HOW TO ACHIEVE FAIR DISTRIBUTION
OF ARTs IN 3 BY 5: FAIR PROCESS AND
LEGITIMACY IN PATIENT SELECTION

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Executive Summary

Abstract: The WHO goal of treating 3 million people with ARTs by 2005 means not treating another 3 million who might benefit. How can the selection of patients be made fairly? This report argues that the solution lies in an appeal to procedural justice. We need to rely on fair procedures when we cannot agree to substantive principles that determine fair distributions. Although we have international agreement on some human rights requirements (a goal of universal access) and prohibitions (no discriminatory exclusions), there is reasonable moral disagreement about many other issues, and fair process can resolve these in ways that achieve legitimacy. The report illustrates the ongoing value controversies underlying three sample issues in patient selection, medical eligibility criteria, siting decisions, and giving priority to health workers, noting other important ones as well, such as cost-recovery. Since there is no consensus on substantive principles of selection for such issues, international agencies and countries need to implement a fair, deliberative process at various levels of decision-making to resolve disagreements and achieve moral legitimacy for the outcomes. Key features of that process are publicity (or transparency, so that rationales for decisions are available to all), stakeholder involvement in agreeing to relevant reasons for making selections, revisability of decisions in light of appeals or new arguments, and enforcement to assure that fair process is involved. Together these conditions make decision-makers accountable for the reasonableness of their resource allocation and priority setting decisions. The report illustrates what these conditions mean at different levels of decision-making, using the examples of medical eligibility, siting, and priority to special groups in scaling up access to ARTs. A program of research and training is sketched so that it is possible to gather and share the lessons learned in implementing these elements of fair process. Implementing fair process in the “3 by 5” program can contribute toward making health systems in general accountable for the legitimacy and fairness of resource allocation decisions. Though scaling up ARTs is a response to an emergency situation, it will be an ongoing emergency and there is no excuse for evading the responsibility to make decisions fairly.

The Problem

Though providing “3 by 5” treatments in a sustainable way to three million people by 2005 would be a remarkable accomplishment, the effort would leave three million others untreated, raising a glaring question of equity. How can we assure fair treatment in selecting patients?

The Need for Fair Process

If we can agree that those at greatest risk should be given a vaccine when we cannot vaccinate all, and we can agree which groups are at greatest risk, we need no fair process for deciding whom to select. But selecting patients for ARTs in the “3 by 5” program poses a different situation. Although we have international agreement on some human rights requirements (a goal of universal access) and prohibitions (no discriminatory exclusions), there is reasonable moral disagreement about many other issues involved in selecting patients for ARTs, and fair process can resolve these in ways that achieve legitimacy. We lack prior agreement on principles of selection for key decisions about selection, and sometimes we ignore underlying ethical disagreements because we think the decisions are technical and involve no value judgments. Siting decisions, for example, may be thought of as merely technical questions about the efficient use of existing capacities, but replicating existing biases in favor of some urban over rural areas in service delivery, for example, will compromise concerns about equity in access. “First come, first served” policies in sites that provide such unequal geographical access, as well as unequal access by income and educational level, will then just replicate existing inequities rather than reflect a policy of respecting all patients equally. When there is such controversy about how to apply and weigh competing principles of distribution, we must resort to fair process, a form of procedural justice, to arrive at agreement about policy. Fair process allows us to achieve legitimacy for ethically controversial decisions that are not resolved by clear agreement on human rights.
requirements (such as a goal of universal access) and human rights prohibitions (discrimination against particular groups).

Competing principles and considerations in 3 by 5

Three issues are discussed to illustrate some of the types of moral controversies that arise around patient selection; other central issues, such as cost-recovery for drugs and services, pose similar disagreements about maximizing benefits vs equity or fairness in treatment of individuals and groups but are not discussed in detail for reasons of space.

Medical eligibility: The recommendations regarding CD4 count levels or clinical diagnoses of AIDS may reflect a concern that we reserve treatment either for those who will have the best expected outcomes from treatment or for those most urgently ill. There may, however, be some patients who would do better with treatments were they provided earlier, when they were less ill, or others who might get some but not optimal expected benefit and are excluded. Should we so heavily weight selection in favor of best outcomes or should we provide some fair chance to others to get some benefit? A fair decision requires a fair, deliberative process about competing values.

