

The Needed Revision of the Belmont Report: An HIV Cure Research Case Study

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The use of human subjects in research gives rise to myriad ethical concerns, which are primarily addressed in the Belmont Report. This set of guidelines for researchers focuses on protecting vulnerable individuals from being taken advantage of in medical studies. Until recently, its breadth has been adequate guidance for contemporary concerns, but these guidelines are now failing to address novel biomedical issues. The structure of the Report creates an inadequate foundation to navigate ethical concerns not explicitly addressed in the paper, exemplified through a case study of HIV cure research. While the HIV crisis is centered in sub-Saharan Africa and largely affecting women and adolescents, cure research is happening almost exclusively in high income countries using white male subjects. This introduces an ethical dilemma, as studies have shown that population and environmental differences could lead to an HIV cure developed on one demographic to be less effective on another. Low-income countries in most need of the cure have inadequate infrastructure to pursue one on their own, leaving large populations excluded from research with no ethical guidelines to protect them. I argue that the Belmont Report must make more explicit the ethical principles that are implied in their report, calling for a distributive justice that makes clear our moral obligation to include vulnerable populations in research studies.

Introduction

Ethical guidelines surrounding human subject selection in biomedical research has historically focused on preventing people from being unjustly used for research gains (1). The Tuskegee syphilis study and the Nazi experimentation on those they imprisoned are perhaps the most well-known examples of unethical patient selection. Both studies exploited unwilling or misinformed subjects due to their accessibility to the researchers (1). Since then, clear standards have been put in place to protect the abuse of human subjects. The Belmont Report contains the leading guidelines for protecting human subjects, directly citing the Tuskegee study and the Nazi experiments as failures of justice (1). Today, studies like these would quickly be called out for being manipulative and harmful. However, an increased recognition of global responsibility along with new biomedical discoveries have introduced a new possibility for unjust human subject selection (2). One example is found in human immunodeficiency virus (HIV) cure research, where reports have shown that sex, environment, and HIV subtype diversity can lead to differing effectivities of a cure among different human populations (2–4). Even with this knowledge, HIV cure research is conducted nearly exclusively in high-income countries (HICs) using adult white male subjects, while the majority of HIV infections are in low-and-middle income countries (LMICs) in Africa (5). African women and adolescents are the most highly infected populations, but they are almost completely excluded from cure

research. In my paper, I will use the case study of HIV cure research to outline how the current language in the Belmont Report is insufficient guidance for the ethical selection of subjects. I will argue, through the principles of respect for persons and beneficence, that the Belmont Report needs to call for a distributive justice and add explicit guidelines that protect vulnerable populations from being excluded from research.

The Ethical Principles of the Belmont Report

In order to set guidelines for protecting human subjects, the Belmont Report roots itself in three basic ethical principles: respect for persons, beneficence, and justice (1). Each principle is then directly applied to an aspect of human subject research, giving clear examples to serve as guidance to researchers. The first principle is respect for persons, used in the Report to guide informed consent procedures. This ethical principle demands that individual autonomy is respected, allowing people to make their own informed decisions if their choices do not harm others (1). The Report defines autonomy in a Kantian manner, writing “an autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation” (1). This autonomy gives humans an inherent dignity, which is the foundation of philosopher Immanuel Kant’s idea of respect for persons, stating that people should “Act so that you treat humanity whether in your own person or in that of another, always as an end and never as a means” (6). In other words, rational beings

should be respected for their dignity and purpose, never being used to reach another person's end. Where the Report differs from Kantian ethics is that it requires researchers to not only protect fully autonomous beings, but to also "protect those with diminished autonomy" (1). This principle is underlined by a natural law ethics, a teleological moral principle that obliges people to both protect and promote basic human goods (7). For natural law ethicists, basic human goods are what humanity needs to flourish, comprised of what the principle defines as the three parts of human nature: knowledge, love, and physical health (7). The Report recognizes that "not every human being is capable of self-determination," going on to state that "some persons are in need of extensive protection" (1). Together, this two-part definition of respect for persons serves as clear guidance for informed consent procedures, ensuring that all humanity, regardless of rationality, is treated with dignity.

