Scarce Resources: The Ethics of Intentional HIV-Positive to HIV-Negative Organ Transplantation in the United States

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There is a major shortage of organs in the United States resulting in thousands of deaths per year. One main approach for responding to this crisis has been to consider expanding criteria for donation to increase the pool of available organs. The HIV Organ Policy Equity Act (HOPE Act) legalized HIV+ to HIV+ organ transplants, allowing HIV+ organs to be used in transplants in the U.S. for the first time. But even with this policy there is still untapped potential in considering HIV+ organs for transplant. Under current law HIV+ living donors cannot donate to HIV- recipients even if no alternative organ is available. Similarly, HIV- potential organ recipients are forbidden from accepting an HIV+ organ even if the organ would otherwise be discarded or would be given to a person on the waitlist who is in less desperate need of it. In the early years of the HIV pandemic these prohibitions were logical as HIV was a deadly disease with no effective treatment. Yet today this is no longer the case and people living with HIV can live long fulfilling lives. As such, legalizing HIV+ to HIV- organ transplantation in the United States has great potential to save lives and improve quality of life. This essay will explore the risks and benefits of this procedure and argue that it is prudent to legalize HIV+ to HIV- transplantation.

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1.0 Overview

This paper will argue in favor of legalizing HIV+ to HIV- organ transplantation in the United States. The paper will be divided into the following sections: background information including an explanation of the HOPE Act and a HIV+ to HIV- transplant case study; an examination of the current organ allocation systems in the US; an analysis of whether HIV+ to HIV- organ transplantation conforms to established biomedical ethical principles; an evaluation of different allocation schemes incorporating HIV+ to HIV- donation; a section explaining how new information could change the conclusion of this analysis; and a conclusion.

2.0 Background

2.1 Introduction

Over 100,000 people in the United States are currently waiting for an organ transplant ("Facts and myths about transplant," n.d.). On average, the shortage of organs results in 20 deaths a day, with the majority of those deaths—about 13 a day—from those waiting for a kidney transplant ("Facts and myths about transplant," n.d.; "Organ donation and transplantation statistics," n.d.). Working to solve this problem demands creativity and innovation. Allowing HIV+ to HIV- organ transplantation has the potential to increase the pool of organs available, save lives, and improve quality of life for transplant recipients. Requiring that the transplants be performed in a research context—as was also a requirement of legalizing HIV+ to HIV+ transplantation—will provide valuable information about the comprehensive impacts of the procedure (National Institute of Allergy and Infectious Diseases, 2019). However, this essay will show that even now, in the absence of this information, the benefits of allowing HIV+ to HIV- transplantation likely outweigh the costs.

2.2 The HOPE Act

The HIV Organ Policy Equity Act (or HOPE Act) was implemented in 2015 ("Hope Act," n.d.). This act legalized HIV+ to HIV+ organ transplantation conducted for research purposes ("Hope Act," n.d.). Before passage of the Act, researchers had estimated that legalizing HIV+ to

HIV+ organ transplantation would increase the total pool of donor organs available by ~350-650 per year (Boyarsky et al., 2011; Richterman et al., 2015). Additionally, once the Act was passed another benefit became apparent in that due to the false-positive rates of tests used to screen for HIV an additional 50-100 donors who were actually HIV- but labeled as HIV+ would be able to donate—as before the passage of the HOPE Act their organs would have been discarded due to concerns about HIV transmission (Boyarsky et al., 2019; Durand et al., 2018). In addition to providing lifesaving organ transplants to HIV+ organ recipients this act benefits HIV- potential recipients as well since increasing the number of transplants lowers the number of people on the waitlist (Boyarsky et al., 2019). However, despite all of these advancements made under the HOPE Act the next section will show that only allowing HIV+ to HIV+ transplantation will not save every life that could be saved by receiving an HIV+ organ.

2.3 Intentional HIV+ to HIV- Transplant Performed in South Africa in 2017

South Africa is similar to the United States in that there is a major shortage of organs available for transplant (Etheredge et al., 2019). The countries also resemble each other in that both have been able to largely transition from the initial state of the HIV pandemic where infection meant death to one where HIV infection can be managed and becomes a chronic illness that one can live with for many years (Etheredge et al., 2019). For the Etheredge et al. team these two considerations meant that there was increased pressure to reconsider policies preventing persons living with HIV to act as donors for HIV- organ recipients (Etheredge et al., 2019). It seemed increasingly doubtful that preventing the possible harm of HIV infection was worth the

consequences of failing to receive a life-saving organ transplant. This was particularly true in one case involving an HIV+ mother and her HIV- daughter who was awaiting liver transplant:

> "As the child's health deteriorated, it became clear that the living donor option, with the child's HIV-positive mother as the donor, was our only hope of saving the child's live. Due to SA's [South Africa's] solid organ shortage, it was highly likely that the child would die before a deceased donor liver could be procured. The HIV-positive living donor option was only pursued after all other willing family members had been found ineligible for living donation. The child remained on our deceased donor waiting list until transplant, and at the time of transplant had been listed for 181 days, almost four times the average for our programme" (Etheredge et al., 2019)

The team had decided to proceed with the transplant expecting the child to become infected with HIV reasoning that the consequences of such an infection would be outweighed by the benefits the organ transplant provided (Etheredge et al., 2019). At the time the article detailing the procedure was published—almost two years after the transplant had taken place—both the mother and the child were in good health and the child seemed to have greatly benefitted from the procedure (Etheredge et al., 2019).

