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ETHICAL USE OF ANTIRETROVIRAL RESOURCES FOR HIV PREVENTION IN RESOURCE POOR SETTINGS

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Abstract

The effectiveness of antiretroviral regimes (ARVs) to reduce risk of HIV transmission from mother to child and as post-exposure prophylaxis has been known for almost two decades. Recent research indicates ARVs can also reduce the risk of HIV transmission via sexual intercourse in two other ways. With pre-exposure prophylaxis (PrEP), ARVs are used to reduce risk of HIV acquisition among persons who are HIV negative and significantly exposed to the virus. With treatment as prevention (TasP), ARVs are used to reduce risk of HIV transmission from persons who are already HIV positive. The development of these new prevention strategies raises a rationing problem: given the chronic shortage of ARVs for HIV-infected persons in need of treatment, is it ethically justified to allocate ARVs for PrEP and/or TasP? This article examines the intuitively appealing view that allocation of ARVs for treatment should be the highest priority, the use of ARVs for TasP should be a secondary priority, and that utilizing ARVs for PrEP would be unethical. I will argue that selective, evidence-based allocation of ARVs for prevention in certain cases could be ethically justified even when there is insufficient anti-retroviral access for all those needing it for treatment.

Keywords

antiretroviral therapy; developing world; HIV/AIDS; Prevention; Rationing; resource allocation; treatment

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The question of how to fairly allocate scarce medical resources is a longstanding and perplexing issue in health policy and bioethics. A common focal point within this debate contrasts treatment and prevention: how much of our limited health resources should be devoted to treating (say) cardiovascular disease versus initiatives to reduce its prevalence? A recent book explores the tensions, assumptions and arguments in the ‘prevention versus treatment’ debate, across a range of diseases and conditions, from economic, historical, philosophical, cultural and religious perspectives.[1] A dominant theme of the book is what one author calls ‘alleviation bias’, i.e. that the lion’s share of medical resources in the United States – expressed in medical coverage, health care expenditures, funding of medical training, medical programs or physician salary levels – are directed towards treatment services to those already sick rather than approaches to promote well-being and prevent

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future disease.[2] For example, for every dollar spent on prevention services and research in the US health care system, eleven dollars are spent on treatment services and research.[3] This is arguably a bias, rather than a reasoned choice, because even when evidence indicates prevention strategies would be equally effective (or superior) as treatment approaches in terms of reduced morbidity and mortality, the latter still tends to be disproportionately prioritized.

Is there an alleviation bias when it comes to HIV? On a broad policy level, some have argued that global HIV programs like the US President's Emergency Fund for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, TB and Malaria placed too heavy an emphasis on providing anti-retroviral drugs (ARVs) to HIV-positive persons and not enough on future-oriented, population level strategies to prevent the spread of new infections.[4] Massively funded past efforts to increase access to ARVs for treatment have not been without pitfalls. While important strides have been made, access remains partial: in sub-Saharan Africa, overall ARV treatment in 2011 was estimated at 49%, with 5,064,000 persons receiving ARVs out of 10.4 million eligible for it.[5] Barriers to treatment access include lack of information, perceived (or real) high cost of ARVs, stigma, transport issues, lack of coordination across health services, and limited community involvement in program planning.[6] Intellectual property laws continue to enable powerful pharmaceutical companies to gain unfair competitive advantage over generic drug manufacturers, and hamper access to newly developed ARV regimes in developing countries.[7–8] And even when treatment resources are available, political, institutional, cultural and economic barriers to treatment adherence persist.[9] Some argue that fighting the epidemic by aggressively pursuing HIV treatment provision is shortsighted and unsustainable, when ARVs have to be provided lifelong and millions of new HIV infections continue to occur each year.[10]

Recent research on two promising new HIV prevention approaches have invigorated and complicated the 'treatment vs. prevention' debate. Both approaches involve the use of ARVs to prevent HIV transmission rather than for treatment purposes alone.