The second ethical principle, beneficence, is understood by the Report as an obligation to "maximize possible benefits and minimize possible harms" (1). Beneficence is not merely charity that exceeds duty, but instead "is understood in a stronger sense, as an obligation" (1). This principle is deeply rooted in a utilitarian ethics. John Stuart Mill, a proponent of utilitarianism, believed that the motivating principle for human action is pleasure in the absence of pain (8). From this foundation he derives the greatest happiness principle, saying the right act is the one that produces the greatest good for the greatest number of people (8). When it comes to medical research, the Report urges that researchers "give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation" (1). However, the document goes beyond this utilitarian definition, corroborating "The Hippocratic maxim 'do no harm'" and writing that it is important to know "when the benefits should be foregone because of the risks" (1). The Report is not a strict utilitarian calculus that looks at the overall end of an action over any effect on individual people. Instead, utilitarianism is checked by natural law ethics, as the maximization of benefits should be done only as long as individuals remain protected (7). This creates a definition of beneficence that is centered on an obligation to best benefit humanity, not allowing individuals to be harmed for the larger benefit of society. Because of these joint roots in natural law, the first two principles of respect for persons and beneficence do not sit in opposition to each other but instead work together towards the same goal: ensuring that the human subjects at the heart of research studies receive the most benefit possible.

The final ethical principle, justice, is not clearly defined in the Belmont Report, limiting the ability of

the principle to ethically guide researchers. The Report begins its discussion of justice by saying "Who ought to receive the benefits of research and bear its burdens?" This is a question of justice, in the sense of 'fairness in distribution' or 'what is deserved'" (1). With continuing dialogue that echoes this line of questioning, the Report outlines the questions justice seeks to address, without ever clearly defining what the Belmont Report's idea of justice is (1). They end their first paragraph by citing five widely accepted ways to understand justice, with no indication of which one they align themselves with (1). This is in stark contrast with respect for persons and beneficence, which have clear ethical roots that allow the principles to be applied to biomedical situations. With justice the Report skips over these roots, and instead heavily relies on applying the principle to human subject selection to reveal a stance on justice. For example, the document states it is unjust to select populations based off of their easy availability or ability to be manipulated (1). Instead, people should be selected "for reasons directly related to the problems being studied" (1). It is also unjust to select people who are unlikely to benefit from the applications of the research. The Report goes further by saying that the socioeconomic position and vulnerability of the subject must be considered in order to see who is better able to bear the burden of research and when, if at all, it is appropriate to place further burdens on disadvantaged groups. These statements work together to set clear guidelines for protecting marginalized groups of people from being unjustly used in research. However, because justice is only worked out through specific examples, it becomes hard to apply this principle to any questions that are not explicitly outlined in the Report. HIV cure research presents issues that go beyond these claims of prevention from a harmful inclusion of subjects. This viral research raises questions of what ethics has to say about excluding people from research and requires a clear definition of justice to answer them.

The Current State of the AIDS Crisis

HIV remains a global health crisis, with the United Nations Program on HIV/AIDS (UNAIDS) reporting 37.7 million people living with HIV in 2020 (9). Out of these cases, 10.2 million people were left untreated and 1.5 million were newly infected that year (9). Although 66% received treatment to virally suppress HIV, there were 680,000 deaths worldwide (9). These infections have been geographically centered in Sub-Saharan Africa, with 67% of infected people being located on the continent (9). The viral spread in these areas has been attributed to a lack of education on the virus, inadequate infrastructure to support retroviral therapy,

and poor access to condoms and testing for sexually transmitted diseases (9). These issues have largely been recognized by local and global organizations and governments, with Africa being the focus of thousands of HIV research projects. Prevention studies have been one of the most utilized approaches, which can be both observational studies on the spread of the virus and active interventions to stop viral transmission. Prevention research has been globally centered in Africa, with one comprehensive study in 2010 that looked at late stage randomized control trials finding 86% of their selected trials took place in Africa (10). These studies have had mixed success, with 90% found to be ineffective in a 2010 report (11). Despite this, the number of new HIV infections decreased by 43% from 2010 to 2020 in Eastern and Southern Africa and decreased by 37% in Western and Central Africa (9). Even with HIV infections being on a decline, the epidemic is still having detrimental impacts most seen in Africa (9). New research, along with an increase in infrastructure and healthcare funding, needs to be focused on the epicenter of the epidemic in order to put an end to the crisis.

