS), and the Agence Nationale de Recherche sur la SIDA stopped short of outright embargo on placebo-controlled trials, but their statement changed the debate.

In April 1998, the *American Journal of Public Health* published six articles relating to this issue.[50] Two editorials specifically addressed the ethics question. Mervyn Susser, then editor-in-chief, argued in favor of placebo-controlled trials in order to generate the information needed to produce treatment regimens affordable in the developing world.[51] Ruth Faden and Nancy Kass were more equivocal.[52] They sought to hold researchers to a high standard of justice, placing the burden of proof on investigators to show why clinical research should be conducted in a population that normally cannot avail itself of the very therapy under study. They rejected cultural relativism in research, but did ask how constraints on spending affect the ethics of research. Faden and Kass thus left open the question of whether it is the role of researchers to redress the impact of deprivation on their subjects.

Heated discussion of these issues continued in professional meetings and journals, expanding into a debate regarding the ethical obligations of researchers to care for the human subjects who participate in their trials. A subsequent study of HIV transmission between heterosexual partners in Uganda[53] elicited new questions about the ethics of research practice and underscored the unsettled nature of the debate.[54] The Uganda study randomly assigned residents of rural villages to receive specially provided care for sexually transmissible infections or usual care; the latter meant referral to government clinics. In addition, no anti retroviral therapy was offered to the several hundred HIV-infected subjects.

One of the outcomes of interest in the Uganda study was new HIV incidence in sex partners of already HIV-positive participants. Anti-retroviral therapy might have reduced the potential for HIV transmission, which would have biased this important study endpoint. The investigators were thus able to reach unbiased conclusions about HIV transmission because "antiretrovial drugs are not available in rural Uganda. Consequently, the HIV-1 RNA levels were not influenced by the use of anti-retroviral drugs."[55] In an editorial response, Angell looked not simply at the scientific benefit of avoiding bias, but also at the human downside. She asked whether it is sufficient for health researchers merely to do no harm, or if a higher standard is in order. She wondered whether investigators from resource-rich countries like the United States ought not be held

responsible for elevating the compromised health condition of the participants in their studies.[56]

Much of the discussion about HIV/AIDS clinical trials turned on the just distribution of the risks and benefits of research among investigators, sponsors, research participants, and non-participants. In this case, such benefits included: the provision of adequate antenatal zidovudine to minimize the vertical transmission of HIV; the offering of better AIDS treatment than prevailing local standards (frequently the local standard is no treatment); the finding of information that is useful for HIV prevention or improved AIDS clinical care; and the attracting of research dollars that can generate employment or bring needed goods into resource-poor countries.

In order to address the problem of just distribution of risks and benefits of research, the assessment of risks in this case must acknowledge that real disease risk, a prediction about likeliness, is embedded in a matrix of broad concerns. A developing country is imperiled by endorsing research, largely in the form of possible financial costs or disruption of existing social and administrative structures. More serious risks are potential human rights violations that are identified but fail to be resolved. The poorer health of citizens in developing countries might become more obvious in the context of Western-sponsored and sometimes hi-tech research; certainly, the inadequacy of health care systems that must run on shoestring budgets becomes both apparent and visible to the world at large once Western research installations illustrate the disparities involved.

Ethical doubt about the HIV/AIDS research in developing countries that these problems generated was exacerbated by questions as to the investigators' equipoise and the adequacy of informed consent. In this case, equipoise, supposedly an indispensable principle of rights-based research ethics, proved to be flexible and open to redefinition once a national border had been crossed. Ratification of the research by local authorities ostensibly operating in citizens' best interest, but with opportunity to reap political or economic gain by cooperating with wealthy countries, clouded the ethical picture from a standpoint of informed consent. Informed consent was revealed in this case to be a protection wholly dependent on a subject's ability to recognize options. It was readily coerced by the wishes of the holders of financial power in resource-scarce situations. In sum, the ethical perspective of rights was confounded by the substantial differences in financial resources between the countries sponsoring the research and those serving as their venue.

We contend that any assertions of altruism in these developing-country studies should have withered in the light of their upshot: The rights of

study subjects to the "highest attainable standard of health," as the WHO constitution avers, were denied. Whether this abrogation of human rights was the fault of feckless funders, self-interested investigators, venal national leadership, or simply a presumptively inert global economic divide became the issue—not the protection of human rights themselves. The rights-based ethical codes failed, and the particular principles those codes motivate, like informed consent and equipoise, were exposed as both inadequate and easily co-opted.

We suggest that the intensity and persistence of controversy over this research bespeaks a fundamental deficiency of the standard ethics-of-rights framework. If the most effective treatment is not available in a country, is research to find one that can be made available—even if it is clearly less effective than the best—permissible? Obviously, once a clinical trial demonstrated the efficacy of an anti-retroviral regimen in reducing perinatal HIV transmission, albeit an expensive regimen, there is no equipoise between placebo and any version of that regimen. Arguments alleging that it is truly not known whether less expensive, abbreviated regimens would be preferable to no treatment at all are disingenuous. Peter Lurie and Sydney Wolfe have advocated equivalency trials, rather than placebo-controlled trials, of HIV/AIDS medications in developing countries.[57] Their argument highlights a potential opt-out to the Helsinki Declaration requirement that subjects receive the best proven therapy. Equipoise is no guide, then, even under Helsinki. Ethical decision-making in this situation has to be more broadly based than reliance on equipoise alone will allow.

