

The Ethical Relevance of “Alternatives” in Health Care Priority Setting – The Case of Preexposure Prophylaxis (PrEP) of HIV

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Preexposure prophylaxis for HIV is a drug that reduces the risk for an HIV-negative person to acquire HIV if taken prior to sex. It has been suggested that it is important for resource allocation decisions that there are alternatives (such as abstinence, masturbation, etc.) for individuals potentially benefitted by this prophylaxis. In this paper we explore this idea from an ethical perspective in relation to three notions often discussed in priority setting ethics, namely responsibility, outcomes, and severity of disease. While the relevance of alternatives may be explained in terms by responsibility-sensitive priority setting, such a view comes with several challenges. We then discuss two other ways in which this intuition could be better explained: (a) in terms of total outcome of health, and (b) in terms of severity of the condition.

INTRODUCTION

Antiretroviral preexposure prophylaxis (PrEP) is one way to prevent individuals from type 1 HIV (HIV-1) infection. PrEP is a class of drugs that reduce the risk of an HIV-negative person to acquire HIV if taken prior to sex. While the ethics of PrEP has been previously discussed in the literature on medical ethics [1-4], see also [5], one crucial question has received insufficient attention in the previous discussion, namely how PrEP should be assessed *from the perspective of health care priority setting*. That is, how should PrEP be prioritized among other

interventions within a healthcare system? Venter et al. [4], suggest that the presence of other options than PrEP (such as condoms or non-penetrative sex) to decrease the HIV risk for the relevant populations may be a morally relevant factor. In this paper, we scrutinize this idea more closely and explore if, and if so how, the presence of alternatives should be considered relevant for priority setting. The analysis utilizes and builds on the previous ethical discussion about priority setting in health care as well as the discussion on the ethics of PrEP. Throughout, PrEP is used as a testing case, but the conclusions have more far-reaching implications. We conclude that while

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Abbreviations: PrEP, preexposure prophylaxis; WHO, World Health Organization; QALY, Quality Adjusted Life Years.

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the moral relevance of alternatives may be explained in terms of responsibility, this is not the best way forward. Instead, we suggest that the moral relevance of alternatives can be accounted for with reference to two other ideas which are less controversial in this context: total health outcome and condition severity.

PREEXPOSURE PROPHYLAXIS (PREP)

PrEP is an umbrella term for pharmaceuticals that an HIV-negative person can take in order to decrease the risk of being infected with HIV. It involves two active substances: emtricitabine and tenofovir disoproxil. The very same substances are also used in combination with other drugs to treat established HIV infections. While the testing case for this paper is concerned with preventative use – prophylaxis for HIV – we will also touch on possible ethical differences between preventative and curative treatment with regard to the presence of alternatives.

If PrEP is taken according to recommendation (one tablet a day¹) it decreases the risk for individuals to be infected with HIV from sex by about 99% and from being infected from injection drug use by about 74% [6].² However, PrEP is less effective if not taken as prescribed and does not protect individuals from other sexually transmitted diseases. Therefore, PrEP does not substitute the use of, for example, condoms, and the recommendations are normally that PrEP should be taken in *combination* with the use of condoms [6-8].

While some have argued that PrEP raises special ethical questions, we agree with Venter et al. [4], that it does not. For instance, the fact that PrEP is a medication with potential adverse effects which is given to otherwise healthy individuals who may be said to take serious risks for the sake of pleasure does not set PrEP radically apart. Indeed, the same can be said about, for instance, malaria prophylaxis in recreational traveling. Furthermore, the fact that patients have alternatives to using PrEP also does not set PrEP apart. As a matter of fact, the presence of alternatives, in this sense, is common in medicine. When it comes to preventive treatments, the good health effects of increased physical activity make this an alternative to most forms of cardiovascular prevention, to name but one example [9,10]. Moreover, the ubiquity of alternatives does not stop at preventive treatment. Indeed, increased physical activity also seems to match the outcome of, for instance, treatment with anti-depressants [11], and cutting down on cigarettes outperforms most treatments for Chronic Obstructive Pulmonary Disease [12]. Furthermore, concerns have been raised about whether PrEP prescription might increase the risk of drug resistance. According to the World Health Organization (WHO) [8] this risk is low, and more importantly, PrEP potentially decreases the number of new cases of HIV which may

