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By Ruth Macklin and Ethan Cowan

ANALYSIS & COMMENTARY

Given Financial Constraints, It Would Be Unethical To Divert Antiretroviral Drugs From Treatment To Prevention

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ABSTRACT Striking advances in HIV prevention have set the stage for renewed debate on setting priorities in the fight against HIV/AIDS. Two new prevention strategies—preexposure prophylaxis and treatment as prevention—use antiretroviral drugs for prevention of HIV/AIDS in addition to treating patients. The potential for success of these new prevention strategies sets up an ethical dilemma: where resources are limited and supplies of lifesaving antiretroviral medications are insufficient to treat those currently living with HIV, how should these resources be divided between treatment and prevention? This article explores several ethical principles used in formulating public health policy. Assuming that limited resources are available for spending on drugs, we conclude that it would be unethical to watch patients with treatable AIDS worsen and die, even with supportive care, so that medications for treatment can be diverted for prevention.

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One of the most vexing problems in health policy is the need to set priorities for allocating limited resources. Whether the limitations are money, human resources, or medical products, policy makers must determine how they should be distributed to those in need.

Although several ethical principles can be used to justify an allocation of resources, there is widespread agreement that an allocation scheme should be equitable. At the same time, a traditional goal of health policy is to maximize beneficial outcomes for the population as a whole.

These two ethical values—equity and health maximization—can conflict. A strategy that emphasizes overall maximization of health is likely to leave out some groups or individuals—for example, people with illnesses so grave that treatment offers little benefit and is so intensive that it diverts resources from others whose health can

be improved. Nowhere are these ethical issues more pressing than in the prevention and treatment of HIV/AIDS.

This article explores a dilemma arising out of recent striking advances in HIV prevention and examines the ethical principles that can be used in setting priorities in the fight against HIV/AIDS.

Scientific Advances In HIV Prevention

Four recent clinical trials demonstrated for the first time that antiretroviral medications currently used to treat HIV-infected people can also be used to prevent infections in uninfected people.^{1–4} These trials used two different prevention strategies.

One strategy, “treatment as prevention,” showed that starting antiretroviral medications in HIV-infected people at an earlier time than

recommended for treatment purposes leads to a dramatic 96 percent decrease in HIV transmission to their uninfected partners.¹

The second strategy, known as “preexposure prophylaxis,” provided uninfected people at high risk for HIV infection with the same antiretroviral medications normally used for treating infected people. In one study, sexual partners of an HIV-infected person who used preexposure prophylaxis had 62–73 percent fewer infections than members of a control group who received placebos.³ Two other studies showed similar promising reductions in HIV infection in men who have sex with men and heterosexual men and women who used preexposure prophylaxis compared to placebo.^{2,4}

Some concerns remain about potential side effects, toxicities, and drug resistance arising from long-term use of antiretroviral medications in otherwise healthy people using preexposure prophylaxis. However, in the aforementioned studies, no serious safety concerns were identified. Studies of two other HIV biomedical prevention strategies—vaccines and microbicide gels—have had mixed results but show some promise.^{5–7} Because vaccines and microbicides are not currently efficacious enough for large-scale use, ethical questions about setting priorities for these prevention strategies are premature.

Ethical Dilemmas In Setting Priorities

The positive results of the treatment-as-prevention and preexposure prophylaxis trials provide much-needed relief to the long quest for even one effective biomedical HIV prevention method. At last, there is hope that many HIV infections can be prevented among people at high risk.

Yet at the same time, this good news raises questions of fairness in the allocation of scarce resources. The antiretroviral medications used in these prevention strategies are a standard component in the cocktail of drugs used to treat HIV infection. In many resource-poor settings, diverting a substantial portion of antiretroviral medications to prevention could result in a shortage for people who are medically eligible for treatment.⁸

Three populations will be competing for these limited resources. First are people who are infected, have advanced disease, and would die without antiretroviral medications. Second are people who are infected but have CD4+ cell counts—a measure of immune-system strength—higher than what would normally trigger treatment under current guidelines.

However, if these people are given antiretroviral medications, they could accrue some direct benefit and, at the same time, avoid infecting others. Third are people at high risk, but currently uninfected, who could be protected from acquiring HIV by taking antiretroviral medications as preexposure prophylaxis.

Given this situation, pressing questions raise an ethical conundrum. How should choices be made between prevention and treatment in resource-constrained settings? What ethical principles are at play, and if they conflict, which should take precedence?

