

## *Facing Ethical Challenges in Rolling Out Antiretroviral Treatment in Resource-Poor Countries: Comment on “They Call It ‘Patient Selection’ in Khayelitsha”*

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It is widely acknowledged that the HIV and AIDS pandemic is a global emergency and that cheap, effective treatment should be provided for as many people as possible worldwide. But there are many challenges to rolling out antiretroviral (ARV) treatment in resource-poor settings. These include the cost of drugs (although these are falling rapidly), sustaining their supply and distribution, the complexity of treatment regimens, selection of patients for treatment, shortage of medical and nursing personnel, inadequacy of healthcare facilities, the need for uninterrupted, lifelong treatment, and monitoring for drug resistance.<sup>1</sup> Great efforts, nationally and internationally, are required to meet these challenges.

Médecins Sans Frontières (MSF) is an organization whose members put into practice values that have generally atrophied in our modern world. Its mission to empathize and “be with” fellow humans who are suffering miserably (usually as a result of the actions of other fellow humans), to witness their plight, and to improve it

is morally exemplary. MSF has made striking contributions in many countries, not least in facilitating access to treatment for multi-drug-resistant tuberculosis and HIV/AIDS.

Renée Fox and Eric Goemaere describe how MSF has laid the foundations for an ambitious program of expanded access to ARV treatment in South Africa,<sup>2</sup> a country undergoing profound sociopolitical change and struggling to cope with HIV/AIDS.<sup>3</sup> MSF’s documented success in Khayelitsha, an impoverished township, has been inspirational both nationally and internationally.<sup>4</sup> Fox and Goemaere also acknowledge that rolling out treatment to all who could potentially benefit is a daunting prospect and one that is fraught with ethical dilemmas. In particular, they point to the dilemmas associated with

- Selection of patients for treatment
- Reluctance by physicians to refuse anyone for ARV treatment
- Reluctance to accept patients’ refusal to begin or continue ARV treatment
- “Queue jumping”
- Balancing public health needs against individual patients needs
- Confidentiality in settings where revealing HIV status is required to qualify for ARV
- Patient mobility across a large country

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- Treatment of women who have participated in mother-to-child prevention programs

It is these ethical dilemmas that constitute the subject of this commentary. Instead of attempting to resolve each dilemma on its own, I shall describe the various ethical principles that need to be considered in such a context. The application of these principles and their ranking requires moral reasoning and consideration of contextual issues to formulate justifiable solutions. This process extends beyond the ambit of this commentary and will not be discussed here.

### **Ethical Principles**

In considering the many ethical dilemmas associated with providing ARVs, it is important to acknowledge that these dilemmas are located in more than one domain. First, and most important for healthcare professionals, are the ethical dilemmas involved in the interpersonal relationships between health workers and individual patients. These have been, and continue to be, the appropriate focus of much attention. Second, and as important, although less well recognized and less deeply felt by clinicians are the ethical dilemmas that arise in the course of working to improve public health.<sup>5</sup> Just as there may be conflict between ethical principles in interpersonal relationships, so there is the potential for conflict among several principles of public health ethics and between the ethics of individual care and public health ethics.

I begin by examining the implications of well-known principles of bioethics for ARV roll-out programs. Then I consider newly formulated principles of public health ethics and how these may conflict with the ethics of individual patient care. Decisionmak-

ing on moral dilemmas requires the ability to consider not only all these principles but also morally relevant aspects of context and the moral agency of healthcare professionals in order to craft, through a process of moral reasoning, a justifiable solution to the dilemmas. I shall conclude with some pragmatic considerations that cannot be avoided.

### *Beneficence and Autonomy*

Given our ability to reduce suffering greatly and prolong life with ARV treatment (even in resource-poor settings) and the extremely adverse implications of nontreatment for individuals, families, and society, the ethical principle of “beneficence” (doing good) requires that as many people as possible receive treatment and the best possible outcomes be achieved. Widespread acknowledgment of the importance of this principle has generated extensive national and international endeavors to expand treatment programs. The fiduciary responsibility of physicians to their patients has been deeply ingrained in medical professionalism for many centuries, and beneficence and respect for individuals lie at the heart of MSF’s mission.

Respect for patient autonomy in decisionmaking about their health has become widely accepted, even though contested by some in the way it might be applied in various settings.<sup>6</sup> Beneficence is deeply ingrained in medical practice and an essential aspect of humanitarian medicine together with the most understandable form of paternalism toward those who persistently refuse to comply. It is necessary to reflect on how beneficence may both overshadow autonomy and thwart public health goals. This is a difficult tension, as healthcare workers see their responsibility predominantly as doing good for individuals under their care (even

if some patients appear to be unwilling and even if the chances of being successful are low), rather than to society at large. Such attitudes coupled with a tendency to practice “rescue medicine” encourage attempts to offer terminal patients treatment that may snatch them only very temporarily from the clutches of death. This approach to everyday clinical care, one that fosters understandable “queue jumping,” needs to be tempered by other considerations about public health (vide infra). Moreover, beneficence, in the absence of patient choice and when resources are limited, also requires that in the face of inevitable death (conceded as a difficult judgment to make with any precision) medical care be directed toward palliation and appropriate terminal care.