Siting: One strategy for scaling up might emphasize using existing resource capacity in some urban tertiary care settings as an efficient way to reach larger numbers of patients quickly, adding other provincial and district sites as capacity could be added. Another strategy might commit some resources immediately to locating treatment sites where underserved populations might get early access to them. Both strategies might have different levels of integration with existing health system structures focused on primary care. Underlying these choices are value judgments about the importance of equity of access, and not simply technical judgments about short-term efficiency. These value issues require a fair deliberative process.

Priority to health workers or other special groups: A principle requiring that we respect patients equally and not make judgments about their social worth seems to imply not favoring access for groups like health workers. But under some conditions of resource scarcity and high prevalence of HIV/AIDS among health workers and others, the ability to carry out basic functions of the health system, including scaling up ARTs, is at risk. How we weight the conditions of scarcity against concerns about equal respect is a value issue requiring fair, deliberative process.

Features of Fair Process

A fair process for setting priorities about the distribution of ARTs has the following central requirements or features.

- **Publicity Condition:** The process must be transparent and involve publicly available rationales for the priorities that are set. People have a basic interest in knowing the grounds for decisions that fundamentally affect their well being.

- **Relevance Condition:** Stakeholders affected by these decisions must agree that the rationales rest on reasons, principles and evidence they view as relevant to making fair decisions about priorities. Community and stakeholder participation and voice must vary in an appropriate way with institutional context.

- **Revisability and Appeals Condition:** The process allows for revisiting and revising decisions in light of new evidence and arguments, and allows for an appeals process that protects those who have legitimate reasons for being an exception to policies adopted.

- **Enforcement or Regulation Condition:** There is a mechanism in place that assures the previous three conditions are met.

Illustrations of Fair Process:

Decisions about patient selection are made at
various levels, both external to a health system and at the national and sub-national level. The report takes the three issues noted earlier and illustrates fair process as it might take place at appropriate levels in each case. For the case of medical eligibility, the process an external agency might follow is described, as is the process a national decision-makers would use in considering acceptance of the agency recommendations. In the siting decisions, both national and sub-national levels of decision-making are illustrated. In the priority to health workers case, national and sub-national decisions are again illustrated, with special attention to the question of local discretion. The following checklist summarizes fair process for all the cases:

**Publicity:**
Does the international agency or national or sub-national decision-maker considering such recommendations:

- Provide public access to the full rationale for its decision about medical eligibility or siting or group priority criteria and not simply to its recommendations?
- Hold public hearings during the process of arriving at its recommendations?
- Are the rationales as accessible as the recommended requirements?
- Are rationales presented in ways comprehensible to people who are interested in understanding them?
- Are stakeholders involved in deliberation about these rationales free to discuss their arguments outside the deliberative process?
- Are complaints that are brought by decision-makers from national and sub-national levels made public so that the responses to the proposals are also publicly accessible?

**Relevant Reasons:**
Does the international agency or national or sub-national decision-maker:

- Undertake a careful, comprehensive gathering of relevant evidence that bears on the empirical background to the various ethical issues that must be addressed? Expand the relevant evidence that is gathered as new arguments are raised that involve empirical assumptions?
- Distinguish empirical from ethical issues so that values are not submerged within technical conclusions by a narrow range of experts?
- Consult with and welcome to the deliberation a broad range of stakeholders affected by the decision? Are they from all relevant groups? Are they from appropriate levels (national, regional, local) at which the effects of recommendations will be felt?
- Support stakeholders during the deliberative process with access to information, an opportunity to understand the evidence, interact with others in the deliberative process?
- Treat disagreements with respect and patience, looking for grounds for reconciliation of views?
- Empower stakeholders to feel like true participants rather than just tokens? Is their involvement valued by other experts, or merely tolerated?
- Make to organize the results of stakeholder deliberation, so that all can see the framework for different positions as clearly as possible and understand what is at issue in cases of disagreement?
- Discuss and deliberate about the process for resolving disagreements, so that people feel the process is fair to them and genuine in its intentions to respect them?
- Develop rationales that are inclusive of points of disagreement, so that others can see the careful nature of the deliberation?
- Make recommendations about priorities and rationales for them that are appropriately respectful of local discretion and authority?
- Do stakeholders involved at each level of decision-making pay careful attention to fair process in deliberation at other levels and consider arguments and resulting rationales in their own deliberations?
- Where priorities among special groups are the issue, have deliberators refined their rationales so that they guard against charges of “favoritism” and concentrate on arguments that all stakeholders can see as relevant?
Revisability:
Does the international agency or national or sub-national decision-maker:
- Invite disagreements raised by national and sub-national level decision-makers and revisit policies in light of these complaints?
- View decisions as best achieved through an iterative process in which new evidence and arguments are welcomed as a chance to improve quality?
- Assure decision-makers at other levels that they have an opportunity and responsibility to raise objections to other levels, requesting reconsideration?
- Assure that appropriate stakeholder are involved in the careful deliberation about revision and that they are treated and supported in the ways described earlier?
- Is there a mechanism for making appeals of decisions, including the grounds for the complaint, a matter of public record as well as the decisions themselves?
- Is the responsiveness to appeals and other complaints seen as part of a quality improvement process, or is it dismissed as rebelliousness or obstructionism?