2.4 Beauchamp and Childress Principles of Biomedical Ethics

In biomedical ethics there are four main principles that are often used to determine whether a medical procedure or system is morally acceptable. These principles, as described by Tom L. Beauchamp & James F. Childress are:

> "(1) *respect for autonomy* (a norm of respecting and supporting autonomous decisions), (2) *nonmaleficence* (a norm avoiding the causation of harm), (3) *beneficence* (a group of norms pertaining to relieving lessening, or preventing harm and providing benefits and balancing benefits against risks and costs), and (4)

> *justice* (a cluster of norms for fairly distributing benefits, risks, and costs)" (Beauchamp & Childress, 2019, p. 13)

These four principles must be balanced against each other with no one principle outweighing all the others. In some situations, the balancing is obvious: "If in a particular case a heath care provider inflicts a minor injury—swelling from a needlestick, say—but simultaneously provides a major benefit such as saving the patient's life, it is justified to conclude that the obligation of beneficence takes priority over the obligation of nonmaleficence in this case" (Beauchamp & Childress, 2019, p. 156). However, in many situations, such as in the case of organ donation, it is not always apparent what the best approach is. Yet, the principle of balancing still plays a role. For example, "Rationing schemes that either minimize or altogether exclude considerations of medical utility are indefensible, but judgments of medical utility are not always sufficient by themselves" (Beauchamp & Childress, 2019, p. 310). Instead, a combination of medical utility and other factors is a more appropriate basis for allocation of scarce resources as "It is generally legitimate to invoke medical utility followed by the use of chance or queuing for scarce resources when medical utility is roughly equal for eligible patients" (Beauchamp & Childress, 2019, p. 312). There are many different ways to construct such a system prioritizing medical utility while considering other values but in many cases what is theoretically possible might not be practical to implement. As such, the next section will investigate how the already-established organ allocation system in the United States is constructed and if/how it balances the principles of biomedical ethics elucidated by Beauchamp & Childress.

3.0 Examination of UNOS/OPTN Guidelines[1]

Before looking at whether HIV+ to HIV- transplantation should be considered, it would be prudent to review the guidelines that are already in place for organ transplantation in the United States—both to understand the values apparent in the current system and to gain a greater appreciation of the general structure that a newly approved procedure would have to feasibly fit into. The following is a general summary of how deceased donor organs are allocated depending on organ type based on guidelines put forth by the Organ Procurement and Transplantation Network (OPTN) under the United Network for Organ Sharing (UNOS). In an effort to be brief, only three organ types will be described—heart, liver, and kidney. Liver and kidney were picked because under current legislation these are the only two organs that HIV+ to HIV+ transplantation is focused on (National Institutes of Health, n.d.). Heart was included because the allocation system for this type of organ is a good middle ground between the very simple liver allocation system and the incredibly complex kidney one. The following descriptions are general summaries—there are exceptions to the rules but the aim of this section is not to give every detail of the allocation systems but rather to identify trends and themes.

[1] All information in this section unless otherwise indicated is from this source: (*Organ Procurement and Transplantation Network Policies*, 2020)

3.1 Allocation of Livers

We will begin by looking at the most straightforward allocation system—the one for livers. For this system there are only two main categories for adult potential recipients: those who have a life expectancy of 7 days without a transplant (status 1A) and everyone else. Pediatric candidates have a similar classification with the addition of a middle category. For the classification (a section of which is provided below) candidates with status 1A (both adult and pediatric) and geographic proximity to the donor get priority, then the middle category pediatric candidates, then individual MELD/PELD (Model for End-Stage Liver Disease/Pediatric End-Stage Liver Disease) scores decreasing in severity alternating between a small geographic area[2] and a medium sized-geographic area[3], before opening up the geographic area to the entire nation and returning to the candidates with more severe cases. So, for example, a person with a MELD/PELD score of 35 within the smallest geographic area has a higher priority than a person with a MELD/PELD score of 15 within the middle geographic area (i.e. classification 13 vs. classification 15). But, the candidate with a MELD/PELD score of 15 within the same region as the donor's Organ Procurement Office (OPO) has a higher priority than a person with status 1A who is only in the same nation. These MELD/PELD scores combine several lab tests for substance concentrations that are tied to liver function, with a higher score indicating the need for an urgent transplant.

[2] Formally, this is the donor's Organ Procurement Office's donation service area
[3] One of 11 established regions that subdivides the entire US

Table 1: Allocation of Liver Sample Table

Classification	Geographic region	Criteria
1	medium	Status 1A
2	medium	Status 1B
3	small	MELD/PELD of 40
4	medium	MELD/PELD of 40
5	small	MELD/PELD of 39
6	medium	MELD/PELD of 39
…	…	…
13	small	MELD/PELD of 35
14	medium	MELD/PELD of 35
15	small	MELD/PELD $\geq$ 15
16	medium	MELD/PELD $\geq$ 15
17	nation	Status 1A
18	nation	Status 1B
…	…	…

This system seems pretty easy to understand—it seeks to maximize the number of lives saved and secondarily to maximize the number of life-years saved. People with the most urgent need of transplant are given priority whether they are an adult or a child. The list then shifts to a special pediatric category—prioritizing those who are likely to live with the organ longer than older candidates. Geographic region is the strangest factor and the hardest one to explain. Historically, geographic proximity to the donor was important because organs would become less viable the longer they were outside a human body—geography had to be prioritized otherwise many organs wouldn't be usable (Institute of Medicine, 1999). With current technology, time outside the body is less of an issue—though still relevant to a certain extent (Institute of Medicine, 1999). There have been many calls to substantially revise the role of geography in the allocation system, and this remains a contentious issue (Snyder et al., 2018; Spaggiari et al., 2019).

3.2 Allocation of Hearts

In the allocation of hearts, an adult candidate can be assigned a status from 1-6, with status 1 indicating the most severe conditions and 6 the least. A pediatric candidate can be assigned status 1A, 1B, or 2, also depending on severity with 1A representing the highest level of severity. Adult donor allocation classifications prioritize the highest (most severe) classes and the smallest geographical regions[4], with the list beginning with the smallest geographical areas and moving down a few statuses before returning to the higher statuses but at a greater distance. For candidates that have the same status and region, the secondary blood type match immediately follows the primary blood type on the list. The pediatric allocation classifications are similar to the adult ones but prioritize the pediatric status over the comparable adult: pediatric 1A then adult 1 then adult 2 then pediatric 1B. So, for example, a person with Pediatric Status 1A who is a secondary blood type match with the donor and within 1000 miles of them has a higher status than someone with Adult Status 2 and a primary blood type match and within 1000 miles (classification 8 vs. 9). So, as we can see, there are a variety of factors that are important in the allocation of hearts. Severity of condition, geographical region, pediatric status, and blood type are all taken into consideration with no one factor outweighing all of the others.