- With *pre-exposure prophylaxis* (PrEP), ARVs are used to reduce risk of HIV acquisition among persons who are HIV negative and significantly exposed to the virus. The Partners PrEP study among serodiscordant couples in Kenya and Uganda was stopped early when interim analyses showed that providing combination ARVs to HIV-negative partners reduced their risk of acquiring HIV by 62%–73%.[11] The iPrEx study showed a 44% reduction in transmission among HIV-negative transgendered women and men who have sex with men who used daily ARVs as prophylaxis.[12] On the basis of these studies, the US Food and Drug Agency (FDA) controversially approved (July 2012) the use of the antiretroviral Truvada as preventative measure for men who have sex with men and uninfected partners of HIV-infected persons.[13]
- With *treatment as prevention* (TASP), ARVs are used to reduce risk of HIV transmission from HIV-positive persons to their sexual partners. A number of observational studies in the past suggested that use of ARVs could reduce the risk of HIV transmission by reducing viral load in semen, genital and rectal secretions. Strong support for the link was recently indicated by a randomized controlled trial

(HTPN 052) that showed early initiation of ARVs produced a 96% reduction in sexual transmission among serodiscordant heterosexual couples.[14] 'Early initiation' in this study meant use of ARVs by HIV-positive persons whose immune systems are relatively less compromised than when patients are recommended to start antiretroviral treatment according to some current guidelines (CD4 counts of less than 350 cells/mm^3). The WHO recently defined TasP more broadly as the use of ARVs for HIV prevention among HIV-positive persons irrespective of their CD4 counts.[15] A new and controversial form of TasP is 'Option B+', an approach where all HIV-positive pregnant women are offered ARVs lifelong regardless of CD4 count. Option B+ can be considered a form of TasP, because the strategy aims to reduce risk of transmission to the women's partners, and not just reduce risk of transmission to their infants or provide them with treatment benefits.[16]

These promising research findings give rise to an ethical challenge: given the shortfall of ARVs for HIV-positive persons who need it for treatment, to what extent should ARV resources be utilized for these prevention approaches? In the following sections, I would like to critically examine a provocative position: namely that it is unethical to allocate ARV resources for PrEP and that TASP can only have subordinate priority when not all HIV-positive persons have access to ARVs for treatment purposes. In the section below, I will argue that this intuitively attractive ethical position has internal weaknesses. In the section that follows, I will suggest that the position is also insufficiently responsive to contextual factors that can strengthen or weaken the ethical case for PreP and TasP in particular cases. In the last section I will explore when these new uses of ARVs could be ethically justified when universal access to antiretroviral treatment has not been attained.

Arguing against PrEP and downgrading TasP

In a recent article, Macklin and Cowan argue that ARV resources ought to be primarily allocated to HIV positive persons clinically eligible for treatment rather than diverting ARV resources for PrEP or TasP.[17] Their core argument rests on three ethical rules and principles: the rule of rescue, the principle of urgent need, and the prioritarian principle. The authors understand the rule of rescue to mean that if ARVs can save the lives of persons with HIV/AIDS, then there is an obligation to provide them, even if this reduces the number of lives that could be saved overall. According to their interpretation of the principle of urgent need, the more sick and endangered a person is by HIV/AIDS, the greater the moral claim to provide ARVs. Those who are threatened by HIV/AIDS – such as healthy persons at high risk of exposure or HIV-positive persons with higher CD4 counts – have a lesser claim than those immediately endangered. Thirdly, Macklin and Cowan contend that the act of providing ARVs to those already sick with HIV/AIDS adheres to the prioritarian principle, since those already sick are worse off than those currently healthy but at high risk for HIV. Macklin and Cowan argue that these rules and principles, taken together, outweigh utilitarian considerations about how many lives might be saved or benefitted by use of ARVs in PrEP or TasP. They conclude, '… it is unethical to deliberately watch patients with treatable HIV/AIDS to worsen and die, even with supportive care, so that medications for treatment can be diverted to prevention.'[18]