Enforcement:
Does the international agency or national or sub-national decision-maker:
- Make itself accountable to lower levels of decision-making for having carried out a fair process in its deliberations?
- Challenge decisions made in response to its recommendations on the grounds that these decisions were not made in accord with fair process?
- Seek international agreements or national regulations on the elements of fair process that should be involved in such priority setting decisions?
- Seek agreements about components of fair process among decision-makers at each level so that standards are clear and departures from them can be challenged.

Improving Fair Process over Time:
The illustrations in the report can be made the basis of case studies for training exercises. As fair procedures are implemented, a research program should be put into place so the lessons learned from this feature of scaling up activities can be examined and shared. That program should include:
- A descriptive record of processes put into practice should be developed.
- A set of research questions should be developed to test the compliance with recommended components of fair process.
- A set of research questions should be developed to examine the effects of fair process on outcomes, including the perceived legitimacy and acceptability of the decisions made. The research questions should identify and try to measure the “value added” of abiding by fair process. Typical questions might be these:
  ➔ Is there less resistance to recommendations when process is perceived to be legitimate and fair?
  ➔ Are more consistent and coherent decisions made when a body of “case law” emerges to frame those decisions?
  ➔ Is there an increased perception of fairness in the system when central elements of fair process are used and made visible?
- Appropriate research techniques should be supported for answering those questions.
- A timeframe for this research agenda should be set so that efforts to extend the “3 by 5” effort into the future with new targets are guided by results learned from the current efforts.
- International support should be gathered for this kind of monitoring and evaluation and research effort. It is just as important a type of research as that aimed at examining the effectiveness of operations put in place or the other outcomes of those operations.
1.0 The Problem: “3 by 5” is also “3 out of 6”

1.1 Goals of “3 by 5”

WHO has set the target of putting three million HIV/AIDS patients into a sustainable regimen of anti-retroviral treatments (ARTs) by the end of 2005 – thus the “3 by 5” slogan. The program goals or “guiding principles” also specify that treatment must be accompanied by improved delivery of preventive measures against HIV and must not undermine the ability of health systems to address other urgent preventive and curative needs.\(^2\) Given the large, rapid infusion of donor resources needed, and given the fragility of many of the health systems where HIV/AIDS incidence is the highest, success is by no means assured,\(^3\) and the risk that “3 by 5” could inadvertently impair HIV prevention programs or other components of the health system is real.\(^4\)

If this bold program is successful, however, and reaches its target, the result will be wonderful: Three million people who would otherwise shortly die will be saved.

1.2 Ethical Challenge of “3 by 5”

But even in its statement of a target, the “3 by 5” program raises a daunting ethical issue: only three million people will be given life-extending drugs out of six million who could benefit from them. “3 by 5” is equivalent to “3 out of 6.” While the former is an inspiring logistical challenge, the latter is a grim ethical challenge. Is there a fair way to select the fortunate three million?

Without an answer to this question about fairness, even a successful “3 by 5” program will face sharp criticism that it has been unfair and ignored a glaring and important issue of equity. Without an approach that establishes legitimacy for the selection decisions that are made, what can be a great achievement will become a focus of angry resentment. When people win millions of dollars in a national lottery, they are viewed as very lucky. No one resents their winning, provided the lottery is fair, or is perceived to be rigged, reactions are very different and very intense. Fairness matters. Imagine the intensity of reactions if the stakes are even higher -- life itself and not just money. Fairness matters even more.

So how do we select people fairly for ARTs? How do we establish legitimacy for ethically sensitive decisions in which there are such high stakes for the winners and losers?