Anti-viral Retro Therapy (ART) is currently the most effective HIV treatment, but it is predicted to be unable to end the epidemic in Africa (2). ART has proven to be successful against the virus, consistently suppressing the viral load to untransmissible amounts in nearly all that receive this treatment. This is currently the closest treatment we have to a cure, with the World Health Organization recommending ART for all HIV-infected individuals (12). While ART has moved from a debilitating to generally safe treatment, there is still immunological damage from the HIV virus. (12). ART is also a lifelong treatment, requiring constant updated medication, as well as reliable care from family or a healthcare professional. While this is able to be sustained in nations with adequate healthcare and economic means, this is often a burden for those living in LMICs (12). ART requires adherence to treatment regimens and access to consistent support and medical treatment. Combined with the health risks that remain with ART, this treatment puts a large amount of stress on healthcare systems and is currently predicted to be an unattainable way to eradicate HIV in LMICs (2). While these nations continue to develop an infrastructure that can maintain treatments like ART, researchers must find an alternative treatment that fits the demands of the nations that need it the most.

HIV Cure Research and the Ethical Dilemma

Many researchers believe that the only way to stop the epidemic, and the need for ART, is a cure that

puts the virus into remission without continual effects and treatment needs (2). A cure could be extremely effective in taking the burden off of LMICs, providing a needed alternative to treating HIV while infrastructure continues to develop. A cure seemed impossible for decades, but recent successes show the real potential of cure research. Long term remission, and possibly total eradication, has been observed in two patients after a transplant of bone-marrow cells lacking the HIV co-receptor CCR5 (12). Additionally, animal models have suggested that “an HIV cure might be induced through the provision of broadly neutralizing antibodies, the generation of an effective antiviral CD8+ T cell response or by knockout of CCR5” (2). There are many novel approaches to curing HIV that are sure to expand as more researchers shift their focus to finding a cure. Even with this progress, some scholars believe a cure will never be able to compete with the success and price of ART (2). Current discourse in the UNAIDS report seems to suggest that a successful treatment is here, and that the work now is to build up the infrastructure and healthcare systems in LMICs so that treatment can be sustained (9). While HIV highlights the need to help develop infrastructure in LMICs, hundreds of thousands of people are still dying as they wait for healthcare to improve. Until this infrastructure can be properly established, an alternative must be made. A onetime cure, while possibly more expensive per single treatment, will inevitably take a massive burden off healthcare systems and individual lives in LMICs.

While the prevalence of HIV in Africa was utilized to conduct prevention studies and some treatment studies, there is essentially no cure research on the continent (2, 3, 5, 12, 13). This discrepancy is largely because prevention studies focus on understanding how the virus spreads within a community and how to implement techniques to prevent propagation. This research does not require as much laboratory infrastructure as cure research, albeit this is a more rapidly attainable infrastructure than the entire healthcare system needed to sustain ART (2). This leads to early human trial phase cure studies to be conducted in HICs on groups of predominantly white men due to the group having the highest infection rate in these areas (2, 3, 5, 12, 13). This greatly contrasts with the infection rates in Africa, with women and adolescents being the most infected populations (9). Not only is the most infected region lacking cure research, but the groups being tested in HICs lack diversity themselves (14). This discrepancy between populations has given rise to concerns of a cure not having equal efficiency in LMICs (2, 4, 12). Studies have suggested that there are important sex differences that could affect cure outcomes (12). There is also HIV subtype diversity between regions and differences in