### *Justice*

Justice in the distribution of healthcare is most commonly thought of in terms of equity. Equity can be defined as the provision of equal shares for equal needs or the allocation of unequal shares for unequal needs as long as proportionality is maintained. However, proportionality is difficult to assess because of incommensurability.<sup>7</sup> Some inequalities in wealth, health, and disease are inevitable aspects of life; therefore eliminating all inequalities is not possible. In addition, not all inequality is inequitable. Inequity refers to those inequalities that are considered to arise from unfairness. In recent years, inequitable disparities in health have become a major focus of attention worldwide. In the HIV era, one of the challenges faced by the South African government is how to institute a program of treatment with ARV drugs in a manner that will meet the equity and human rights requirements of the South African Constitution.<sup>8</sup> Many inequities in healthcare arise because of the vast differences in

access to healthcare in the private and public sectors and across wealthy and poor regions in the country.

As many more people require treatment than can be treated immediately, the ethical principle of justice (as fairness) is relevant in selecting those who will be treated. Being fair to all people means, at the least, providing equitable access to treatment with ARVs. Therefore children and people in rural areas must be included early in roll-out programs, as they are the least likely to access treatment without additional support. As equity also requires avoiding discrimination, there may be a need to give priority to redressing inequities based on previous discrimination.<sup>9</sup>

Because there is no universally accepted theory of justice that will allow implementation of fairness on substantive grounds, it has been necessary to resort to a fair process in the allocation of scarce resources. American scholars Daniels and Sabin have proposed a process for priority setting that they have called “accountability for reasonableness.”<sup>10</sup> This framework requires that four conditions be met.

1. Decisions regarding which healthcare needs are to be given priority must be based on evidence and reasons considered by fair-minded people to be contextually relevant.
2. The rationale for decisions must be publicly accessible.
3. Allowance must be made for appeals so that previous decisions can be reconsidered in the light of new evidence or arguments.
4. There must be a process of regulation or enforcement that facilitates the implementation of the previous three conditions.

Application of this priority setting process allows for the development of

rational practices that can be applied consistently and that avoid problems associated with the total clinical freedom desired by many physicians when resource constraints have to be faced and equitable public policies developed. Such a process, although required in setting policies for priorities in ARV roll-out programs when resources are limited, conflicts with the desires of physicians to do everything possible for each and every patient under their care. This illustrates how even within the individual care paradigm there may be conflict between ethical principles.

Fairness to patients with many other chronic and treatable diseases, and even those for which only palliation can be provided, requires that an ARV roll-out program should not be carried out separately from healthcare for other diseases. So instead of isolated vertical programs only delivering ARVs, the latter should be provided within integrated and strengthened primary healthcare facilities so as not to eclipse or undermine other essential components of healthcare.<sup>11</sup> The priority-setting process should include such considerations too.

### **Public Health Challenges**

As the HIV pandemic is a problem for whole populations as well as for individuals, ethical principles that focus on the rights of individuals to be treated equally and fairly should be balanced against the need to achieve the greatest potential public health benefits. Although caring health professionals will have difficulty acknowledging this, it is a fact that although population health is influenced by the health of individuals, it is also more than merely the aggregate of the health of many individuals. Public health activities must therefore of necessity be directed at enhancing the health of

whole populations. This goal may conflict with the desire to always place the rights and needs of individuals above those of society.

The needs of society also require giving consideration to preferential access to treatment to healthcare workers, teachers, and those whose work is essential for social stability. Placing the needs of public health above the rights of individuals and discriminating in favor of those who would seem to be somewhat privileged (another form of queue jumping) are problematic from rights and equity perspectives, and should only be undertaken through transparent and publicly accountable decisionmaking processes.<sup>12</sup>

As failure to take medication regularly may lead to multi-drug-resistant infection, with profoundly adverse cost and health implications for individuals and society, it is an ethical imperative within the public health agenda to prevent emergence of resistance.<sup>13</sup> Consideration of this ethical imperative can allow selection of patients who are willing to share confidentiality if there is empirical evidence that requiring candidates for ARV treatment to disclose their status to at least one family member enhances adherence.