1.3 Plan of this report

This document offers some guidance about selecting people fairly. Section 2 presents an argument that fair selection requires a fair, deliberative process and not simply an application of principles of equitable distribution, since in general we lack consensus on such principles for this kind of complex patient selection problem. To anticipate some objections, fair process is not a

\(^1\) The main ideas about fair process in this paper were developed in collaboration with James Sabin, MD, over a period of a ten years with support from various foundations, including the Greenwall Foundation, Robert Wood Johnson Foundation, National Science Foundation, and SAMSA. I thank Jim Sabin and Russell Teagarden for helpful comments on drafts of this paper, Alex Capron and Andreas Reis for providing me with some useful sources, and for their comments I thank participants in the Priority Setting and HIV/AIDS Faculty Working Groups at Harvard, and participants in the WHO and UNAIDS consultation on Equity in the Three by Five Program, Geneva, Jan 26-27, 2004.

\(^2\) “ARV treatment should be planned and implemented as an integral component of the continuum of care, treatment and prevention. Planning and implementing ARV treatment programmes must be based on responding to the community’s care, treatment and prevention needs. It will also be important to situate ARV treatment programmes within existing health systems. Although most health systems in resource limited settings tend to be underdeveloped and overstretched, situating ARV treatment programmes within such health systems can be an opportunity to strengthen them (emphasis in original).” Dhaliwal et al, A Public Health Approach for Scaling up ARV Treatment: A Toolkit for programme managers. August 2003, draft.

\(^3\) McCoy, D. Health Sector Responses to HIV/AIDS and treatment access in southern Africa: Addressing equity. Equinet Discussion Paper No. 10, Oct 2003, p.13: “…there are signs that targets set for resource generation will not be met. As of March 2002, the projected annual costs of the Fund [GFATM] were less than the pledges received from donor governments and corporations, and the money promised by donors at the end of this year [2003] is $1.371m less than the money that the Fund needs.”

way of avoiding hard choices, nor a device for delaying necessary action. Rather, fair process provides legitimacy for the hard decisions we must make, even in the kind of global emergency posed by the HIV/AIDS epidemic. Nor does the need for fair process to resolve moral controversy undercut human rights. This deliberative space is recognized by human rights advocates, for it is subject to procedures of negotiation under the notion of “progressive realizability, and it is recognized by those familiar with the fact that principles of justice sometimes conflict and a there may be no clear consensus on how to resolve reasonable disagreements about the weight or scope given them. So both human rights approaches and appeals to ethics agree on the need for a fair, deliberative process to provide legitimacy for decisions made in the deliberative space between clear requirements on which there is moral consensus and clear prohibitions.

Section 3 elaborates that argument for fair process by examining in somewhat greater detail some of the controversies that surround giving priorities to some groups of patients over others. Section 4 provides a general discussion of several key requirements of fair process for this kind of priority setting problem and explains why meeting these conditions helps establish legitimacy for the decisions. Together these conditions hold decision-makers accountable for the reasonableness of their decisions, an approach toward priority setting that has been endorsed by the Fourth International Conference on Priority Setting, held in Oslo, Norway, September 2002. Section 5 provides practical illustrations of what this approach might look like at different levels of decision-making regarding the implementation of “3 by 5.” Section 6 reminds the reader that training and research are needed if we are to be able to develop and improve fair process over time and demonstrate its advantages.

2.0 Fairness matters, but why fair process?

2.1 Principles and Process

Selecting people fairly, I shall argue, requires a fair, deliberative process at various levels of decision-making in society. Later (in Sections 4 and 5) I shall describe key conditions or features that must be present if the process is to be fair to all and accepted as such. I shall also illustrate with some examples what that process might look like at different levels of decision-making.

Before getting to these central goals of this paper, I want to explain why I emphasize the need for fair process rather than simply arguing for principles of distribution that we can all accept as determining what counts as fair. My point is not that we can dispense with such principles; we cannot. Rather, we accept the relevance of various distributive principles that sometimes conflict. Further, we often do not agree on the weight they should be given in specific cases. Because we do not have consensus on how these principles should be weighted and applied — because they are morally contentious — we need a fair process to resolve our disagreements and arrive at outcomes people can accept as fair.