limit the need for lifelong courses of curative treatment and thus contribute to an overall positive effect on drug resistance. All in all, our contention is that far from being a standout case, most ethical issues previously discussed related to PrEP are not unique to it. Accordingly, we will proceed from the assumption that PrEP is a safe and effective way to prevent HIV, and that it can be ethically analyzed in a similar way as comparable interventions. Hence, rather than aiming for a conclusion about how PrEP should be assessed from the perspective of priority setting, our focus will be on one characteristic of PrEP which is not *specific* to PrEP but rather well *illustrated* by PrEP, and it may have important implications for priority setting theory. Consider this quote by Venter et al [4]:

Our view is that PrEP (at current prices) is not currently an effective use of state resources in countries where it would mean less people with HIV being treated, for the following, combined reasons. *There are options for people who want to avoid infection* (abstinence, condoms, monogamy, masturbation, non-penetrative sex, and regular HIV testing of partners), while there is no other life-saving treatment available for people who have HIV. The drugs used in PrEP are the same as those prescribed in many commonplace antiretroviral regimens to treat people with HIV (p. 273, our italics).

In the following, we will scrutinize the moral intuition that priority setting should take into consideration whether there are alternatives and pit this intuition against other considerations in priority setting. As we do so, we will use the above quote loosely. That is, our main interest here is not in clarifying the position of Venter et al., but rather to explore what ideas of moral relevance may be harvested here.

SPECIFYING THE IDEA OF “ALTERNATIVES”

In the following discussion, “alternatives” will be used to refer to *actions over which individuals have adequate control, and that are performed solely or partly to achieve the same health goal (preventive or curative) as might otherwise have been achieved by using a prescribed medication*. In this sense, attending to sexual abstinence, monogamy, or using a condom etc. here qualify as “alternatives” to PrEP. To be more precise, our interest here is not primarily in the alternatives themselves, but rather in the fact that in some cases, patients have obvious alternatives to medical treatment, whereas in other cases they do not have such alternatives.

The view presented by Venter et al. [4] seems to be that whereas PrEP should not be offered within publicly funded health care if that means that less curative treatment is being offered, *curative* treatment for individuals

with established HIV-infection should be offered. This indicates that the authors do not ascribe weight to the fact that *previously* there may have been alternatives even for those who today have established HIV infection. Indeed, the idea in Venter et al. [4] seems to be that the presence of alternatives has a particular moral relevance only when it comes to preventive treatment, and not in cases of curative treatment. We believe that this claim is difficult to justify from an ethical perspective. Instead, we suggest that the relevant distinction is between situations where the patient *presently has* alternatives and situations where the patient *previously had* alternatives, when one tries to answer the question of whether alternatives are relevant at all. In the following, we will therefore not make any principled difference between preventive treatment and curative treatment but rather discuss the normative importance of alternatives (present and past) in a way which encompasses both.

ETHICAL PRINCIPLES IN PRIORITY SETTING – COMMON EXAMPLES

In our discussion of the moral relevance of alternatives, we will refer to current ethical principles in priority setting. Although different healthcare systems have different approaches to explicit priority setting [13-15], a set of core ethical principles may be identified that are commonly used and accepted.

First, there is normally some explicit or implicit idea about *formal equality*, implying that morally irrelevant features of patient populations should not be allowed to affect priority setting. This idea often functions to prevent discrimination. For example, a patient's sexual orientation is commonly seen as morally irrelevant in priority setting [13-17]. The idea of formal equality is commonly seen as a *restriction* on priority setting, rather than as a guiding principle as to how health care priorities should be set. In the present context it is enough to note that formal equality cautions against drawing any normative conclusions regarding PrEP because it has to do with sexual behavior rather than anything else. Similarly, it cautions against drawing normative conclusions based on the prevalent anti-HIV stigma, see [5]. All in all, then, it seems unlikely that the presence of alternatives would gain its possible relevance for priority setting by appeals to formal equality, and we will leave this principle aside in the following.