Over the years, contributors to the literature in bioethics and health policy have articulated several leading principles for setting priorities.^{9–14} Yet there is no agreement on which ethical principle should take precedence. Application of different principles yields different priorities for treatment versus prevention. Each principle points to unique criteria or concerns that must be considered.

When principles conflict, it becomes necessary to balance competing concerns. There is no correct way of achieving this balance. Moreover, there is no consensus on how the different principles ought to be weighted, or on what weight should be given to the goal of maximizing health compared to other social goods such as education or environmental protection.⁹

To arrive at a single, overarching principle, one option is simply to abandon the attempt and instead use a procedural approach. Norman Daniels, a leading contributor to the literature on justice in health policy, has argued that it is virtually impossible to arrive at agreement on which ethical principle to use in priority setting.^{15,16} Daniels advocates a procedural approach that includes the following conditions: publicity (transparency about the grounds for decisions); relevant reasons (appeals to justifications that all can accept as relevant to meeting health needs fairly); and revision and complaints (procedures for revising decisions in light of challenges).

Yet as important as fair processes are in making health policy decisions, this approach remains unsatisfactory for those who claim that well-established ethical principles should be used in a reasoned argument to justify hard choices.¹⁷ The ethical principles commonly used for analyzing the vexing question of setting priorities are discussed in the next section.

Overview Of Ethical Principles

UTILITARIAN The most widely used principle in formulating health policy is the utilitarian principle: Choose the option with the best balance of

beneficial over harmful consequences. As straightforward as this may appear, the principle is open to several different interpretations. When the utilitarian principle is interpreted as promoting the most efficient or cost-effective way to reach the desired goals, it fails to build in constraints of equity. This is because maximizing health benefits would mean giving priority to people whose medical condition is such that they will respond better to treatment and will be likely to survive for the longest time. This would result in excluding patients whose HIV disease has progressed to a point where only a temporary health benefit can be expected. This is an example of a problem known as fair chances versus best outcomes.¹⁰

A nonmonetary interpretation of the utilitarian principle in the context of HIV/AIDS requires specifying which consequences are to count: preventing new infections, preventing deaths, or preventing suffering. This is a tough call, especially because it involves a wealth of empirical data, plus the need for predictions: How effective will the preventive method be overall? How many deaths can be averted by using resources for treatment rather than prevention, or the reverse? It's evident that use of this principle can yield a variety of results depending on an array of goals, empirical facts, and circumstances.

As one of the authors (Ruth Macklin) has noted elsewhere, a utilitarian approach to HIV treatment could call for treating the greatest number of people, even if some (the sickest) could benefit only temporarily.⁹ This interpretation builds in an equity requirement that gives all medically eligible people a fair chance at treatment, even if that option would not result in the best overall health outcome for the population. International HIV/AIDS treatment guidelines set a CD4+ cell count threshold for initiating treatment based on best medical evidence for reducing morbidity and mortality among HIV-infected people. Ethical factors do not play a role in medical eligibility criteria.

EQUITY The principle of equity is as follows: When faced with a competing choice between prevention and treatment, divide resources so that outcomes are distributed as equitably as possible. This principle is the basis for schemes that emphasize health equity over health maximization. The goal is to reduce disparities in health status among different groups or strata in society: the poor, women, people living in rural areas, ethnic or racial minorities, and others.⁹

However, dividing resources equally between prevention and treatment might not be equitable. This is because the effectiveness of current

prevention methods means that allocating a smaller amount of antiretroviral medication to prevention could have additive effects. Antiretroviral medication used for treatment as prevention could reduce HIV infections in multiple partners, which would ultimately save lives and curtail the spread of HIV in the population. Providing even a small amount of antiretroviral medication for preexposure prophylaxis to people most at risk, such as sex workers and people who inject drugs, could have a large impact on reducing the spread of HIV, assuming that users adhere to the regimen.

URGENT NEED The principle of urgent need can be stated as such: "People's medical needs give rise to moral claims to the health care resources necessary to meet those needs, ...equally urgent needs give rise to equal moral claims, and...more urgent needs give rise to stronger moral claims."^{11(p6)} In the context of allocating medicines for treatment versus prevention, this principle is open to two different interpretations. It can mean how soon deaths from nontreatment or nonprevention will occur.¹² Or it can mean how badly off people will be without treatment or a means of prevention.¹²

Depending on the interpretation, application of this principle yields different results for the primacy of treatment or prevention. HIV-infected people need treatment sooner or later, or they will die, and current medical recommendations are designed to provide treatment before patients become too sick and debilitated. Although preventing new cases of HIV is clearly an urgent public health need, it may be seen as less urgent—even for uninfected people at high risk—because they are still healthy and may not become infected.