[4] Regions for hearts are defined by proximity to donor—for example within 500 miles of the donor

Table 2: Allocation of Hearts Sample Table

Classification	Geographic Region	Status
1	500 miles	Adult Status 1/Pediatric Status 1A, primary blood type match with donor
2	500 miles	Adult Status 1/Pediatric Status 1A, secondary blood type match with donor
3	500 miles	Adult Status 2, primary blood type match with donor
4	500 miles	Adult Status 2, secondary blood type match with donor
…	…	…
8	1000 miles	Adult Status 1/Pediatric Status 1A, secondary blood type match with donor
9	1000 miles	Adult Status 2, primary blood type match with donor
10	1000 miles	Adult Status 2, secondary blood type match with donor
11	250 miles	Adult Status 4, primary blood type match with donor
12	250 miles	Adult Status 4, secondary blood type match with donor
…	…	…

But why are all these factors so important? Severity of condition is pretty obvious just like it was with livers—it prioritizes the people who need the organ most so that the allocation is set up to save as many lives as possible. Pediatric status is similarly easy to explain: in general, we want organs to go to children who have not yet had the opportunity to live for a substantial period of time. Additionally, we want organs to be used for as long as possible, and a 16-year-old is more likely to live several more decades with a transplant than an 80-year-old or even a 50-year-old. It is notable that Adult Status 2 is prioritized over Pediatric Status 1B, since this means that severity of condition is balanced with pediatric status instead of all organs first being offered to pediatric candidates. Blood type at first seems an odd factor to consider but becomes more obvious when

one considers that graft loss is a serious concern with organ transplant. If we wanted to maximize the number of years that a person lives with an organ we would want to make sure that the particular organ was as compatible as possible with the potential recipient, and blood type would be a significant biological indication of compatibility. So, for potential recipients that are otherwise equal—same status and distance from donor—it makes sense to prioritize the potential recipients who are more likely to be able to live with the organ for a longer period of time, i.e. those with primary blood type matches are prioritized over those with secondary blood type matches. Finally, once again we see that geographic proximity to the donor remains a relevant factor.

3.3 Allocation of Kidneys

Let's now turn to another, more complicated, organ type—the kidney. Like with hearts kidney allocation depends on many factors. However, unlike hearts, these factors are associated with several scores (often acronyms) that determine allocation. The first score to be aware of is the kidney donor profile index (KDPI) score, which as the name suggests is a score associated with the donor, not the recipient. This score represents the percentage of kidneys that are expected to be of better quality than the kidney the score is assigned to. So, for example, a kidney with a KDPI of 90% is expected to be of lower quality than 90% of kidneys recovered for donation. Several factors determine KDPI including but not limited to age, creatinine concentration[5], weight, and HCV status—all given specific weights in a formula that outputs a number that can be turned into the KDPI score. Different KDPI ranges are given different allocation lists for recipients, with the

[5] A measure of how well the donor kidneys are able to filter blood

biggest difference between the lists being that as KDPI increases several criteria on the list are combined. For example, there are 69 different allocation categories a potential recipient could be placed in for a kidney with a KDPI score of 0-20%, but only 37 for a kidney with a KDPI >85%. Despite this difference, the allocation categories tend to follow the same general pattern. Potential recipients with the highest CPRA (Calculated Panel Reactive Antibodies—a measure of the percent of donors on the waiting list that are incompatible with that particular potential recipient) are given organs first, starting with the smallest geographical region[6] and then working outward. Once 100%-98% CPRA candidates have been exhausted, the priority is given to candidates younger than 18 (except for the >85% KDPI list, which does not mention pediatric candidates) and candidates with a top 20% EPTS (Estimated Post Transplant Survival) score are given priority—a score which is calculated based on candidate age, time on dialysis, history of organ transplant, and diabetes diagnosis. Candidates with CPRAs of 21%-79% soon follow, then the geographic area is broadened. In general, candidates with zero antigen mismatches with the donor organ are given priority over similar cases without. So, for example, a candidate with a CPRA of 100%, a permissible or identical blood type, within the small geographic region, and with a 0-ABDR mismatch is given priority over a candidate that meets all the same criteria except the 0-ABDR mismatch (classification 1 vs. 2).

[6] The geographic regions are the same as for livers (OPO DSA and OPO Region)

Table 3: Allocation of Kidneys Sample Table (KDPI>85%)

Classification	Geographic Area	Criteria	Donor Blood Type
1	small	0-ABDR mismatch, CPRA: 100%, blood type permissible or identical	Any
2	small	CPRA: 100%, blood type permissible or identical	Any
3	medium	0-ABDR mismatch, CPRA: 100%, blood type permissible or identical	Any
4	medium	CPRA: 100%, blood type permissible or identical	Any
…	…	…	…
13	small	0-ABDR mismatch, blood type permissible or identical	Any
14	medium	0-ABDR mismatch, CPRA≥80%, blood type identical	Any
15	nation	0-ABDR mismatch, CPRA≥80%, blood type identical	Any
16	medium	0-ABDR mismatch, 21%≤CPRA≤79%, blood type identical	Any
17	nation	0-ABDR mismatch, 21%≤CPRA≤79%, blood type identical	Any
18	small	0-ABDR mismatch, blood type B	O
19	medium	0-ABDR mismatch, CPRA≥80%, blood type B	O
…	…	…	…

Within each classification, a points system is used to give priority. This points system incorporates a variety of factors such as waiting time, CPRA score, and whether the candidate is a prior living donor.