Second, a more contentious question is whether self-inflicted conditions should be ascribed a lower priority due to patient's personal responsibility for her ill health [18]. While several frameworks for priority setting explicitly advise against doing so [15,16] others are more open in this regard [14].

Third, the extent to which interventions can benefit

patients is commonly considered of uncontroversial relevance in priority setting, see eg, [19]. Beneficence may be analyzed on its own or related to the cost for interventions to yield data for the cost-effectiveness of the intervention.

Fourth, most approaches give weight to the *severity* of the condition targeted by the intervention considered in the priority setting process. This means that interventions targeting severe conditions should receive a higher priority than interventions targeting less severe conditions. However, it is contentious why and how this should be done more specifically, see eg, [20].

With this said, we will proceed to analyze whether the possible moral relevance of alternatives may be explained by reference to personal responsibility, beneficence, and/or severity of the disease.

DOES RESPONSIBILITY EXPLAIN THE POSSIBLE MORAL RELEVANCE OF ALTERNATIVES?

To argue in favor of the relevance of alternatives one might claim something like this: *when there are alternatives to medical treatment, the patient has a responsibility to (try to) use these alternatives*. The aim of this section is to explore whether such a reference to responsibility can support the suggestion that the presence of alternatives is morally relevant to priority setting.

As previously noted, the thought that personal responsibility (for one's health and/or for one's health care need) should play a role in priority setting is controversial. Nevertheless, a number of studies suggest that this notion has some public support, see eg, [21], and some normative theories on distributive justice (notably luck egalitarianism and desertism) may be invoked to support such a view [22,23].³

An operationalization of this notion about responsibility may be illustrated by a thought experiment. Consider Ada and Bert who both have lung cancer. Ada is a life-long smoker and has been well aware of the risks of smoking since before she started smoking. Bert, in contrast, has been unknowingly exposed to asbestos in his workplace. Ascribing weight to personal responsibility in priority setting would imply that treatment for Bert should be prioritized over treatment for Ada, due to the difference in responsibility (given that Ada and Bert are alike in all other relevant respects).

To put this thinking into the present context we must examine what, exactly, it is that people are thought to be responsible *for*. In the case of Ada and Bert, most who support responsibility-sensitive priority setting would say that *at least*⁴ it is Ada's responsibility not to let the cost of her smoking impact Bert's access to treatment. Thus, if, for example, there is only one treatment for their condition available Ada should accept that care for her will be

rationed, rather than care for Bert. Now, in the example Ada and Bert have the same condition but for different causes,⁵ which differ with regard to their relation to personal responsibility. Obviously, this is different from the possible role played by responsibility in PrEP and its alternatives.^{6,7} Most importantly, the possible normative relevance of alternatives in the PrEP case is unrelated to the fact that choosing one alternative is less healthy than another (as, *ex hypothesi*, the medical treatment and the alternatives are different routes to achieve the same goal.⁸

There may nevertheless be a common moral intuition which explains the moral relevance of responsibility with regard to PrEP and its alternatives *as well as* in the case of Ada and Bert, above. This intuition is expressed in the following way by Ronald Dworkin: “People are not responsible unless they make choices with an eye to the costs to others of the choices that they make” [24]. In the case of Ada and Bert, the possible “cost to others” is the cost in terms of health foregone *for Bert* if treatment is given to Ada. In PrEP and its alternatives, the “cost to others” is the opportunity cost if the individual uses PrEP rather than, for instance, a condom (presuming that condoms are not subsidized from the healthcare budget at a great cost). That is, the resources spent on PrEP could have been used to benefit other patients in the healthcare system (which is, of course, true for most health care interventions).