PRIORITARIAN The prioritarian principle: Ensure that resources are provided to the least advantaged members or groups in society.¹³ But who are the least advantaged in the context of HIV/AIDS? Those who are already infected? Those at greatest risk of becoming infected? The poorest people? The most vulnerable? This principle overlaps with the principle of equity, because the economically least advantaged classes have generally been underserved, have had less access to health care, and have a worse health status than more affluent groups; as a result, they have lacked equitable access and health outcomes.⁹

RULE OF RESCUE The rule-of-rescue principle is as follows: "The fact that we can save identified people whose lives are imminently threatened by AIDS creates an obligation to do so that must be honored, even if so doing reduces the number of lives saved overall."^{14(p1670)} This principle is in direct conflict with one interpretation of the

utilitarian principle, which mandates saving the most lives.

EQUAL WORTH The principle of equal worth can be stated in this way: “Because every life is of equal worth, we must offer the same level of care to every person in need.”^{14(p1669)} As Dan Brock and Daniel Wikler interpret this principle, “it calls upon us to value each person’s life independently of his or her economic or other value to society or to others, and regardless of social position or stigma.”^{14(p1669)} This principle could be considered a variant of the principle of equity, because it mandates nondiscrimination against people who might lack equitable access based on perceptions of their social worth. We include it here in our list of ethical principles because it is sometimes stated as a principle distinct from that of equity.

Treatment Versus Prevention

Past analyses of the HIV treatment-versus-prevention dilemma have been cast in terms of cost effectiveness or persistent limits of available funding. A 2002 article published in the journal *Lancet* argued for the primacy of prevention over treatment even when it means denying treatment to medically eligible HIV-infected people: “Now, for perhaps the first time in history,” the authors wrote, “we must decide whether economic reality will permit an informed debate about rationing that could result in millions of patients receiving supportive care, but not treatment, to prevent many more millions from becoming afflicted with the disease.”¹⁸ Not only is this argument cast entirely in economic terms, but also the calculations are based on what was the cost of various modes of prevention used in 2002 (counseling, condoms), not the cost of antiretroviral medications today that are used both for prevention and treatment.

The authors of an article published in *Health Affairs* in 2009 employed a sophisticated ethical analysis and drew a similar conclusion, preferring spending for prevention rather than treatment.¹⁴ Brock and Wikler correctly noted that financial resources available for HIV/AIDS will be limited for the indefinite future. They rejected the applicability of the equal-worth principle, pointing out that it can support either side in the treatment-versus-prevention debate. In addition, they contended that the principle is relevant to physicians’ personal code of conduct but inapplicable to the issue of HIV/AIDS funding. They also claimed that it is “more plausible as a statement of utopian aspirations than as a guide to current policy.”^{14(p1670)} If the rule were adhered to, money would soon run out.

Although Brock and Wikler rejected the prin-

ciple of equal worth as useful in determining how funds should be allocated for treatment or prevention, they extended the principle in support of their own conclusion. Building in an equity requirement, they stated, “If every life is of equal value, then all else being equal, saving more lives achieves higher value so long as the beneficiaries are selected fairly.”^{14(p1669)}

The two articles discussed above make the case for prevention over treatment using monetary resources as the basis for allocation decisions. However, given the recent success of using antiretroviral medications for prevention, policy makers now face the challenge of determining what proportion of the currently available antiretroviral drug supply, as opposed to the economic resources to fund conventional treatment versus prevention, should be devoted to HIV prevention using antiretroviral drugs and what proportion to treatment.

The utilitarian principle supports using whatever mix of medicine for treatment and prevention will produce the greatest balance of health benefits over harms. The prioritarian principle is problematic for making allocations between prevention and treatment. Both those in need of HIV treatment and those at high risk who can benefit most from prevention can be considered to be “worst off” in their respective categories of HIV-infected and uninfected people. Arguably, however, a strong case can be made that sick people are worse off than healthy people, so on a comparative basis, antiretroviral medications should go first to HIV-infected people who meet the medical criteria for treatment.

Dividing resources equitably has to take into account a considerable number of important empirical considerations: How many people are in need of treatment, and what percentage of those are in urgent need? What is the rate of infection in the country or region? How many people are already being treated for HIV in the country?

Brock and Wikler questioned the applicability of the urgent-need principle to the type of allocation decision discussed here.¹⁴ Although they recognized the importance of urgent need as a principle governing allocation decisions in the clinical setting, where some patients will die if not treated urgently, they contended that the principle applies only under conditions of temporary scarcity. They pointed out (correctly) that the situation with HIV/AIDS is persistent rather than temporary scarcity.