concurrent infections that affect the viral reservoir in the body (12). A similar problem has already emerged with ART, with recent research suggesting that the treatment has differential toxicities between white male populations in comparison to younger and predominantly female African populations (2). These differences have led to a medical concern of the lack of cure research in African nations, arguing that region-specific issues must be addressed (2–4, 12). Excluding these nations from early phase research trials may create great limitations for developing a cure that fully works in Africa (2, 12). Including patients from LMICs early in the process of clinical research could also make it easier to include these same populations in later stage research and to scale up an effective cure, as community trust and laboratory infrastructure could already be established (2, 3, 12). These findings illuminate a clear scientific and public health concern for the exclusion of certain populations in research, but no ethical argument has been made. I will argue that these medical uncertainties ethically require global institutions to actively seek out the participation of more diverse subjects so that solutions can best benefit the people who need them the most.

The Belmont Report's Current Response

If HIV cure research is analyzed through the current guidance of the Report, the practices could broadly adhere to the proper selection of human subjects. As outlined earlier, the Report focuses on preventing vulnerable individuals from being used for research gains. The guidance for human subject selection urges researchers to choose subjects based off “the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons” (1). Right now, it is mostly white men in HICs that are participating in cure studies. This population is more able to bear the burdens of cure research financially, as well as repercussions that may come from novel technologies being introduced. Early-phase research studies typically use patients already on effective ART, so participation puts them at greater risk as they transition to an unproven treatment (3). Active efforts to include infected populations from LMICs into cure studies when there are people more able to bare the possible burdens of this uncertain treatment could lead to exploitative situations where disadvantaged groups are used as research subjects for the advantage of others. The Report also says to select subjects “for reasons directly related to the problems being studied” (1). Current patient selection is not a matter of intentional exclusion, but they are instead conducting research on the populations most effected in their own

countries. White men are the most infected group in the places conducting cure research, so they are the best populations in HICs to use for these studies. If patient safety was the only concern with HIV cure research, then the current selection of subjects could be viewed as ethical. Researchers are developing a cure that people in LMICs likely will have some benefit from, without having to use these populations for uncertain research.

While it will remain crucially important to protect the health and autonomy of people participating in research studies, the above application of the Report fails to address the new ethical dilemma that HIV cure research presents. Cures are still in the early stages of development, and researchers are unsure what kind of treatments will emerge. If a potentially harmful one is developed, then it will remain essential to make sure patients can take the burden. The abuse of subjects needs to be continuously checked throughout all research studies, but there is an entirely separate issue presented in HIV cure research that needs to be addressed independently of these concerns. As HIV studies have shown, pathogens can affect populations differently based on sex, subtypes, and environment. Studies on one population can no longer be guaranteed to extrapolate to the global population. These discoveries reveal a new form of subject selection justice: a justice in preventing the exclusion of populations from research that need the benefits of an effective solution. There is nothing in the Report's discussion on the selection of subjects that addresses this issue. Instead, all discussions on human subject selection are focused on what was presented above: the protection of individuals who are partaking in research studies. Because the Report defines justice only through these limited subject selection guidelines, population exclusion becomes difficult to address as there is no clear foundational ethical principle to respond to novel issues. The Report will never be able to effectively serve as guidance for the selection of subjects beyond its explicit examples if justice is left undefined. Because of this, I argue that the Report needs to be updated with a clear definition of justice, as well as written guidelines that respond to an exclusion of subjects. While the Report was created to protect vulnerable people from being used, modern issues call for an expansion of the Report that morally obliges the inclusion of vulnerable individuals. To begin understanding what this definition of justice could look like, I turn to the Report's well-defined principles of respect for persons and beneficence, using HIV cure research as a case study to show how these revisions can be practically applied.