As can be seen, the claim that there is an obligation to be responsible, understood as avoiding costs to others, may apply in the case of down-prioritizing the treatment for Ada rather than Bert as well as recommending that PrEP should not be offered to patients for which there are alternatives. Now, two pressing questions arise. First, does the claim that there is an obligation to be responsible stand up to scrutiny? Second, which is the most reasonable operationalization of this claim?

In response to the first question, we note that there is a vast literature discussing the ethical merit of using patients’ responsibility for their health states in priority setting [18]. We take the strongest case for responsibility sensitive priority setting to be, following Dworkin above, that it may save prudent patients from having to bear the costs of imprudent patients’ poor health choices. However, there are several serious challenges that must be dealt with before responsibility can be used for priority setting purposes. Here, we will limit ourselves to three challenges that we find pressing. First, down-prioritizing patients who have not taken care of their health seems like adding insult to burden and risks increasing health disparities in society. Second, it is conceptually difficult to find a workable definition of responsibility in health matters,⁹ and epistemically difficult to ascertain whether patients have lived up to the proposed standards of responsibility. Third, many forms of irresponsible health behavior are

already sanctioned, for instance by alcohol or tobacco taxes, which seems to decrease the importance of further measures against this group of patients, see further [18].

Accordingly, to account for the moral relevance of alternatives in terms of responsibility would have to take on several well-known challenges involved with any kind of responsibility-sensitive doctrine in priority setting. However, we believe that the moral appeal of alternatives in priority setting can be explained in a much simpler way, which does not go by way of responsibility.

DOES THE IMPACT ON OUTCOMES EXPLAIN THE POSSIBLE MORAL RELEVANCE OF ALTERNATIVES?

According to Venter et al. [4] the relevant question is whether individuals have alternatives presently available to them. Having alternatives, and acting on one rather than another, in this sense, may affect the future. This is the sense in which the presence of alternatives may affect the medical prognosis (on a group level). To the extent that it does so it should affect priority setting along with other aspects that affect the medical prognosis in a given situation. To illustrate, consider the analogy between the presence/absence of alternatives and the presence/absence of spontaneous remission.

Consider patient groups *C* and *D* (so called because they have diseases *c* and *d*). The patient groups each comprise of six individuals, and all individuals are presently at health level 0.5 (on a scale between 0-1 where 0 is death and 1 full health). There is treatment for both diseases (let us call the treatments *c'* and *d'*) and both treatments are fully effective – they restore individuals in the group to health level 1. The treatments are equally costly. Suppose further that the health budget can only support one of the treatments *c'* or *d'* (and, oddly, that no other priority setting decisions can be made to allow for the financing of both *c'* and *d'*). Now, it so happens that disease *c* is known to last about 2 years without treatment. As for untreated disease *d*, it is known to follow either of two different disease trajectories: 50% of the patients with *d* will have it for about 2 years, whereas 50% will spontaneously recover within the first year. Alas, there is no way of knowing before-hand who among the patients with *d* who would spontaneously recover without treatment. Therefore, all six patients in both groups can be said to need treatment. Hence, the question arises: should treatment *c'* or *d'* be prioritized?

Now, we take it to be non-controversial that, irrespective of what precise weight an approach puts on health benefits (as compared to other criteria) in priority setting, the net gain in health by prioritizing *c'* over *d'* makes doing so the obvious choice. A commonly employed outcome measure of health improvements is Quality

Adjusted Life Years (QALYs), see eg, [25]. For readers familiar with QALYs the example may be explained in the following way. To provide treatment to the patients in *C* is better than to provide treatment to the patients in *D* because by providing treatment to the patients in *C* we gain six QALYs; by providing treatment to the patients in *D* we gain only three QALYs. The opportunity cost of providing treatment to the patients in *D* instead of *C* is thus that three QALYs are foregone, see further [25].