An ethics grounded in the morality of rights can be made more appropriate for the rapidly emerging global health community and better able to safeguard human rights by tempering it with an ethics based on responsibility and care. Ethical guidance to researchers and practitioners in these situations should have recognized the disparities in resources, access to health care services, and expectations about health and longevity encountered in international research. But, it should also go beyond that, to acknowledge those disparities' consequences as well. The impact of researchers' interventions should be shown explicitly to accord with those of health care providers: To begin by doing no harm, proceed to ensure that harm is not done to patients/subjects inadvertently or incidentally, seek to satisfy individuals' needs, and only then aim to benefit humankind. Specifically, before research begins in a developing country, an ethics of care would ask researchers to assess the ways in which subjects in that country are presently denied access to the human right of adequate health. This approach would highlight and support professionalism and articulate

the alliance of health care with health research.

While a truly care-based model resists codification, we suggest that two key outcomes of the explicit linkage of research with care would emerge. First, an additional ethical standard would be posited: How does the proposed research seek to address inequities, eliminate the identified disparities, or otherwise respond to the absence of adequate health? An investigation in the mid-1990s that compared two different approaches to preventing mother-to-fetus HIV transmission with one as effective as that demonstrated in the ACTG-076 would meet this test. Similarly, a study of sexually transmitted diseases (STDs) and HIV transmission in Uganda that offered anti-retroviral therapy and one of two different forms of STD treatment would meet the test. Research comparing an alternative regimen for interruption of vertical HIV transmission to placebo would fail this test, as would the Quinn protocol that studied HIV transmission rates in the absence of anti-retroviral therapy. We note that both of the hypothetical investigations that would meet the proposed ethical standard would do so even if the investigations were carried out in the United States.

Secondly, at the level of individual researchers, sound ethics would require care. Specifically, investigators would consider not merely each prospective subject's consent to participate as a test criterion for ethical enrollment. Rather, they would assess whether participating in the planned study would alleviate or exacerbate health problems for each prospective subject. They would evaluate this question in light of each participant's social and economic situation. For the subjects in the poorest countries, this test would mean attending to possibly multiple and complex problems involving family and social groups (e.g., waterborne parasites, malaria, food or water scarcity, and infant diarrhea, in addition to HIV). When competing potential benefits emerged, the researcher would seek a path that generated the broadest benefit (e.g., for the family as well as the patient) or minimized potential harm or loss. The assessment would therefore be different for a head of household or family breadwinner than for a child, different for a person who is ill than for a healthy one, and different for men or women who have regular jobs than for the unemployed. The researcher would consider the potential toxicity of chemotherapeutic regimens, logistical difficulties of reaching study or treatment clinics, and the social hardships arising from the possible loss of a family member if treatment is ineffective. While the hands-on practice of delivering care might be left to professional care providers, researchers would be enjoined to make decisions that are based in the practice of care.

V. PROPOSAL

We propose that the question of what constitutes care and harm must be central to the research process. Caring, and attention to the multi-tiered complexities of upholding the human right of each individual to receive care, can serve as the foundation for clinical-research ethics that avoid harm. Technical and administrative fixes to ethical problems, like novel study designs or better oversight by international agencies, are aimed at resolving the distribution-of-justice problem, but they fail to address the fundamental question about preserving individual rights and offering good individual care. Solutions distributing risks and rewards among groups, the utilitarian moral path, fail to alleviate harm and fall short of guaranteeing the best care. Rather than distributive justice, research ethics should be guided by individual responsibility and care.

An ethical framework based on responsibility and caring is practicable for researchers and clinicians. In contrast to the difficulty most individuals experience in trying to elucidate abstract justice, both researchers and clinicians usually can discern a scale of harm to individuals either arising from a given action or pre-existing. Their professionalism lies in their ability to gauge harms accurately and assess how their own actions in a particular situation will reduce harms. Thus, standards for research ethics can take the form of supporting professional decision-making in assessing potential harms within observable relationships among those who stand to lose or gain. Ethical choice can be based on minimizing observable harms and ensuring that those who need care receive it.

Such a basis for ethics in research means that manifold health disparities might have to be redressed before research can be done. The search for a single, just standard of clinical and/or research practice will inevitably be compromised by the social and economic reality of global disparities in health status, access, and resources. Recognizing that justice will be compromised by any solution in the current context, the morality of care and human rights compels social action by health care providers. The response to Angell's question about the researchers' responsibility for the economic distress of the place where they are conducting research is answerable: Resolving disparity cannot be separated from the conduct of ethical research.

What we are proposing amounts to a reconfiguration of the debate around research ethics. We believe that the aims of health care and public health are served by organizing the discussion of international justice in research around the principle of caring and the avoidance of harm. This discussion, which should involve both investigators and health care

providers, will be of more general applicability than to the HIV/AIDS field alone.

Most painful moral problems are not simple choices between competing rights, but complex situations of conflicting responsibilities. Resolution requires an approach that is contextual and narrative, rather than formal and abstract. Morality of care tempers the rules of rights and justice, including those of human rights. It moves the researcher into alliance with the health care provider and places both in the shoes of the knowing caregiver: charging them with responsibility for the welfare of real individuals, asking them to act professionally within observable interpersonal relationships and in the context of real social forces, and seeking to reduce harms.

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