Table 4: Kidney Points Sample Table

Criteria	Points
Waiting time	1/365 points for each day
Aged 0-10 at time of match and a 0-ABDR mismatch with the donor	4 points
Aged 11-17 at time of match and a 0-ABDR mismatch with the donor	3 points
Prior living donor	4 points
CPRA at least 20%	Increases according to CPRA score, ex. 20-29%=0.08 points, 60-69%=0.81 points, 80-84%=2.46 points, 96%=12.17 points

There's a lot that goes into the kidney allocation system but we can still extract out some general values from how it is set up. Different lists for different KDPIs indicate a desire to treat allocation of preferred organs differently from those deemed less favored. The fact that the allocation categories are combined as KDPI increases suggests that each of the factors that go into creating the different allocation categories matter less in comparison to each other when the organ is determined to be of lower quality according to KDPI score. Prioritizing recipients with higher CPRA scores points to an attempt to maximize equity among potential recipients—those with the highest CPRA scores have the lowest chance of finding a match, so if one comes up it would likely be the only one they would ever get whereas candidates with lower CPRA scores can be relatively certain that another match will come along in time. As such, this principle also works to maximize the number of lives saved, as people who are compatible with many different organ types only get organ offers that are not compatible with those with many restrictions. As far as zero antigen mismatch is concerned, this is similar to matching blood type in heart transplants—minimizing graft loss when possible. Once again we see that geographic region plays a role in allocation. The

points system serves to balance several factors against each other. But most of these factors seem to have an underlying value of fairness—those who have been on the waitlist longer are given priority along with those who have previously donated an organ and now need one. The prioritization of prior living donors also works to incentivize living donation, increasing the pool of available organs overall.

In general, the reason the kidney allocation system is more complicated than heart or liver is that patients with nonfunctional kidneys can live for considerably longer periods of time than those with a nonfunctional heart or liver. This means that there are considerably more people on the wait list for kidneys in general and more people on the wait list who are not at immediate risk of death—so other factors besides immediate need become relevant.

3.4 Summary

Even though there are many differences in the allocation systems it seems there are also some repeating themes and underlying values. Prioritizing those who need the organ most seems to be a consideration that runs through all three of the allocation systems we have looked at—and by extension saving the most lives seems to be an important goal for the allocation system. This goal is balanced with a desire to prioritize pediatric candidates and other candidates who would be likely to live with the transplanted organ for the longest period of time. Fairness also seems to be an important secondary consideration once all candidates who are in desperate need of an organ have been considered. Factors like prioritizing prior living donors serve to incentivize an increase in the pool of organs offered, thereby also saving as many lives as possible.

4.0 Application of Values to Proposed HIV+ to HIV- Transplantation Procedure

Because of the myriad of factors that go into developing health care policy determining whether a particular principle—or in this case procedure—can be practically executed is no simple task. We have seen from the analysis of OPTN/UNOS's guidelines that no one factor outweighs all the others, and that many different considerations are relevant to this particular discussion. As such, it is prudent to consider how the proposed HIV+ to HIV- transplant procedure does or does not conform with the identified values of organ donation in the United States. This is what I will endeavor to do in the following sections.

4.1 Considerations of Beneficence and Nonmaleficence

In the previous section it was determined that saving the most lives was an important goal for OPTN/UNOS. On this consideration alone it seems that the proposed procedure would be likely to align with this goal. In general, "If we wanted to maximize transplant, we would want a system that accepts organs that are known in advance to be somewhat suboptimal" (Veatch, 2000, p. 240). This makes sense, as demand for organs currently outstrips supply, and "[t]he median waiting time for an organ is 1-7 years and can be significantly longer for highly sensitized or difficult to match recipients" (Kucirka et al., 2011). Increasing the number of organs deemed transplantable should reduce the waiting time for an organ and thus increase transplants and reduce the number of people who die while on the waitlist. It is tempting to argue that since HIV+ to HIV+ transplantation is already allowed, that opening up transplantation to HIV+ to HIV- cases would not actually increase

the number of transplants—as the HIV+ organs are already deemed transplantable (albeit only in some cases). What this argument fails to consider is that even if a particular organ is determined to be of a high enough quality to be used in a transplant, it must be matched to a candidate for that transplant to be carried out. We have seen in the previous section that several factors impact whether a candidate can be matched with a donor organ—notably geography and biological considerations like blood type. The HIV+ population in the United States is small—about 13 per 100,000 people—and as such, it is likely that there will be some cases where HIV+ organs are considered transplantable but there is no HIV+ candidate who meets the appropriate criteria to accept that organ for transplantation (HIV.gov, June 2020). Widening the pool of candidates to those who are HIV- but willing to accept an HIV+ organ would increase the likelihood that an HIV+ donor organ is able to be matched with a candidate. It is not a ridiculous assumption that there might be HIV- candidates willing to accept HIV+ organs—particularly candidates who are in such desperate need of an organ that rejecting the offer likely means death. Philosopher Robert Veatch put it the following way:

> "If death is the only alternative for someone who cannot obtain a negative organ, I do not see why someone would decline. There is no firm evidence on the incidence of transmission in such a situation. The risk surely should be presumed to be high. But the risk of dying without transplant may also be very high. Given the fact that people with infection are now living many years symptom free, I can imagine some people preferring that risk to certain, rapid death" (Veatch, 2000, p. 252)

Veatch made this argument in 2000 and treatment for HIV has improved since then. If a logical argument could be put forth twenty years ago on why some patients might consider HIV+ to HIV- donation, it is easy to see why some might make the same argument today and decide that they would be better off accepting an HIV+ organ. Considerations of beneficence compel us to

honor the decisions that benefit people when possible. As such, the idea that lives could be saved as a result of this procedure should be taken very seriously.

When considering a new procedure, it is logical to ask what the risks are. Transplant providers would likely be concerned that HIV+ to HIV- donation is not worth the potential risks it entails—HIV transmission being the main concern. "Transmission of viral infections through solid organ transplantation can lead to adverse outcomes for recipients, including reduced quality of life, graft loss, and death" (Singer et al., 2008). Indeed, nonmaleficence is another principle that Beauchamp and Childress emphasize balancing against other factors. The arguments put forth in the previous paragraph about how the new procedure could increase the number of lives saved become less convincing if it is the case that HIV transmission is extremely likely and leads to a poor quality of life—or even a reduced lifespan—after transplant. As such, the next section will detail what we know and can infer about HIV+ to HIV- transplantation and what a candidate who agrees to such a procedure can expect.