Before further analysis, it is important to reflect about the nature and coherence of this position. First, Macklin and Cowan judge the ethical status of allocations for PrEP and TasP differently. Use of ARV resources for PreP is considered unethical, because it consists of using ARVs for uncertain preventive benefit when it would almost certainly benefit needy HIV/AIDS patients.[19] (From which it follows that the FDA approval of Truvada for PreP, the production of Truvada for PreP by Gilead Sciences, the prescription of Truvada for PreP by doctors and the prophylactic use of Truvada by individuals are all ethically wrong.) On the other hand, early initiation of ARVs for TasP according to Macklin and Cowan can be ethically justified, albeit as a subordinate priority, because of potential patient and population benefits: the HIV-positive persons receiving early treatment would end up needing ARVs anyway, and TasP shows some promise as effective population-level approach to reduce HIV prevalence. Macklin and Cowan's ethical distinction between PreP and TasP, however, is unstable. Universal access to antiretrovirals for treatment may be very far off (or never attained) due to financial and other constraints, the predicted rise of new infections, changes in treatment eligibility criteria, and challenges in delivering ARVs in resource-poor settings, and so there will likely be millions of sick HIV-positive people needing ARVs for the foreseeable future.[20] Assuming that is the case, how is diverting ARV resources to PreP tantamount to watching patients with treatable HIV/AIDS worsen and die, whereas diverting ARV resources for TasP is ethically acceptable even when there are patients in immediate need of ARVs but do not have access? Given their arguments for prioritizing use of ARVs for treatment from the rule of rescue, urgent need and the prioritarian principle – meant to trump utilitarian allocations of ARV resources – it would be more consistent to say that allocating ARVs for PrEP *and* TasP is ethically wrong in a context of treatment scarcity. Second, Macklin and Cowan are not making the sweeping claim that all HIV/AIDS resources should be devoted to treatment at the expense of prevention. They do not discourage allocation of HIV/AIDS resources for a wide array of prevention strategies. Their reservations are specifically about the ethics of deploying antiretrovirals for PrEP and TasP. But this distinction between ARVs for prevention and non-ARV prevention approaches is also problematic. If treatment of the urgently sick is ethically paramount, why shouldn't resources for conventional, non-ARV prevention approaches be diverted to increase access to ARVs for persons suffering with clinical AIDS? The same reasons not to devote resources to PrEP and less to TasP – rule of rescue, urgency of need, prioritarian principle – can be applied to *any* prevention approach.[21]

Arguing ARV resources should be used primarily for treating patients rather than prevention purposes when resources are limited is psychologically compelling. It engages with (hopefully widespread) feelings of compassion towards those who are currently suffering and whose lives are in jeopardy. The principles used by Macklin and Cowan – the rule of rescue, urgency of need, the prioritarian principle – ultimately stem from our fundamental concern for the well-being of persons. The importance of human compassion is not in doubt. The question here is whether appeals to compassion and associated moral principles justify an emphatic prioritization of ARVs for treatment that ethically rules out or relegates novel uses of ARVs for prevention in epidemic circumstances.

The rule of rescue

The rule of rescue suggests that an individual's suffering and potential death should eclipse all other ethical considerations: if we can help, we ought to do so, even if more lives could be saved or more suffering averted by doing something else. As stated, the rule starts from assumptions whose reasonableness is under question. The rule implicitly values saving lives and reducing suffering of identifiable persons here and now over the lives and sufferings of (perhaps less identifiable) future persons, even though it seems reasonable to think that suffering and death of persons in the future are no less real and equally morally significant. An argument in favor of ARVs for treatment, rather than for prevention, based on the rule of rescue alone seems circular.