The point of this analogy is, of course, that we claim that “spontaneous recovery” can be exchanged for “using safe and effective alternatives”. If *C* is substituted for a patient group that have no alternatives, and *D* for a patient group where there are alternatives – which will be used by 50% if they do not get treatment – the patients in *C* should be prioritized for the same reason as in the illustration with spontaneous recovery above. Indeed, why should the existence of alternatives not have a similar normative role as spontaneous recovery? If there are good reasons to believe that some patients, if denied standard treatment, will use alternatives instead, and that these alternatives are safe and effective, this provides a reason for prioritizing other treatments where there are no alternatives because this will lead to better overall outcome in terms of health.

This being said some aspects merit special mention. First, some patients in group *D* (the untreated group) who for whatever reason do not use alternatives, and accordingly remain ill for about 2 years may feel unjustly treated. However, the underlying reason for why they did not receive treatment was not to punish them for not using alternatives but simply because the total health outcome would be better this way. Second, this does not mean that the presence of *any kind of* alternative is relevant to priority setting. The extent to which people, in fact have, access to and adequate control over alternatives should, from a methodological point of view, be assessed as a relevant part of the opportunity cost, rather than an independent criterion for priority setting (this would be double counting the relevance of alternatives). The relevance of the presence of alternatives is already, and should therefore already be, part and parcel of properly done health economic evaluations.

DOES THE ASSOCIATION WITH SEVERITY OF THE CONDITION EXPLAIN THE MORAL RELEVANCE OF ALTERNATIVES?

We will now investigate a final way in which the possible moral relevance of the presence of alternatives may be explained. In priorities setting, *the severity of the patient's condition* is commonly considered an important aspect [20]. There are several different characteristics that may make one condition worse than some other condi-

tion. For example, experienced pain and/or anxiety, and decreased level of mobility.

Consider the severity of the condition targeted by PrEP. PrEP targets a population, *at risk* for acquiring HIV where there are alternatives. We will now analyze whether the availability of alternatives is a further plausible characteristic relevant for assessments of severity (presumably, a characteristic that functions to lessen a condition's severity).

Should conditions where there are alternatives be considered less severe than comparable conditions where there are no alternatives? This question needs further specification. First, note that the question of the moral relevance of alternatives for severity is conceptually distinct from the question of responsibility discussed above. To claim that PrEP should receive a lower priority because the population should be held responsible is one thing, whereas to claim that the presence of alternatives makes the severity of a given condition less severe is quite another. Second, the question of whether the presence of alternatives affects the severity of a condition should also be kept separate from the question of how the assessment of severity should be adapted in situations (such as here) where we are not dealing with the severity of an established condition, but rather with the severity of a situation where there is a risk for a condition. One crucial question to decide for severity assessments for preventative measures is whether the assessment of severity should start with assessing the severity of the potentially resulting condition, and then reduce the severity with respect to the likelihood of getting this condition or simply assess the severity of the resulting condition, see eg, [20]. However, our discussion about alternatives as an aspect of severity does not hinge on a particular answer to that question.

Several easily available intuitions seem to support the view that conditions that do have alternatives should be considered less severe than comparable conditions where there are no alternatives. Situations without alternatives easily invite intuitions of fatality or hopelessness (“There are simply no other options”). Accordingly, from an intuitive point of view, one may think that it seems better for a person to be part of a group where individuals have alternatives, compared to be part of a group in which there are no alternatives. However, to the extent that people actually perceive situations with alternatives as preferable, this preference is likely already captured in the health state evaluations that underpin priority setting in health care. Again, then, alternatives may be morally important in priority setting but this does not justify accounting for their presence twice.