HIV transmission risk is not only a concern for HIV+ to HIV- transplantation, but HIV+ to HIV+ transplantation as well. Because it is possible to be infected with more than one strain of HIV, "One of the main theoretical risks [of HIV+ to HIV+ transplantation] is donor-to-recipient HIV superinfection, defined as recipient acquisition of a distinct HIV strain from the donor" (Boyarsky et al., 2019). Considering that organ transplantation likely carries a higher risk of infection than intravenous drug use or sexual contact, there was great concern that HIV superinfection was extremely likely (Boyarsky et al., 2019; Muller & Barday, 2018). However, as of 2019, "superinfection is thought to occur rarely on ART [Antiretroviral Therapy]" which suggests that the process of preparing the organ for transplant as well as effective management of the infection through ART might be sufficient to prevent infection (Boyarsky et al., 2019). Yet, it

should be noted that lack of incidence of HIV superinfection through transplant does not mean that a HIV- person who is exposed to the virus through transplantation carries a similar reduced risk of infection from the donor. Superinfection is associated with an increased viral load, to the point where the latter is often thought of as necessary for the former. Take for example this quote from an article about a series of HIV+ to HIV+ transplants: "Initial concerns about transplanting HIV-positive allografts into HIV-positive recipients in this clinic revolved around the possibility of HIV superinfection. However, all recipients remained virally suppressed several years after the transplant" (Muller & Barday, 2018). But, it could be the case that the transplant recipients were indeed infected with another strain of the virus, but that their current medications were able to suppress both strains. This problem of diagnosing HIV infection while on treatment pertains to the 2017 South Africa case as well. Throughout their report, Etheredge et al. consistently report the recipient's HIV status as indeterminate, even considering that the article was written almost two years after the procedure was performed (Etheredge et al., 2019). The difficulty with diagnosis for Muller & Barday and Etheredge et al. lies in the fact that the very tests used to diagnose HIV infection fail when a patient is already effectively managing the infection through ART, and the only way to know for certain whether the organ recipient had indeed contracted HIV would be to withdraw treatment and monitor—which could be life-threatening in an immunosuppressed patient (Etheredge et al., 2019). So, it is very likely that were HIV+ to HIV- donation to be enacted, the recipient of the organ would not definitively know whether they had been infected—possibly for the rest of their life. The psychological burden of such an experience should be taken into account when determining the possible risks and benefits of HIV+ to HIV- donation, and as of right now, those who consent to undergo the procedure should expect to become infected with the virus and be prepared to undergo treatment for HIV for the rest of their lives.

Since we have been unable to establish whether HIV transmission through organ transplant could be prevented, it is useful to analyze the potential consequences of becoming infected with the virus. "Combined antiretroviral therapy (ART) has made HIV infection a manageable chronic disease, allowing a near normal lifespan" (Miro et al., 2019). Regarding transplant, both graft survival times and patient survival times are similar between HIV+ and HIV- transplant recipients[7] (Locke et al., 2015). What is more difficult to quantify but still an important part of living with HIV is the stigma associated with the disease. The harm of the ongoing stigma is likely to affect each potential organ recipient differently, where some might consider it as an absolute contraindication to receiving an organ from a HIV+ donor whereas it might not matter much to others. As such, part of the consent process for this procedure should include a discussion of how HIV stigma could affect the potential recipient's life were they to receive an organ from a HIV+ donor.

What should also be considered in determining the possible consequences of HIV+ to HIV- transplantation is the potential that the organ recipient could infect others with the virus—in particular, others who might not have access to appropriate treatment for the disease. The harm that could be caused to others would be an acceptable reason to constrain the autonomous choices of the potential organ recipient (Beauchamp & Childress, 2019, p. 105). As discussed previously, when a person infected with HIV is effectively managing the infection with ART, transmission risk is thought to be extremely low[8] (Boyarsky et al., 2019). This is known as "treatment as prevention" (HIV.gov, February 2020). So, the organ recipient has a great incentive to take the

[7] Notably, this is not the case when the recipient is infected with both HIV and HCV, as these patients experience reduced graft survival and patient survival times (Locke et al., 2015)

[8] Transmission through sex: effectively no risk; transmission through pregnancy, labor, and delivery: 1% or less; transmission related to drug use: still unknown but risk is likely reduced (Centers for Disease Control and Prevention, n.d.)

medication that will prevent transmission of HIV because it is also the exact medication that will stop the virus from attacking their own body. And, as has been established, it is unclear whether or not an organ transplant from a HIV+ donor to a HIV- recipient will indeed result in transmission. However, if we assume that transmission does occur, if the organ recipient in this case was unable to control the infection—either because no effective course of treatment could be found or because of a lack of compliance—then it is entirely possible that the recipient could infect others with HIV. Since this risk of transmission directly comes from the organ transplant procedure, determining whether this is an acceptable potential consequence of the procedure is vital. It is useful at this point to return to the discussion of HIV+ to HIV+ transplantation, because while the transmission risks are not identical, they do share some commonalities. As we have seen, even though uncontrollable superinfection has not in practice manifested as a common consequence of the procedure, at the time of legalizing HIV+ to HIV+ transplantation it was a serious concern. This suggests that it was considered an acceptable risk that there was the possibility that some organ recipients could receive organs that would directly make it so the organ recipient could transmit the infection from themselves to others. Regarding HIV+ to HIV- transplant, there are a lot of events that must take place for the infection to be transmitted—the organ recipient must be infected with HIV through transplant *and* they must fail to control the infection *and* they must participate in an activity where HIV transmission could take place. If any one of these three events fails to occur, transmission will similarly not occur. What is likely to occur as a result of HIV+ to HIV- transplantation is that the organ recipient will receive an organ that they desperately need and will likely extend their life and improve its quality—even if they do become infected with HIV. Thus, the potential risk of infecting others with HIV seems outweighed by the likely benefits of the organ transplant. However, if once this procedure is approved a substantial amount of HIV transmissions

from organ recipient to others are reported (i.e. far more than anticipated) the ethical analysis could change, as in this case it would be less clear that the benefits of this type of transplant outweigh the harms.

5.0 Considerations of Patient Consent for HIV+ to HIV- Organ Transplantation

The ability of a patient to consent to a medical procedure is an important concern in any medical circumstance and is related to the respect for autonomy principle referenced earlier. When a procedure with unknown benefits and harms is considered, patient consent deserves greater attention and care than in more ordinary circumstances. Under the HOPE Act, this greater attention manifests in the form of a requirement for a HOPE independent recipient advocate (HIRA)[9] (Bollinger et al., 2019). Under HOPE guidelines this advocate must:

> "i) promote and protect the interests of the HIV-positive recipient (including with respect to having access to a suitable HIV-negative organ if it becomes available)[10] and take steps to ensure that the HIV-positive recipient's decision is informed and free from coercion; ii) review whether the potential HIV-positive recipient has received information regarding the results of SOT [Solid Organ Transplantation] in general and transplantation in HIV-positive recipients in particular and the unknown risks associated with HIV-positive transplant; and iii) demonstrate knowledge of HIV infection and transplantation" (National Institutes of Health, n.d.).