Urgency of need

This argument starts from the reasonable (empirical) assumption that some human needs are more urgent than others. By urgency, we are invited to imagine what would happen if a sick person does not timeously receive adequate health care resources necessary to meet her needs. Urgent health needs are those that must be met, and met soon, if the person is not be become (very) badly off. Here is where a contrast can be drawn between HIV treatment and prevention: while the needs for prevention may be important, but they are not as urgent as those who may die if they do not receive antiretroviral treatment (soon). This contrast is then used to support the conclusion that ARVs should be allocated to treatment rather than novel prevention approaches when ARV access is limited. However, faced with chronic scarcity, prioritizing ARVs for treatment rather than prevention simply pushes urgency of need into the future and potentially increases its prevalence. Why should we think treating urgent cases now is an approach ethically superior to preventing (possibly even more) urgent cases in the future? Like the rule of rescue argument, the urgency of need argument assumes that the lives and well-being of identifiable persons in the present have a higher value than the lives and well-being of less-identifiable persons in the future. But that assumption is what the argument needs to justify.[22]

Prioritarian principle

This intuitively appealing principle characterizes HIV-positive persons clinically eligible for ARVs as worse off than HIV-negative persons who are merely at risk for acquiring HIV, and claims that when beneficial resources are scarce, priority should go to those who are more badly off than others. In many contexts (including triage), this principle can offer useful guidance when allocating scarce resources. However, systematically favoring treatment over new prevention approaches could result in many people joining the category of the 'worse off' by becoming HIV-infected. The question then becomes: why should we care more about those who are worse off now than those (perhaps more numerous) who will become worse off in the future? When they become worse off is only a matter of timing, and the prioritarian principle does not itself make clear why timing is morally relevant.

The above arguments try to support what could be called a *hic et nunc* compassion-based position. Such arguments strongly appeal to clinicians regularly faced with sick patients and have professional obligations in regard to their care. Giving priority to current and proximate harm also appeals intuitively to laypersons with Good Samaritan dispositions,

faced with suffering of (nearby) strangers and adhering to 'agent-relative' obligations.[23] Why *hic et nunc* compassion-based views predominate in policy and bioethics debates on treatment versus prevention – including those related to the HIV/AIDS epidemic – is an interesting political, psychological, and philosophical question, especially given that some of its key supporting arguments seem weak on reflection.

Contextual factors strengthening or weakening the ethical case for TasP and PrEP

Rather than proposing a rigid normative scheme about the use of ARV resources based on ethical principles, it is worth considering an alternative model incorporating ethical principles as well as contextual considerations that can weaken or strengthen the ethical case for using ARVs in PrEP or TasP. The ethical case for these new uses of ARVs will depend on variety of factors, some of which will vary significantly in different settings. I mention a few of these factors before more explicitly tackling the question of when the selective use of ARVs in PrEP and TasP could be ethically justifiable.

Questions about efficacy

The efficacy of PrEP remains murky. While the Partners PrEP and iPrEx studies indicated that HIV-negative persons significantly reduce their risk of acquiring HIV via sexual intercourse by using ARVs prophylactically, two recent studies with women (VOICE 003 and FEM-PREP) showed no reduction of risk.[24–25] To build confidence in PrEP's efficacy, the striking differences in research results need to be satisfactorily explained.[26] With TasP, efficacy data is more conclusive: HPTN 052 showed that initiating ARVs early in a person's infection reduces risk of transmission to the HIV-negative partner by 96 percent. But further research is needed about TasP efficacy with other at-risk groups, such as intravenous drug users and men who have sex with men.

Questions about effectiveness

Even if a biomedical intervention demonstrates efficacy in reducing HIV transmission within the controlled environment of a research trial, it may be hard to replicate the same effects in real world circumstances. To some extent, TasP has essentially been implemented in HIV treatment programs in Canada, USA, France and Australia over the last years, and these 'natural experiments' suggest that the protective effect of TasP may be significantly less than research trials suggest.[27] A recent study presented at the XIX International AIDS Conference in Washington (July 2012) concluded that use of ARVs did not reduce risk of transmission among heterosexual couples in a rural Ugandan ARV program.[28] Another important limitation of TasP is that HIV-positive persons are most infectious during the weeks immediately after they acquire HIV. How much HIV transmission takes place during the period of acute HIV infection is a matter of continuing scientific debate, but the worry is that even early initiation of ARVs may come too late to prevent many infections. More research is needed to assess how much of a limitation acute infection poses for TasP, and the extent to which alternative strategies to detect and prevent HIV transmission during the period of acute infection will have to be developed.[29]