Furthermore, it seems even better to be part of a population in which many rather than few actually choose the alternative. Perhaps because it gives a hint that the alternative is accessible in some sense. However, even

if the presence of alternatives combined with empirical support that these alternatives are often chosen make belonging to such a group more attractive than where none of these things are in place, the empirical issue seems to provide only part of the explanation. As has been argued, it may matter to the individual patient to know she has alternatives. We will now turn to another question, and that is whether it also matters, objectively, whether there are alternatives. That is, it is worse for someone to be in a group in which there are no alternatives irrespective of his or her attitudes towards the fact that there are no such alternatives. Thus, may we say that regardless of whether patients know it or not and whether they care about it or not, it *is* better to have alternatives? To have only *one* way, A, to intervene with regard to one's health seems worse than to have two ways, A or B. Therefore, to be in a group in which there no alternatives is worse than to be in a group where there are alternatives. The intuitive sense in which the group with alternatives seems better can be explained in the following sense. If one is in the group where there are alternatives the individual's health may, as a matter of fact, be more robust in the sense that the individual can live a healthy life despite certain disruptive events. That is, if one is in a group in which there is a plan B rather than in a group in which treatments are irreplaceable.

CONCLUSIONS

Drawing on Venter et al. [4] we have, in this paper focused on if, and if so why, the presence of alternatives is morally relevant for priority setting. Although it may seem as if such a view primarily would be explained by a reference to holding patients responsible, responsibility-sensitive priority setting comes with a number of challenges. Furthermore, we have argued that there are two other ways in which this intuition could be better explained. First, in terms of total outcome of health. In situations where the availability of alternatives makes the prognosis of a group better, this is relevant for priority setting in much the same way and for the same reason as is the presence of spontaneous remission. However, as this relevance is accounted for by properly done health economic evaluations it does not merit using the presence of alternatives as a further criterion in priority setting. Indeed, that would be accounting for the moral relevance of alternatives twice. Second, in terms of severity of the condition, while a part of what makes a condition worse if there are no alternatives may already be accounted for in the initial assessment of the severity of the condition (for example, to the extent it matters for the patient) there may be one part that is not already accounted for. While we have tentatively sketched one attempt for how that could be done (in terms of robustness) we believe that

this would need further analysis to be considered relevant to priority setting.

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Notes:

¹Most studies of the effect of PrEP are concerned with continuous PrEP usage by people exposed to risk. There are also studies which suggest that PrEP may be taken as needed when one suspects that one will be exposed to this risk, see eg, [26]. However, in the following we leave such use of PrEP aside.

²For simplicity, we will discuss PrEP as it is used to prevent HIV via sexual transmission. We nevertheless believe that our argument is in principle valid also for PrEP as used to prevent HIV from intravenous transmission (although several empirical details, such as the extent to which the patients have adequate control over their actions, may differ).

³It has been claimed that referring to responsibility in priority setting functions as a covert way of moralizing over undesired behavior [27]. As PrEP concerns sexual behavior, this worry may be salient in the present context. Indeed, it has been argued that the view of PrEP as "different" derives from the fact that it has to do with sex [4].

⁴A stronger version of this thought would be to say that Ada is responsible to maintain her good health (here: by not smoking) [28,29].

⁵Hence, this view does not focus on which alternatives are presently open to Ada and Bert, but rather on which alternatives were previously open to them (compare the discussion above).

⁶Determining the priority setting of treatment of HIV for patient groups with risky sexual behavior versus patient groups who got HIV through contaminated blood in blood transfusions may be another context which raise the same ethical intuitions as the case of Ada and Bert.

⁷It is also different from another possible operationalization of the intuition about preventing "cost to others". This operationalization – which has been called *ex ante* – suggests that behavior which commonly leads to bad health should be taxed as a way to avoid prudent taxpayers' taking on the cost incurred by irresponsible patients' behavior [30].

⁸Although PrEP may result in some, fairly mild, adverse effects we assume that they are not more severe in terms of health-related life quality than many of the alternatives which arguably come with a prize of their own. At least this seems to be the opinion of those who prefer taking PrEP and engaging in sexual activities over, for instance, engaging in sexual abstinence.

⁹This challenge is relevant in the present context since, as has been previously mentioned, the presence of alternatives to medical treatment is by no means an unusual feature in priority

setting situations. Hence, responsibility-minded policymakers would need to conceptually delineate which kind of alternatives should be taken into account.

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