The need for a high degree of adherence to treatment for life, and therefore to sustain large and growing ARV treatment programs, poses major challenges to the public health system. It should be recalled that it was not possible to ensure adherence to 6 months of treatment to cure tuberculosis for less than 100,000 new cases per year in South Africa in the pre-AIDS era.<sup>14</sup> So the challenge of ensuring life-long adherence to treatment with ARVs for 500,000 people while simultaneously treating escalating numbers of people with tuberculosis is formidable.

Long-term adherence is dependent on having an appropriate infrastructure for healthcare delivery with ade-

quate access through clinics, well spaced across the country, to facilitate accessibility for all,<sup>15</sup> especially in a country where patients are migratory and may move from one part of the country to another for social or economic reasons. Maintenance of a continuous supply of drugs, monitoring of compliance, and active involvement of communities are also essential. One of the major challenges to ambitious roll-out programs, for example, the World Health Organization's 3 × 5 program, is to develop and sustain the primary care infrastructure and staffing required to deliver appropriate care.<sup>16</sup>

Selecting patients who are most likely to adhere to treatment for the long term can reduce the possibility of drug resistance. The public health necessity to prevent the emergence of multi-drug-resistant HIV may justify overriding individual rights to treatment for those who may not be able to adhere. Compassionate healthcare workers will wish to treat every patient, even those who are close to death or may not be able to adhere to treatment long term and who will probably benefit minimally. They may also be tempted to begin treatment in patients who will move out of the area and become potentially nonadherent because they cannot be tracked. On the one hand, placing the good of society at large ahead of the good of specific individuals is painful for healthcare staff, as illustrated by Fox and Goemaere's paper. On the other hand, the greater social good should not be ignored. Public health practices, like personal medical care, need to be supported by justifiable principles of public health ethics and due process in their application—to ensure consistency and accountability in practice.<sup>17</sup>

As indicated earlier, beneficence, paternalistic attitudes, and a tendency to practice "rescue medicine" with no at-

tempt spared in treating terminal patients in the hope that death can be averted are understandable aspects of conventional daily medical practice. But these need to be tempered by some understanding of the limits of medicine and of the rationality of policies that could be developed to promote equity and social utility in tandem with good care for individuals.

### *Principles of Public Health Ethics*

Public health ethics, a new field within bioethics, is receiving considerable scholarly attention, prompted in part by experiences with the HIV/AIDS pandemic and other new infectious diseases like SARS.<sup>18</sup> Several principles of public health ethics have been proposed and how these are to be used with justification in different circumstances will be the subject of ongoing studies and debate. At this stage their potential relevance to rolling out ARV treatment can be briefly summarized as follows:

- The *effectiveness principle* requires evidence of the effectiveness of a measure in improving public health if other moral considerations (such as individual rights and freedoms) are to be infringed. ARVs are effective but only if taken with a high degree of adherence for prolonged periods. If adherence falls below 80%–90%, then the effectiveness of treatment diminishes and the risk of resistant strains emerging increases.<sup>19</sup> Unless high levels of adherence can be achieved, the long-term effectiveness of treatment at the level of individuals and the public will be diminished.
- The *proportionality principle* requires that a positive balance be achieved between potential benefits of a public health interven-

tion and the adverse effects of infringing individual human rights. As the potential benefits of adherence are great and the potential for resistance increases as adherence decreases, this principle also supports measures that increase adherence—even if this should require exclusion of some patients.

- The *necessity principle* requires that no other method of achieving the required adherence would have less conflict with other moral considerations—in this case the right of individuals to treatment.
- The *harm principle* states that the only justification for restricting the liberty of an individual or group is to prevent harm to others. As allowing resistance to emerge is potentially harmful to others, the harm principle supports exclusion of nonadherent patients if the other principles are met.
- The *least restrictive means principle* requires that less coercive means (e.g., education, facilitation, and discussion) must first be tried before it is justified to implement more intrusive public health measures. For example, systematic attempts must be made to facilitate adherence with ARVs (preparing patients for treatment) before excluding those who are likely to be nonadherent or removing nonadherent patients from treatment programs.
- The *reciprocity principle* requires that the state provide appropriate assistance to individuals to facilitate their meeting their public responsibility to adhere to treatment. This should include linkages between treatment centers in different parts of the country to ensure that patients who move have continuous access to treatment.
- The *transparency principle* requires that the public health decision-

making process be as clear and accountable as possible, as well as free of political interference. Thus decisionmaking policies must be undertaken openly and with as wide public participation as achievable.

*Balancing Individual Rights against the Common Good*

Clearly a balance or harmony must be achieved between the rights of individuals and the public health needs of society. The aim is to maximize adherence by enhancing social ownership and cooperation, reducing stigma, and preserving individual dignity. Social destabilization must also be prevented, for example, by treating all, and not only some, members of families and close-knit societies. This consideration makes it desirable to treat HIV-positive mothers who participate in mother-to-child prevention programs. If women are migratory, then every effort should be made to ensure that ARV treatment can be provided close to their homes. Social stability can also be preserved by ensuring that those suffering from HIV/AIDS are not given highly preferential treatment with neglect of those who need treatment for chronic and other diseases requiring medical attention. For example, it would be distressing and disruptive for the family if ARV treatment is provided for a patient while neglecting to treat the diabetes and arthritis of the spouse. The need for individuals to take some responsibility for their own health should also be stressed.