The issues of adherence, risk compensation, drug resistance and safety pose significant challenges to the potential effectiveness of PrEP and TasP. Adherence to medication is a common problem in HIV treatment programs: ensuring ARVs are taken appropriately is likely to be no less (and may be more) demanding when it is used for prevention among those who are HIV-negative or are HIV-positive but asymptomatic.[30] There are worries that even if PrEP and TasP can reduce HIV transmission risk, this gain may be cancelled out or reversed by ARV users (or their partners) engaging in more risky sexual behavior due to exaggerated beliefs about the drug's protectiveness.[31] In addition, neither PrEP nor TasP protect against sexually transmitted infections (STIs) other than HIV. Both approaches could demotivate use of condoms and other traditional prevention methods, and necessitate aggressive screening and treatment of STIs. There is also potential for the development of resistant HIV strains among those who start ARVs early with TasP, and the side-effects of taking ARVs longer than in standard HIV treatment is currently unknown.

Background epidemic conditions

The case for use of ARVs in PreP or TasP will depend partly on the local HIV prevalence and incidence, and whether the epidemic is generalized or concentrated. Williams et al. (2012) use mathematical models to compare PrEP and TasP in terms of reduction of person-years requiring ARVs for treatment. They argue that where the incidence of HIV is less than 5% or the risk-reduction using PrEP is less than 50%, TasP is favored over PrEP; otherwise PrEP is favored over TasP. They conclude PrEP should best be limited for use among specific populations with annual HIV incidence greater than 5%.[32]

Background health system and social conditions

If the local health system infrastructure in a resource-poor setting is too weak to effectively deliver these new prevention approaches, if there are a very high number of HIV-positive persons in urgent need of ARVs for treatment, or if the local community appears reluctant to embrace PrEP and TasP, these kinds of unfavorable conditions count against their introduction. Like other prevention interventions in the past, successful implementation of PrEP or TasP will require a supportive network of adequate health services and community engagement.

Resource commitments

Using ARVs for prevention would require massive investment in HIV testing in order to initiate early treatment (TasP) or to confirm and reconfirm that persons at risk for HIV are indeed HIV-negative (PrEP). Even after decades of effort, only a minority of HIV-positive persons in low-resource settings with high HIV prevalence knows their HIV status. Significant human and infrastructural resource investment would have to be mobilized for the monitoring, counseling and referral to health care services involved in TasP and PrEP, with the accompanying risk of diverting important resources from other health sectors.

What is the upshot of the above factors and considerations for the ethics of using TasP and PrEP? It suggests the answer to the question, 'Is it ethical to devote ARV resources to prevention approaches when not all have ARVs for treatment?' is not a categorical 'no', but a conditional 'it depends.' Whereas *hic et nunc* compassion-based arguments mentioned

earlier largely sought to exclude or relegate ARVs for prevention purposes by appeal to ethical principles, whether their use should be ruled in or out here are based partly on contingent circumstances. If (for example) the evidence base of effectiveness for PrEP and TasP grows stronger, the ethical case for allocating ARV resources for these prevention approaches grows stronger with it. Conversely, the data may show these strategies have a limited impact, weakening the ethical grounds for their use. Similarly, there are good ethical arguments against use of TasP and PrEP in settings where the health infrastructure is too weak to support responsible delivery of these approaches. But that does not rule out future ethical implementation, even when there is no universal access to ARVs for treatment. Global access to ARVs for treatment only increased dramatically over the last decade due to strong political commitment, intense international collaboration and significant financial investment. There is no reason why similar efforts, at least to some extent, could not successfully enhance the ethical implementation of PrEP and TasP as parts within a combination HIV prevention strategy.

When could selective use of ARVs in PrEP and TasP be ethically justifiable?