Still, if the question is whether to use limited antiretroviral medications for treating HIV-infected people who are eligible for treatment; treating those who are infected but not yet eligible (treatment as prevention); or reducing healthy individuals’ risk of acquiring the virus

(preexposure prophylaxis), urgent need does seem relevant. Frances Kamm's interpretation of the principle of urgent need that counts time till death—even if that time is not immediate—is an appropriate criterion to use.¹²

A major practical difficulty in striking an ethically sound balance between treatment and prevention is the huge number of people in sub-Saharan Africa and elsewhere who are HIV infected but have never been tested. People who have symptoms of HIV infection are readily detectable, and their urgent need for treatment is evident. In the absence of testing, people who might otherwise be eligible for treatment as prevention or preexposure prophylaxis are not identified.

Thus, the success of biomedical prevention programs depends on a global campaign to scale up HIV testing. Those who favor using available funds for prevention have to factor in the cost of widespread testing for millions of people. Until testing is broadly expanded, using antiretroviral medications for prevention can have only a limited impact on slowing the spread of HIV/AIDS in highly affected communities.

Budget Allocations In PEPFAR

The President's Emergency Plan for AIDS Relief (PEPFAR) provides one example of how policy makers have addressed the difficult challenge of prioritizing the needs for HIV testing, treatment, and prevention to most effectively combat the spread of HIV/AIDS.

For priority setting to be ethically sound, it must accord with scientific findings and technical capability. This is simply another way of saying that ethics requires allocation of resources to be based on evidence. Armed with current information about the efficacy of treatment as prevention and preexposure prophylaxis, policy makers should avoid making rigid determinations of specific percentages to be allocated for prevention and treatment.

In this regard, it is instructive to look at lessons learned from the experience of PEPFAR's first five-year strategy. In 2007 the Institute of Medicine delivered its independent evaluation of PEPFAR to Congress, in which it criticized inflexible budget allocations. The report said: "Congress wisely required that the 'strategy shall maintain sufficient flexibility and remain responsive to the ever-changing nature of the HIV/AIDS pandemic.' However, Congress also required that the program adhere to a fairly large set of specific budget allocations."^{19(p10)} The Institute of Medicine report commented that there was too little information for the budget allocations to be evidence based; moreover, those

allocations adversely affected implementation of the program.

Although this criticism was meant to apply to all the budgetary allocations, one of the categories in the budget stipulated for prevention was especially problematic. Of the total PEPFAR budget in the first five-year strategy, 20 percent was for "HIV/AIDS prevention, of which at least 33 percent should be expended for abstinence-until-marriage programs."^{19(p10)}

Allocating such a large portion of the entire prevention budget to abstinence educational programs was not an evidence-based decision; also, it reflected the ideological views of members of Congress who enacted the legislation authorizing funding for PEPFAR.

Fortunately, Congress's reauthorization of PEPFAR in 2008 led to a new five-year strategy with much-improved plans for allocating resources to prevention and treatment programs. A telling portion of the current strategy is evident in this statement: "PEPFAR is expanding its emphasis on HIV prevention, and matching interventions and investments with epidemiological trends and needs in order to improve impact."²⁰ It would still be a mistake, however, to specify in advance rigid percentages of the PEPFAR budget that all countries should adopt for treatment or prevention before evidence is available about the specific needs and circumstances in different countries. As Stefano Bertozzi has noted: "The correct answer, the right proportion, the optimal way to reduce death and disease from HIV should be guided by the countries [sic] specific situation—both the epidemiology of the country and the current response of the country."²¹ Future scientific advances in vaccines, microbicide research, and HIV treatment will also require increased flexibility in budget allocation decisions.

PEPFAR's response to new scientific evidence shows the prudence of such flexibility.²² Although the current five-year strategy was developed before the recent findings of the efficacy of treatment as prevention and preexposure prophylaxis, the plan makes reference to this eventuality: "There is currently a great deal of research under way involving the preventive impacts of treatment, including studies regarding the protective effect of preexposure prophylaxis with antiretrovirals. If efficacy is shown, demonstration projects will be essential to determining the feasibility of this approach, resource requirements, and the potential for scale-up."²²