The area of moral disagreement in which fair process must be applied falls in between some points of solid international consensus on what is morally required or morally prohibited. Human rights thus prohibit discrimination in access to ARTs and other treatments and assure everyone of a right to health. But the space in between these points of agreement is an area of moral controversy that requires fair deliberative process. As I noted earlier, this deliberative space is recognized by human rights advocates, for it is subject to procedures of negotiation under the notion of “progressive realizability, and it is recognized by those familiar with the fact that principles of justice sometimes conflict and a there may be no clear consensus on how to resolve reasonable disagreements about the weight or scope given them.

To better understand the need for fair process in resolving moral controversy, start with a simple case. Suppose we have a vaccine to treat a new and threatening strain of influenza, but we only have enough of the vaccine to treat a third of the population. Suppose as well that we all agree that those people at greatest risk of death from influenza should be given priority in receiving the vaccine. (Of course, some may insist that fairness requires we give people at lower risk of death at least some chance at access to vaccines, perhaps proportional to their risk; I leave this complication aside for the sake of simplifying the illustration.) We think of this as a special case of the widely accepted principle of distribution—or principle of equity—that says we should give priority to meeting greater health needs over lesser ones. Finally, suppose that children under age five and people over age sixty-five are the subgroups at greatest risk and that they include about one-third of the population. Then our principle of fair distribution implies we should give priority to children and the elderly in flu vaccine distribution.

Notice that in this simple case, an appeal to fair process seems irrelevant or worse. For example, I earlier alluded to an unrigged lottery as an example of a fair process, at least for distributing rewards to winners in a legal form of gambling. That specific fair process, random selection, would work against satisfying the principle of equity that we all agree should apply in flu vaccine distribution. More generally, in cases where there is a consensus on the relevant principles of distribution and agreement on just how they apply to the case, fair process seems unnecessary, and possibly even a confounding factor. The simple case of flu vaccines suggests that if all can agree what the fair outcome is, then we are worse off invoking a fair process, whether it is random selection or a committee vote, to select recipients.

2.2. Procedural Justice

2.2.1 Imperfect and Perfect Procedural Justice: prior principle of fairness accepted

This simple case should not mislead us about less simple cases. Sometimes we need a fair procedure even when we can agree on a principle for fair distribution. For example, we all can agree that all and only those who committed certain crimes should be convicted of them. Unfortunately, we need a fair process to determine whether the evidence is adequate to show that someone indicted for a crime actually is guilty of it. That fair process is a trial, which has rules of evidence and procedure intended to lead us to as reliable a conclusion as possible. Since well-conducted trials sometimes lead to the conviction of innocent people, and since guilty people sometimes are not found guilty, we should consider criminal trials a form of imperfect procedural justice (Rawls 1971).

Sometimes we have prior acceptance of a principle of fair distribution and we can construct a foolproof procedure for arriving at the distribution it specifies. If we have a birthday cake that (we agree) should be cut into equal pieces to achieve a fair distribution to celebrants, then we may rely on asking the birthday child to cut the cake and take the last piece. The child has a strong incentive to cut the cake carefully into equal pieces. When we have such a reliable procedure, we can refer to it as perfect procedural justice.

2.2.2 Pure Procedural Justice: no prior principle of fairness accepted

Unfortunately, our “3 by 5” problem of selection is different from both of these examples. In them there is prior agreement on the principle that determines a fair outcome, and the procedure is a way of approximating or achieving that outcome. In “3 by 5,” in contrast, we are likely to encounter significant disagreement about the priority to be given various principles of distribution that people think are relevant. Where we lack consensus on principles of distribution, fair process is necessary to resolve disagreements in a way that all stakeholders can accept as fair. (We may, however, have some

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agreement on constraints, such as human rights constraints, that rule out certain distributions because they are in general unjust, even if we do not have agreement on principles that determine what counts as fair; see 2.3) In such cases, the outcome of fair process defines what counts as fair, since we lack prior agreement on principles that can serve that function. We can think of these cases as examples of pure procedural justice.