There seems one circumstance in which it seems clearly ethically justified: HIV prevention research. Without research on treatment as prevention, we have no way of knowing whether and to what extent these approaches could assist in the struggle against HIV/AIDS, and there is no way of conducting such research without using ARVs for primarily non-clinical reasons. Those who believe antiretrovirals should never be diverted for prevention when ARVs are scarce would either have to carve out (and justify) a special exception for HIV prevention research or would have to defend the radical claim that such research is essentially unethical and should not take place.

Other cases are more complicated, partly hypothetical and undeniably controversial. In a time of scarcity and financial constraints, with human lives at stake, cost-effectiveness analyses of the use of scarce medical resources are highly ethically salient.[33] It would be irresponsible to ignore the fact that for every 100 patients put on ARVs per year, another 200 become infected, and will need ARVs in the future when treatment access may be as partial (or worse) than it is now.[34] Decisions in the short term we make about balancing treatment and prevention will affect the availability of treatment in the long term. If reliable cost-effectiveness analyses indicate that a significant number of lives could be saved by means of implementing TasP or PrEP programs at an equal or lesser cost than treatment programs, it would be ethically questionable to rule out inclusion of these prevention programs as part of an comprehensive response to the HIV/AIDS epidemic. If these programs prove cost-effective, failure to allocate resources to them would express ‘alleviation bias’ in a naked form.

When thinking about resource allocation, TasP and PrEP are currently not on the same scientific, operational or ethical footing. TasP can be considered an extension and intensification of the long ongoing struggle to provide universal access to ARVs, with increasing evidence of a potential triple benefit: improving the health of HIV positive persons, reducing transmission to others, and cost-effectiveness relative to delaying

treatment. Through global programs like PEPFAR and the Global Fund, there is much accumulated knowledge about how to deliver ARVs to patients. Research on PrEP, on the other hand, is still in a nascent stage, provides no medical benefit (and may pose some risk) to the user, and it is much less clear how it should be implemented for maximum public health impact. As far as using ARVs for prevention is concerned, there are stronger (including ethical) reasons to allocate ARVs for TasP than for PrEP. Would it be unethical, as Macklin and Cowan argue, to allocate *any* resources to PrEP? The clinical benefit of ARVs for those with HIV/AIDS will likely always be greater and more certain than the protective effect of PrEP, which – like many non-HIV-related prevention interventions – will only be partially protective and realize a positive impact in the aggregate. This is a comparison between ARVs for treatment and for prevention that the latter cannot win. It seems more appropriate to climb down from a comparative standard of virtual certain benefit, and say that if there is data supporting effectiveness at some level of protection, the benefits would ethically justify selective allocation of ARVs for prophylactic use in some groups in some settings, including settings where antiretroviral treatment is scarce.

The most effective use of ARVs for prevention is likely to target HIV-negative persons at the highest risk of acquiring HIV infection and HIV-positive persons with the highest likelihood to pass on the virus to others. Those who fit these descriptions are most likely to be stigmatized and disadvantaged groups: men who have sex with men, serodiscordant couples, sex workers, injection drug users, truck drivers, teachers or young female partners of older males.[35] Here is where some of the most difficult tradeoffs will take place:

- *Treatment or TasP?* Should priority access to ARVs be given to those clinically eligible for it under standard treatment criteria, or should it be given to HIV-positive persons likely to spread the virus if they are not started on ARVs as early as possible?
- *Treatment or PrEP?* Should priority access to ARVs be given to those clinically eligible for it under standard criteria, or should it be given to HIV-negative persons highly exposed to the virus?
- *TasP or PrEP?* Should priority access to ARVs be given to HIV-positive persons more likely to spread the virus if they are not started on ARVs as early as possible or HIV-negative persons highly exposed to the virus?