According to HIRAs themselves, their main responsibilities are "to ensure potential participants understand the risks and benefits of receiving and HIV-infected organ and to confirm that their decision to participate in the HOPE transplant research study [is] voluntary" (Bollinger et al., 2019). These two considerations only apply to potential recipients who wish to participate in HOPE Act research—i.e. by being willing to accept an HIV+ organ—and as such HIRA-type advocates are not necessary for the majority of potential organ recipients.

[9] Independent advocates are not a usual part of transplant procedures (Bollinger et al., 2019)
[10] i.e. choosing to participate in HOPE Act research and have the possibility of receiving HIV+ organs does not mean that a potential recipient has to forfeit their position on the waitlist for HIV- organs

However, there are additional arguments to suggest that requiring independent advocates for HOPE Act related participation may also be unnecessary and potentially harmful. There is the concern that requiring interaction with an independent advocate may "inadvertently increase participants' fear in the research by implying that the study's risks are so great as to warrant confirmation of their decision to participate in addition to the usual consent processes that are in place" (Bollinger et al., 2019). This is particularly notable given that "most high-risk research studies do not require independent advocates for potential study participants" (Bollinger et al., 2019). As such "the HIRA requirement may signal that HIV D+ to HIV R+ transplants warrant special protections that could inadvertently be associated with HIV-related stigma," rather than reflect an accurate depiction of the risks of the procedure (Bollinger et al., 2019). Because independent advocates are a limited resource in healthcare it is important to constantly evaluate whether the advocate is necessary for the given context or if the resources would be better used in other circumstances (Bollinger et al., 2019).

A scheme similar to the HIRA system was used in the 2017 South Africa case, where Etheredge et al. wrote that a vital part of the consent process for the parents in this case was the independent donor advocate (IDA)[11] (Etheredge et al., 2019). Etheredge et al. write that they "were acutely aware of entering unknown territory and went to great lengths to ensure appropriate and detailed communication. [They] emphasized that [they] were unsure whether the child would contract HIV. [They] also took care to ensure that both parents had the capacity and social support to care for an HIV-positive child in the future" (Etheredge et al., 2019). They note that the IDA played a crucial role in this regard, meeting with the parents several times before the procedure

[11] Donor, not recipient, because in this case the mother was donating part of her liver to her very young child and as such was consenting on her behalf (along with the father of the child)

and functioning as an informal representative for the parents post-transplant (Etheredge et al., 2019). Considering how unusual this procedure was and the myriad of risks involved the use of an advocate in this case seems justified despite the extra amount resources required. It seems reasonable to propose that an independent recipient advocate should also be a part of the process for HIV+ to HIV- organ transplantation in the United States as well—were this policy to be enacted—given that the risks of such a procedure would be similarly unknown as they were in South Africa four years ago. Furthermore, the ability to accept an HIV- organ should a suitable one become available to the potential recipient should continue to be the case and should be emphasized as part of the research protocol. As more information on the expected harms and benefits of the procedure become available through research it would be possible to reevaluate whether the independent advocate was still necessary or if the resources could be diverted elsewhere.

5.1 Rights of Donors and Other Considerations of Fairness

Up until now, autonomy has been discussed only in the context of the potential organ recipient, but the consideration is pertinent to the potential donor as well. Up until recently, people living with HIV in the United States did not have the ability to donate their organs—either through living donation or after death, but "[w]ith the passage of the HOPE Act, persons living with HIV now have the opportunity, indeed the right, to authorize deceased donation or become living donors under an IRB-approved protocol" (Durand et al., 2016). The word 'right' here is important, suggesting that the interests of the person living with HIV who wants to donate their organs have special protection that could only be considered void with the introduction of valid reasoning.

Otherwise, because of considerations of fairness, the interests of HIV+ potential donors should be treated with the same respect given to HIV- potential donors.

Indeed, there are several major interests to consider. Respect for autonomy persists even after death; "[j]ust like there is a duty to respect the will of the individual for disposition of assets, so we must respect his or her wishes about what will happen with his or her body" (Veatch, 2000, p. 146). If that wish includes a desire to donate one's organs, this desire should be honored unless there exists a compelling reason not to do so. Years before the passage of the HOPE Act, it seemed that the compelling reason in the case of people living with HIV was obvious—HIV was an extremely deadly disease that significantly reduced quality of life. Asking a potential organ recipient to consent to the risks of an operation under the pretense of saving their life only to have the recipient gain an organ that would lead to their imminent death makes no sense, and as such, it was acceptable to disregard the interest an HIV+ person might have in donating their organs. But, as HIV treatment improved, the restriction on allowing people living with HIV to donate their organs begins to seem more arbitrary than it had in the past. This was particularly true in cases of living organ donation, as the potential donors in these cases often had a connection to the potential recipients and wanted to ensure their welfare. Etheredge et al. explain that this was part of the reason why they felt it was ethically justified to perform the HIV+ to HIV- transplant in 2017:

> "We have had a number of HIV-positive parents in our setting express a desire to be living liver donors for their critically ill children. Declining these parents as living donors has become increasingly unjustifiable given the very small deceased donor pool in [South Africa]; and because many of these parents are virally suppressed and would otherwise fulfil our eligibility criteria as living donors" (Etheredge et al., 2019)

These parents had an interest in protecting their children and—with new treatments for HIV—it seemed arbitrary that they were not allowed to act as living donors. As such, denying

these parents the right to donate their organs to their children seems ethically indefensible under considerations of fairness, in addition to considerations of beneficence and nonmaleficence that have been previously shown to apply to the potential organ recipient in these cases.