Dilemmas regarding implementation of public health ethics and overriding the freedoms of individuals will be greatest for those societies that are intolerant of any infringement of individual liberties in the name of the common good. Putting public health above the needs of individual patients

will also be extremely difficult for healthcare workers. But it should be acknowledged that organizations such as MSF and other large medical institutions have a responsibility to meet public health expectations while also providing care for individual patients and sustaining the moral agency (virtues) of physicians.<sup>20</sup> The challenge is to create harmony between the rights of individuals and responsibility to society in ways that promote both individuality and solidarity and that also sustain the moral integrity of caring health professionals. There are no simple solutions to such complex challenges. Ongoing dialogue, operational research, and incorporation of learning experiences will be essential components of the roll-out process.

### *Preventing New Infections*

If the pandemic is to be attenuated, it is as important to prevent new infections as it is to treat those who are infected. Therefore prevention programs are also vital and should include the most effective and simple method available—prevention of mother-to-child transmission. However, more will be required—including alleviation of poverty, improvement of nutritional status and living conditions, education, promotion of safe sex practices, and other behavioral changes. Both good treatment and good prevention programs are required, as these complement each other in a broad and holistic approach to dealing with the pandemic.<sup>21</sup>

### **Some Pragmatic Considerations**

As existing disparities in South Africa and many developing countries are so wide, and it will be difficult to achieve all the desired goals, it is necessary to consider and implement some trade-offs early in the roll-out process. For example, the feared adverse long-term

consequence of using cheaper generic drugs (emergence of resistance) has to be balanced against providing treatment for more patients to alleviate suffering and save more lives in the short term. Safe and effective long-term use of generic drugs requires that their quality be sustained at high levels.

There are insufficient doctors and nurses to provide for all the healthcare needs in developing countries, including South Africa. One reason for this is that many of those trained locally and poorly paid are regrettably recruited by other countries or leave for other reasons.<sup>22</sup> Recruitment of healthcare personnel from developing countries to the industrialized world, without provision of any compensation to developing countries for their investment in the training of professionals, is now increasingly acknowledged as unethical. Because of shortages of conventionally trained health professionals, additional personnel will have to be included in the delivery and monitoring of ARV treatment. They could include community health workers, traditional healers, and people living with HIV/AIDS. Trade-offs will have to be made in balancing the level of knowledge and training required by such personnel against the need for treating large numbers of patients.

To avoid delays in initiating the roll-out of ARVs and subsequent loss of life while rural healthcare facilities are being developed, a trade-off is also required between the right of individuals to equity in access to ARVs and the public health need to maximize good outcomes. So roll-out programs should begin where healthcare facilities exist, and every effort must be made to include deprived areas as rapidly as possible.

### **The Future**

The emergence and spread of HIV/AIDS (like the emergence and spread

of multidrug resistance to old diseases such as malaria and tuberculosis, as well the emergence of other new infectious diseases—including SARS and Avian flu) should be viewed as evidence of instability in a complex global system. Such instability cannot be neglected. Although medical care for individuals and generous provision of resources from the Global Fund and other sources are necessary, philanthropy and biomedical care are only short-term responses and they are not sufficient. For sustainable improvement in population health, it is also essential to address the upstream global economic forces that cause and perpetuate the poverty that promotes the emergence and spread of infectious diseases.<sup>23</sup>

Our humanity depends on showing some solidarity with our fellow humans.<sup>24</sup> Unless ways can be found for reducing global injustice by remodeling the global economy to allow a modicum of redistribution of massive economic growth toward the marginalized poor majority of the world, the lives of all everywhere will be less secure. The ethics of how nations and powerful transnational corporations interact with each other to influence global health directly and indirectly are, I venture to suggest, the most important ethical and practical issues facing humankind in the 21st century.<sup>25</sup>

## Notes

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11. See note 3, Benatar 2004.
12. See note 10, Daniels, Sabin 1997.
13. See note 1, Curran et al. 2004; Lamptey P, Wilson D. Scaling up AIDS treatment: What is the potential impact & what are the risks. *PloS Medicine* 2005;2(2):0102–4; McCoy D,



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14. See note 3, Benatar 2004.
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  16. See note 1, Curran et al. 2004; note 3, Benatar 2004.
  17. See note 5, Childress et al. 2002, Upshur 2002, Benatar 2003, Kass 2004; note 10 Daniels, Sabin 1997.
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