The first conflict, between use of ARVs for immediate clinical need or for TasP, is most pertinent to this discussion. At the clinic level, it seems imperative to prioritize HIV-positive persons for ARVs who are sick and would benefit: doing otherwise would be a case of ‘deliberately watching patients with treatable HIV/AIDS worsen and die.’ However, it is not clear to what extent this approach to ARV allocation should predominate at the policy level once the public health obligation of epidemic control is factored in.[36] The main reasons in favor of allocating a portion of overall ARV resources to TasP initiatives, even in a context of scarcity, are: (a) there are not enough resources to meet all clinical needs for ARVs in any case (b) those who receive ARVs via TasP gain health benefits and would need ARVs sooner or later (c) there is potential for a population-level reduction in HIV transmission via TasP (d) widening the category of who should be treated with ARVs could have positive

knock-on effects if accompanied (as it should be) by increased investments in local health infrastructure. But while a fairly strong case can be made, it is important to be honest and explicit about the ethical significance of pursuing TasP (or PrEP) in a context of ARV resource scarcity. To say that TasP has *any* importance (secondary or otherwise) within ARV allocation implies tolerance of some sacrifice in human lives. When there is not enough ARV resources for all those currently sick with HIV/AIDS, every allocation of ARVs for early treatment or PrEP for those who are still relatively healthy could (in theory) have been used to treat someone worse off or dying. Unless one is in the grip of an industrial-strength alleviation bias, there must be some threshold at which rationing of ARVs for prevention becomes acceptable despite the sacrifice of human lives involved.

These painful conflicts are obviously not novel. ARVs for purely clinical purposes have been explicitly or implicitly rationed for years.[37] Ethical debates about ARV treatment rationing are also not new. Discussions have centered on identifying ethically relevant criteria for rationing decisions[38] and how decisions about criteria can be reached fairly.[39] Lessons from that debate are relevant to the new world of TasP and PrEP. First, the salient decision criteria will be ethically heterogeneous: some will focus on the most effective use of scarce ARV resources and maximizing lives saved, while others will express concerns about respect for persons, equity and justice. Bringing TasP and PrEP into the conversation may increase focus on utilitarian considerations, but there is no good reason to other moral considerations will be crowded out. Second, progress has been made in identifying what a fair process of ARV allocation involves and its limitations. Faced with vexing allocation policy decisions, Daniels argues that if decisions emerge from a transparent and impartial process, makes use of information deemed relevant by an inclusive body of shareholders, has sufficient room for revision in the light of new evidence and arguments, and has mechanisms to ensure accountability and enforcement of the above conditions, then those rationing decisions are just, as long as the outcome does not constitute a violation of human rights.[40] However, even a well-ordered deliberative process does not guarantee that the best substantive ethical arguments are proposed, much less prevail. Bioethicists (personally involved in policy-decision making processes or not) have an obligation to pursue and present such arguments as best they can.[41] Third, the process and the arguments need to be sensitive to the particular context – social, political, institutional, and epidemiological – where the allocation decisions will be made and their consequences will play out. Empirical studies of actual HIV treatment allocation schemes show how context shapes allocation.[42] As suggested in the previous section, the ethical case for allocating ARVs for PrEP and TasP will be stronger or weaker depending partly on factors such as emerging scientific data on efficacy; local HIV prevalence and incidence; generalized versus concentrated epidemics; prior investments in HIV treatment or prevention; absorption capacity of local health care infrastructure for these initiatives; percentage of HIV-positive persons in urgent need of ARVs locally; existence of data on community attitudes and beliefs regarding the use of TasP and PrEP.

CONCLUSION

Given the current uncertainties, ethical arguments in favor of using ARVs for TasP or PrEP are inevitably hypothetical in part. Much research is still needed to establish the likely

impact and cost-effectiveness of these strategies in reducing HIV transmission. Responsible implementation would involve dedicating substantial resources to careful monitoring and evaluation, HIV testing and counseling, awareness-raising in communities and structural interventions to reduce vulnerability to HIV infection.[43] The focus of this article was to argue that under certain conditions it could be ethical to use ARVs for TasP and PrEP even when there are those still needing ARVs for treatment. The only way to firmly close or narrow the ethical door on TasP and PrEP is to value treatment of HIV emphatically more than HIV prevention in the midst of a deadly and complex epidemic, and to presume these new approaches will not have a positive impact on the struggle against HIV/AIDS worth making sacrifices for.

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Biography

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