While arguably the major interests of potential donors are the ones already discussed, there are a few other potential interests that should be given attention. There are particular benefits of organ donation related to people living with HIV, which "include reduced stigma, support of community through helping [people living with HIV] awaiting transplant, and belief that the HOPE Act creates a more equitable opportunity for transplantation for [people living with HIV]" (Nguyen et al., 2018). Expanding transplant guidelines to include HIV+ to HIV- donation could further reduce stigma and expand community.

Allowing for HIV+ to HIV- transplantation could also create an even more equitable transplant system for everyone, HIV+ and HIV- alike. Currently, HIV+ potential recipients are eligible to receive both HIV+ and HIV- donor organs, whereas HIV- potential recipients are only eligible to receive HIV- donor organs. Considering that treatment for HIV has improved to the point where it is possible to live a very good life with the virus it seems unfair that HIV- potential recipients are excluded from a pool of organs that they could potentially benefit from receiving—solely because they themselves are not infected with the virus. Allowing HIV+ to HIV- transplantation would serve to mitigate this unfair standard.

6.0 Allocation Structure Incorporating HIV+ to HIV- Donation

Making HIV+ to HIV- transplantation permissible does not mean that HIV status has to be removed as a consideration in allocation structure. Indeed, there are three main approaches to incorporating the new policy into the existing system—1. HIV status of potential recipient has no impact on allocation, 2. HIV status has some impact i.e. HIV+ potential recipients have access to HIV+ organs before HIV- recipients at the same classification, 3. HIV- potential recipients only have access to HIV+ organs once all HIV+ potential recipients have been offered the organs. An example schematic of these three structures along with the existing structure is offered in the table below—using the allocation of livers as an illustration. Unlike in the previous section however, the following schemes should be understood for how HIV+ organs are to be allocated—not organs in general.

Table 5: Allocation of HIV+ Livers Existing Structure

Classification	Geographic region	Criteria
1	medium	Status 1A, HIV+
2	medium	Status 1B, HIV+
3	small	MELD/PELD of 40, HIV+
4	medium	MELD/PELD of 40, HIV+
5	small	MELD/PELD of 39, HIV+
6	medium	MELD/PELD of 39, HIV+
…	…	…
13	small	MELD/PELD of 35, HIV+
14	medium	MELD/PELD of 35, HIV+
15	small	MELD/PELD $\geq$ 15, HIV+
16	medium	MELD/PELD $\geq$ 15, HIV+
17	nation	Status 1A, HIV+
18	nation	Status 1B, HIV+
…	…	…

Table 6: Allocation of HIV+ Livers Proposed Structure 1

Classification	Geographic region	Criteria
1	medium	Status 1A, HIV+ or HIV-
2	medium	Status 1B, HIV+ or HIV-
3	small	MELD/PELD of 40, HIV+ or HIV-
4	medium	MELD/PELD of 40, HIV+ or HIV-
5	small	MELD/PELD of 39, HIV+ or HIV-
6	medium	MELD/PELD of 39, HIV+ or HIV-
…	…	…
13	small	MELD/PELD of 35, HIV+ or HIV-
14	medium	MELD/PELD of 35, HIV+ or HIV-
15	small	MELD/PELD $\geq$ 15, HIV+ or HIV-
16	medium	MELD/PELD $\geq$ 15, HIV+ or HIV-
17	nation	Status 1A, HIV+ or HIV-
18	nation	Status 1B, HIV+ or HIV-
…	…	…

Table 7: Allocation of HIV+ Livers Proposed Structure 2

Classification	Geographic region	Criteria
1	medium	Status 1A, HIV+
2	medium	Status 1A, HIV-
3	medium	Status 1B, HIV+
4	medium	Status 1B, HIV-
5	small	MELD/PELD of 40, HIV+
6	small	MELD/PELD of 40, HIV-
7	medium	MELD/PELD of 40, HIV+
8	medium	MELD/PELD of 40, HIV-
9	small	MELD/PELD of 39, HIV+
10	small	MELD/PELD of 39, HIV-
11	medium	MELD/PELD of 39, HIV+
12	medium	MELD/PELD of 39, HIV-
…	…	…
26	small	MELD/PELD of 35, HIV+
27	small	MELD/PELD of 35, HIV-
28	medium	MELD/PELD of 35, HIV+
29	medium	MELD/PELD of 35, HIV-
30	small	MELD/PELD $\geq$ 15, HIV+
31	small	MELD/PELD $\geq$ 15, HIV-
32	medium	MELD/PELD $\geq$ 15, HIV+
33	medium	MELD/PELD $\geq$ 15, HIV-
34	nation	Status 1A, HIV+
35	nation	Status 1A, HIV-
36	nation	Status 1B, HIV+
37	nation	Status 1B, HIV-
…	…	…

Table 8: Allocation of HIV+ Livers Proposed Structure 3

Classification	Geographic region	Criteria
1	medium	Status 1A, HIV+
2	medium	Status 1B, HIV+
3	small	MELD/PELD of 40, HIV+
4	medium	MELD/PELD of 40, HIV+
5	small	MELD/PELD of 39, HIV+
6	medium	MELD/PELD of 39, HIV+
…	…	…
13	small	MELD/PELD of 35, HIV+
14	medium	MELD/PELD of 35, HIV+
15	small	MELD/PELD $\geq$ 15, HIV+
16	medium	MELD/PELD $\geq$ 15, HIV+
17	nation	Status 1A, HIV+
18	nation	Status 1B, HIV+
…	…	…
52	nation	Any MELD/PELD in need of other method of hepatic support, and blood type compatible with the donor
53	medium	Status 1A, HIV-
54	medium	Status 1B, HIV-
55	small	MELD/PELD of 40, HIV-
56	medium	MELD/PELD of 40, HIV-
57	small	MELD/PELD of 39, HIV-
58	medium	MELD/PELD of 39, HIV-
…	…	…
65	small	MELD/PELD of 35, HIV-
66	medium	MELD/PELD of 35, HIV-
67	small	MELD/PELD $\geq$ 15, HIV-
68	medium	MELD/PELD $\geq$ 15, HIV-
69	nation	Status 1A, HIV-
70	nation	Status 1B, HIV-
…	…	…

Each of these schemes has merit but Structure 2 seems to do the best at balancing our existing knowledge with considerations of fairness. Structure 1, by not taking HIV status into account, ignores the fact that the US has more experience with HIV+ to HIV+ transplantation than with HIV+ to HIV- and that as such the risks are better known and understood for this already-established practice. Structure 3 on the other hand goes too far in prioritizing HIV+ potential

recipients to the extent where a HIV+ person who is not in desperate need of an organ could obtain one before a HIV- person who does desperately need it. Structure 2 recognizes that HIV+ to HIV+ transplantation might be slightly preferable to HIV+ to HIV-, but does not let this consideration get in the way of prioritizing lives and life-years saved.