What is particularly troublesome about the “3 by 5” case is that there are various principles of distribution – ethical principles – that are relevant, yet reasonable people will disagree about which ones should be given greater weight or priority when the conflict. For example, some people might insist that fairness requires treating each person with HIV/AIDS as having equal worth, or as requiring treatment with equal respect, in the Kantian sense that people are not treated merely as means to an end, or has having claims on others based on their needs alone that must be respected as a matter of fairness. Some of them may then conclude that we can demonstrate equal worth or equal respect or respect for claims of fairness only through a random selection procedure, or, as a practical approximation to that, through “first come/first served” selection practices. (From their perspective, random selection would be an instance of perfect procedural justice, and “first come/first served” an instance of imperfect procedural justice, since there may be some bias in access.) Other people might say, with equal conviction backed by vigorous argument, that priority should be given to some groups of people, such as health workers, since without their ongoing participation, fewer people will be reached with ARTs. Others will support priority for yet other groups for other reasons.

These disagreements are clearly moral disagreements. Some will reject principles advanced by others altogether. Others may see the principles as relevant, but assign different priority to them in cases of conflict. The difficult task we face is to describe a process through which moral disagreements can be resolved in a way that all can accept as fair or legitimate. Some apparently fair procedures, including democratic ones, do not meet this criterion. For example, imagine straightforward majority voting. We accept such votes as a procedure for resolving some kinds of disputes, but majority rule is more acceptable as a way of resolving disputes about preferences than about values. We are unlikely to think “majority rule makes right” any more than we think “might makes right.” Disputes about value require careful deliberation and argument, so the process for resolving them should be appropriately deliberative. (I return to this point in Section 4.3.)

2.3 Human rights as partial constraints

I want to emphasize the importance of a human rights framework for assuring people fair access to treatment, including country level obligations to respect those rights. I noted earlier that a human rights framework does guarantee people freedom from various forms of discrimination. A right to health also means that there must be put in place a health system that provides entitlements to health protection. The goal is to assure “equal opportunity for people to enjoy the highest attainable standard of health,” although this goal is “progressively realizable” in light of the stage of development of different countries.

Nevertheless, these protections, especially in light of progressive realizability, do not provide a specific way to resolve disputes about many of the claims about priorities that arise regarding “3 by 5.” They would clearly count against giving priority to one dominant ethnic group,

(7) Some philosophers insist the fair process defines only what is publicly seen as fair for some policy purposes, but that fairness has to be specified independently of such a process; I ignore this objection here since our task is to specify what we can publicly agree to as fair.


while giving low priority to others. The human rights prohibition on discrimination rules that out. But the argument that some vulnerable populations, consisting of some traditionally excluded groups, should be given priority over other groups is not ruled out nor resolved solely by the appeal to human rights protections. Similarly, even if all should be given equal opportunity to achieve the highest attainable degree of health, that arguably does not preclude giving priority to some groups for special reasons, such as health care workers in contexts where inadequate personnel exist to administer ARTs. Or so some will reasonably argue.

In short, there is a space for deliberation in which reasonable people will disagree about what is ethically required, either from a human rights perspective or from other ethical conceptions. Fair process is required to resolve those disputes in ways that have moral authority or legitimacy.

2.4 Pluralism is not skepticism

I also want to avoid one possible misinterpretation of what I have said. I am not a skeptic who is saying that there is no principled, “right” answer to how we should allocate ARTs in the “3 by 5.” It is entirely possible that adequate ethical inquiry would, over the long term, produce agreement on such a principled view. I strongly encourage such inquiry, even if its short term results are but one input among several into a fair process.

My claim is more modest and not intended to be skeptical: we have no consensus now or in the foreseeable future on principles of the sort and with the specificity that would lead us to agree on the answer. Since we need answers to a practical problem in real time, we need fair process. In addition, the fact of persistent moral disagreement may well be a result of the complexity of these issues and the fact that under conditions that encourage liberty of thought and expression, people will develop different world views that contain somewhat different moral beliefs.11 For example, some people rest their moral views on claims or authority deriving from religious beliefs. Others do not, but instead hold one of many secular comprehensive moral views of the world. The problem of pluralism arises both within and across countries, and that compels us to find a fair process that allows us to cooperate in ways we can accept as legitimate and fair despite our other disagreements, including disagreements about values.

2.5 Summary

I have argued that we do not have consensus on principles of distribution that can address the ethical problem of patient selection at the heart of “3 by 5” program, despite our agreement on some points clearly specified by appeals to human rights. That lack of consensus compels us to seek an account of fair process for resolving moral disputes about patient selection. We need an account of appropriate procedural justice for this kind of problem, a task postponed until Section 4. In Section 3, in order to strengthen the argument in favor of the need for an account of fair process, we shall examine in more detail some of the claims that are already in the literature about selecting recipients in the “3 by 5” effort. (I undertake no comprehensive review here, especially of the complex philosophical literature).12 We can then return to the task of describing what features might make a process fair and its outcome be acceptable as a way of resolving the disputes that will arise.