The Ethical Foundations of the Belmont Report as a Guide for Understanding Subject Exclusion

The principle of beneficence begins to reveal that the Report inherently calls for a distributive justice, showing researchers that they have a positive obligation to help those in need. Beneficence, rooted in both utilitarianism and natural law, currently obliges researchers to consider how their experiments can be designed to best benefit human subjects without causing harm (1). When applying the principle to just patient selection in HIV cure research, the way to create the greatest overall benefit is to prioritize helping those who are impacted by the virus in the greatest numbers. Right now, it is women and adolescents in African nations that need a cure the most as they are suffering from more deaths than any other population and are the ones least likely to benefit from current treatment options (2). HIV treatments have been a failure of beneficence, unable to benefit the populations most negatively impacted by the virus. A cure for HIV is the opportunity to reverse this disparity being seen with ART and create a treatment that addresses the issues of the most effected people. This inclusion does not require an exclusion of those in HICs, but instead an expansion of current efforts to greater aid the global population. This application of beneficence to subject selection begins to show that the Report is inherently built on claims of distributive justice. At its roots, distributive justice is concerned with ensuring members of society have a just allocation of benefits. This is in line with the Report's understanding of beneficence, which requires progress to not be held by a few, but instead be used to lead to the greatest good. In the case of HIV cure research, this maximization of benefits happens to be on the side of the vulnerable, fully aligning with the principles of distributive justice. However, this may not always be the case as there could be instances where an illness most predominantly affects the privileged and getting the most "benefit" from research means overlooking the needs of the marginalized. What beneficence fails to provide, that distributive justice requires, is an obligation to not only create the most good, but to prioritize vulnerable people even if it means the privileged receive less benefit.

If beneficence is used to inform both a definition of justice and the selection of human subjects, one might argue that maximizing benefits in research is an impractical slippery slope. There are always going to be diverse groups of people affected by a given disease and there is only so much one institution can do. A research system cannot be built off continuously searching for the best benefit a project could have. If this became standard, no research would ever actually get done as better possibilities would continuously arise, and

research would need to be constantly halted to consider these new methods. I agree that it is not practical to continuously search for better benefits of research. That is why the Report is by no means a pure utilitarian calculus, checking much of these claims with other core ethical principles. Beneficence is not an obligation to create the project that maximally benefits all human existence. Instead, the Report treats beneficence to show that research has a duty to best help people within the current scopes of the project, giving "forethought to the maximization of benefits" and recognizing "the longer-term benefits and risks" that may result (1). A well-defined definition of distributive justice would hopefully do the same. Justice would not mean that researchers need to find the absolute most in need person to center their research around. Instead, an explicit definition of distributive justice and increased patient selection guidelines would remind researchers to consider larger research impacts, showing them that it is important to make considerations beyond the current framework of protecting subject abuse. In the case of HIV cure research, there is published information showing that where research is conducted, and who it is conducted on, can impact thousands of lives. There is a clear indication that African women and adolescents need a cure more than any other group in the world and that their bodies may interact differently with a cure than the people currently being tested (2). If institutions begin allocating funding towards the inclusion of blood samples from these populations or the development of laboratories in LMICs it would not be the start of a slippery slope, but instead the bare minimum of what truly just research should do.

When the principles of beneficence and respect for persons are looked at in unison, the Report calls for a distributive justice that includes putting the vulnerable first. As described earlier, the Report's language in both the beneficence and respect for persons sections is underlined by the natural law belief of aiding human flourishing (1). There is also a clear definition of respect for persons that expands on Kant's ideas of respect for autonomy and human dignity by prioritizing protecting those with diminished autonomy (1). Together, these principles form a complete idea of distributive justice, emphasizing that researchers have an obligation to not only maximize good, but to also prioritize those most in need. How this definition of justice could manifest itself in clear guidelines can again be seen through the application of HIV cure research. While there is scientific purpose to conducting research on white men in HICs, just patient selection obliges researchers and institutions to make sure vulnerable populations are not left behind. With this globalized understanding, choosing the most impacted local populations becomes