6.1 Special Considerations for HIV+ to HIV- Living Donation

As previously discussed in the section on donor's rights living donation often involves a relationship between the donor and the recipient that is not present with deceased donor transplants. Because of this, the donor in this case is likely donating an organ (or part of an organ) that otherwise would not be donated—because their special relationship to the recipient is what is motivating them to donate the organ. Thus, allowing HIV+ to HIV- living donation has a great potential to increase the total number of organs available for transplant because the organ from the living donor is only added to that potential pool of donor organs because of the donor's relationship to the recipient. This increase in the total number of available organs is probably even more certain with allowing HIV+ to HIV- living donation than HIV+ to HIV- deceased donation because with living donation one can be certain that an organ that otherwise would not have been available has been transplanted—whereas while that is certainly possible with HIV+ to HIV- donation it is not a guarantee.

Another consideration pertinent to HIV+ to HIV- living donation is the fact that in general living donation transplantations have better outcomes than deceased-donor transplantation—for example, the graft half-life for a living donor kidney is more than a year longer than a deceased donor kidney with a 0-20% KDPI, and the difference is even greater for kidneys with higher KDPIs

(“Kidney Donor,” n.d.). If the choice for the recipient is between a HIV+ organ from a living donor and a HIV- organ from a deceased donor, the benefits from receiving an organ from a living donor might be enough to outweigh the potential harms that could come from receiving an organ from a deceased donor.

7.0 What We Still Don't Know and How this Information Could Change our Ethical Analysis

There have been several times in this discussion where an important statistic is simply not known because intentional HIV+ to HIV- organ transplant is such a new idea. If HIV+ to HIV- transplantation were to be implemented these would be the rates to pay the closest attention to in research.

Firstly, it is technically unknown if under this new guideline more organs will actually be used or if instead just the people who receive the organs will change. I previously put forth arguments suggesting why it is likely that more organs will be transplanted, but I admit that it is still possible that in practice this new procedure does not increase the number of transplants or the number of lives saved. The arguments in favor of the procedure in terms of beneficence considerations would then be weaker because the possible benefits would be less likely to outweigh the harms of transplanting an HIV+ organ into an HIV- person. A second important consideration is rates of compliance with post-transplant treatment. We often talk about compliance/adherence to post-transplant medication as an issue in organ donation—with the idea that organs should only be given to those who will adhere to the treatment necessary to sustain the graft (and therefore, not "waste" the organ). But in cases where recipients contract HIV as a result of the transplant, not adhering to treatment could have the additional consequence of spreading HIV to those who if the transplant had not been done, would not have been infected. The harms that such transmissions from the recipient to others would cause would have to be outweighed by the benefits of the transplant—i.e. in saving more lives and improving quality of life for the recipient. Lastly, as with any new procedure, there are 'unknown unknowns' which could manifest

and greatly change the cost/benefit ratio. Importantly however, these unknowns are not reasons to prohibit HIV+ to HIV- transplantation a priori—rather they are important factors to research should the procedure be enacted. As more information becomes available and these arguments turn from speculation to observed phenomenon the true benefits and risks of HIV+ to HIV- transplantation will be known and a more informed ethical analysis can occur.

8.0 Moving Forward: Potential Benefits of HIV+ to HIV- Organ Transplantation to Organ Recipients not at Immediate Risk of Death

Up until now I have mainly been arguing for the allowance of HIV+ to HIV- transplantation for potential organ recipients who would likely not receive another organ offer—and as such have their lives dependent on whether or not they would be allowed to accept an HIV+ organ offered to them. In this section however, I would like to discuss other HIV- potential recipients who might benefit from HIV+ transplantation. In the case of kidney failure in particular the need for an immediate transplant isn't as great because a person can live for several years on dialysis ("What Is dialysis?," 2015). Because of the ability to live for long periods of time on dialysis the potential organ recipient can be fairly confident that should they reject a kidney offered to them it will not be the last one they are offered. The question then for many people waiting for a kidney transplant is whether to accept any kidney offered to them or wait for a kidney deemed "better" in some way—for example a kidney with a lower KDPI or from a younger donor. It seems that in most cases—whether the kidney is "worse" because it comes from an older donor, has a higher KDPI, or has a greater risk of HIV or HCV infection—the potential organ recipient is still better off accepting the "worse" kidney than waiting for another (Bae et al., 2019; Bowring et al., 2018; Ruck & Segev, 2018). It then seems logical to suppose that there might be cases where an HIV- potential recipient would be better off accepting an HIV+ kidney that becomes available to them instead of waiting for an HIV- kidney. Because HIV+ to HIV- transplantation is currently not well understood when the procedure is first legalized it would be sensible to confine it to those who will likely die without an organ—any organ. Additionally, HIV- people who have the ability to wait for an HIV- organ would likely be inclined to do so given how unknown the risks of receiving

an HIV+ organ. But, if as more information becomes available the procedure consistently results in good outcomes with few downsides then expanding access to those who are not at immediate risk of death but could still benefit from the procedure would be prudent.

9.0 Conclusion

No one policy is going to solve the organ shortage in the United States. But, in a country where so many are waiting for an organ with so few available even a small change in policy has the potential to save lives. Because of the advances in HIV treatment and prevention HIV+ to HIV- organ transplantation has become a policy worth considering in an effort to achieve the combined goals of reducing the organ shortage and saving lives. There are many unknowns associated with this procedure but none of them warrant prohibiting the procedure in of itself given the likely benefits that are also associated with it. Research on the outcomes of the procedure once it is implemented will help eliminate these unknowns and determine whether it is prudent to continue such procedures given current medical technology. Thus, legalizing HIV+ to HIV- transplantation associated with research in the United States is ethically justified.

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