Various statements in PEPFAR's current five-year strategy also reveal a commitment to the ethical principles discussed in this article, although without referring to the principles by name or even specifically as ethical considera-

tions. Phrases such as “identifying greatest need” and “the needs of most-at risk populations,” and special comments showing emphasis on stigmatized and marginalized groups such as men who have sex with men, people who inject drugs, and sex workers (still unfortunately referred to in the PEPFAR documents as “persons in prostitution”), illustrate a commitment to the prioritarian principle.²²

The ultimate goal, of course, is to achieve a utilitarian outcome tempered by considerations of equity and urgent need. PEPFAR’s current allocation strategy demonstrates how a utilitarian goal can be met while still adhering to the ethical principles used in formulating policy. Of course, conflicts will always arise as old interventions are optimized or become obsolete and new interventions are discovered. The key is to constantly reexamine the empirical evidence, maintain flexibility, and have a mechanism in place to scrutinize allocation decisions with ethical principles in mind.

Conclusion

Because ethical principles can conflict, reasonable people may disagree about which principle should take precedence. In the case at hand, the most salient conflicts are between the utilitarian obligation to try to prevent the most overall deaths from HIV/AIDS and several other key ethical rules and principles. These are, first, the rule of rescue, which mandates treatment for those who will die without treatment; second, the principle of urgent need, which requires treatment for people sick and suffering from HIV/AIDS; and third, the prioritarian principle, which argues that currently sick people are worse off than healthy people, even those who may be at high risk of becoming HIV infected. We contend that these three principles, taken together, outweigh the utilitarian principle in this situation of resource allocation.

We conclude that it is unethical to deliberately watch patients with treatable HIV/AIDS worsen and die, even with supportive care, if medica-

tions for treatment are diverted to preexposure prophylaxis. Patients who have HIV/AIDS but whose disease is in early stages have a virtual certainty of benefiting from antiretroviral medications. Much greater uncertainty surrounds the benefits for prevention with preexposure prophylaxis. The effectiveness of that method depends on constant and appropriate use by people who engage in high-risk behavior.

Using antiretroviral medications for treatment as prevention takes second place in a prioritization scheme because these same people would eventually become medically eligible for treatment if not started on early treatment. Giving second priority to treatment as prevention may be the best policy option in countries that have the highest burden of disease. Among the recently demonstrated biomedical preventive methods, treatment as prevention showed the greatest efficacy, and therefore the most promise of reducing the spread of HIV infection in the population.

Although Brock and Wikler discussed how financial resources should be allocated and our analysis refers exclusively to antiretroviral medications, the overall conclusions are consistent. Fortunately, preventive methods other than drugs are available, and money within a larger prevention budget can be used for male and female condom distribution; male circumcision; behavioral interventions; prevention of mother-to-child transmission; counseling; and, if efficacy is satisfactorily demonstrated, vaginal and rectal microbicides.

Of course, the best single hope for large-scale, effective prevention lies in the elusive quest for a preventive vaccine. Unlike drugs for preexposure prophylaxis and treatment as prevention, a vaccine does not require a diversion of medicine needed for treatment of sick people. But as long as it is antiretroviral medications that need to be allocated between prevention and treatment, our conclusion gives first priority to treatment, and second priority to the treatment-as-prevention strategy. ■

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Ruth Macklin is a professor of bioethics at the Albert Einstein College of Medicine.

In this month's *Health Affairs*, Ruth Macklin and Ethan Cowan weigh the new ethical issues surrounding the use of antiretroviral drugs for prevention versus treatment of ill patients with HIV. Assuming that limited resources are available for spending on drugs, they conclude for various reasons that it would be unethical to use the drugs for prevention if it meant withholding them from sick patients, and therefore watching those patients with treatable AIDS "worsen and die."

Macklin is a professor of bioethics in the Department of Epidemiology and Population Health at Albert Einstein College of Medicine, in the Bronx, New York. She has published more than 200 scholarly articles and chapters on bioethics, law, medicine, philosophy, and the social sciences. She is the author or editor of eleven books, including *Against Relativism* (1999) and *Double Standards in Medical Research in*

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Cowan is an assistant professor of emergency medicine and of epidemiology and population health at the Albert Einstein College of Medicine. He has established himself as a young investigator with expertise in studying the ethical implications of clinical practice. He is an accomplished educator in bioethics, and he teaches and lectures at the local, regional, and international levels.

Cowan's main research interests are the ethics of HIV testing, treatment, and research. He has been awarded two grants from the National Institutes of Health for his work and is currently funded to investigate the ethical implications of provider-initiated HIV testing in the emergency department setting. Cowan earned his master's degree in clinical research methods at the Albert Einstein College of Medicine, and he received his medical degree from New York University.