an exclusion. Not only is this a failure to recognize what will lead to the most benefit, but it also fails to recognize the dignity of people living in LMICs. All humanity has an equal right to life, and honoring the dignity of those in LMICs means giving them equal access to an effective cure. New Report guidelines would not require middle-aged white men in HICs to be completely ignored, but instead urge for diversity in early-stage trials to ensure that the developing cure does not impact populations differently. If there is no distinction, then the cure can continue to develop using more easily available subjects because this availability does not diminish the dignity of others or lead to the reduction of any benefits. If there is a difference and later stage trials are pursued, then there is an obligation to create cures that work with each population. Throughout this, it is important to ensure that all subject's autonomy is respected when including research subjects. While there is an obligation to address issues of diversity, the pursuit for adequate representation should not override the individual decision to be a research subject. The Report includes utilitarian, Kantian, and natural law principles because there is a recognition of the needed balance between all three. I urge the Report to more clearly define these principles when it comes to patient selection, citing examples of an unethical exclusion of subjects from research.

Some might argue that if the Report calls for a form of distributive justice, guidelines would infringe on the autonomy of researchers and institutions. The Report already seemingly suggests that people have the right to decide what causes they want to put resources towards, as it states, "to respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others" (1). Researchers, and those who fund them, are autonomous beings able to make rational decisions. In the case of HIV cure research, there is nothing irrational about conducting research to try to cure people in HICs of a life-threatening illness. Furthermore, the fact that a cure might be less effective on one population is not necessarily a "clearly detrimental" outcome as the cure would still be a great help to these populations, just to a potentially lesser extent. These points are well supported by natural rights ethics. This moral framework believes not infringing on basic rights is the only thing duty requires, and anything else is above duty (15). Those who prescribe to this ethics will likely never support a moral or legal obligation to conduct research for groups who cannot do it themselves. A similar argument could be made from a purely Kantian standpoint, which believes a duty to others is an imperfect duty that does not always need to be acted upon (6). However, Kantian ethics also requires

that human dignity and the right to life must always be respected, and this is exactly what the Report has worked towards and will continue working towards under new revisions. Often, fully respecting human dignity will require directing research down a specific path, obliging certain subjects to be chosen. The Report has always been written with positive rights, morally obliging research to do something. Standing by an explicit statement of distributive justice would simply be a continuance and strengthening of this history. Making a clear stance could let researchers know that there is more to the process of selecting subjects than preventing harm during trials. In the case of HIV cure research, people are faced with the decision of honoring unbounded researcher autonomy or patient dignity. The latter has a much greater risk of leading to detrimental harm to humans as it not only contradicts the principle of respect for persons but also leads to a greater loss of life, making the just action to include diversity in HIV cure research.

Conclusion

The Report has historically been used to protect marginalized groups of people from being unjustly used for the advancement of biomedical research. Modern medical issues, such as HIV cure research, require these ethical guidelines to be expanded, addressing population exclusion from research. The Report contains ethical principles that definitively respond to this issue, but the failure to specifically speak on subject exclusion has allowed current research to be conducted under the belief that it is ethical. In my paper, I demonstrate that the Report is rooted in utilitarian, Kantian, and natural law ethics. The principles work together to implicitly form a definition of distributive justice, arguing for maximizing the benefits of research, while also prioritizing subjects with diminished autonomy. I urge the Report to make clear their stance on justice, creating guidelines that apply justice to modern subject selection issues. With this definition of justice, I explore how a revised Belmont Report could guide HIV cure research. In the face of possible differences in cure outcomes between populations, these factors must be taken into consideration to ensure everyone can benefit from a cure and maintain an equal dignity. The inclusion of African populations is not only morally right but morally obligatory, as exclusion may cause direct harm to infected populations. There still is a limit on the maximization of benefit, with practicality and researcher autonomy remaining important to consider. Because of this, it will be important to explore the most realistic ways to obtain representation of global diversity while inadequate infrastructure remains an issue. New strategies must also be contrived to better allow medical

and ethical issues to be known to HIV researchers. As research progresses, proper communication and consent with African women and adolescents will become crucially important.

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