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(11) Rawls argues that under conditions of liberty, the complexity of judgments about meaning and value in life (“the burdens of judgment”) will inevitably lead to “reasonable pluralism” in comprehensive view of the world. See John Rawls, Political Liberalism. New York: Columbia University Press, 1993.

(12) For an outline of a more complete range of issues, see Macklin, 2003, op. cit.)
3.0 Priorities in “3 by 5”: Competing principles and considerations

In this section, I shall limit my focus to three issues where controversy is present, but I ignore other controversies that are equally important. For example, because of time and space limitations, I will say little here about the centrally important issue of cost-recovery for ARTs, including the sale of anti-retroviral drugs at cost. There is considerable evidence that even very low prices for anti-retroviral drugs and treatments will act as a major deterrent to very poor families. There is also evidence that exemption programs for the poor often do not work as planned and provide some occasion for corruption, as does that sale of treatments itself. So there are strong equity considerations that weigh against cost-recovery. At the same time, proponents of cost-recovery argue that it permits resources to be stretched further, with more people saved, and that it improves sustainability.

Some also argue that fairness or equity requires some systems to recover costs, since those systems already charge user-fees for other medical services. It would be unfair to exempt people with HIV/AIDS from the obligations imposed on other kinds of patients who also have serious illnesses. Other people might reply to this argument that no one with serious illness should face user-fees that stand as a barrier to access, and that a system is more fair if fewer people face that problem. On this view, insisting on consistency may be politically useful but does not increase fairness.

Obviously, how these maximization and fairness arguments are weighed by different people will be a matter of controversy. It clearly is a moral disagreement that requires careful deliberation. By leaving this issue aside, I do not mean to deny its importance: it is one of the most important issues in the whole debate about patient selection. Like the issues I discuss in more detail shortly, it calls for fair process.

I focus, then, on three other issues that have had some discussion in the literature on equity and selection, in part because some of them may involve less familiar issues than the more prominent question about cost-recovery.

3.1 Medical Eligibility Criteria

WHO recommendations for medical eligibility suggest that patients with CD4 counts below 200 receive treatment, or, if testing is not possible, that those with clinically diagnosed AIDS receive treatment. This guideline leaves it to national programs to decide whether to treat patients earlier in their illness, for example, with CD4 counts below 350. In resource rich countries, some practitioners urge such earlier treatment, though there is some controversy about the degree of benefit that results. In making its recommendation for resource poor countries, the WHO guideline sets eligibility at the lower CD4 level with the claim that benefits at that level are well demonstrated and it will permit resources to go further.

3.1.1 Technical and Value Mix

It should be clear that this recommendation about medical eligibility thus incorporates both technical or medical judgments about benefit and value judgments about when resource limits must be weighed against patient benefits. By leaving it to the discretion of countries to treat somewhat healthier patients who may benefit, but are not as urgently ill, WHO draws a conservative line that gives considerable weight to urgency. In this way, the eligibility criteria embody a rationing principle (presumably about priority to urgency of need or to producing best outcomes) that is itself a matter of some moral controversy. Some patients who then do not qualify, on the official WHO criteria, might argue that they would do better if given access to the drugs before they meet the existing criteria than they will once they actually meet the criteria. They might argue, and some providers in richer countries would agree, that they are denied the potentially greater benefit in order to give a lesser benefit to others who are more urgently ill.

(13) It is an issue that arises at the international and national levels and is thus subject to similar recommendations to those made in 5.1 and 5.2 below.
It is an important feature of treatment protocols that there be in place some way to assure patient compliance with drug regimens. This may involve community based workers, but there has also in some places been a discussion of the importance of family supports for drug recipients. This proposal of family supports, and some other proposals about psycho-social measures of patient readiness to comply, such as regularity of clinic visits, should not be confused with purely medical requirements. They reflect a value judgment that needs to be made explicit. The requirement would mean that some who simply lack family, perhaps because of prior AIDS deaths or perhaps because of other choices or misfortunes, will be denied any benefit at all, as Macklin notes. It is worth noting that in the early days of the development of renal dialysis, when machines were a scarce resource, an “ethics” committee in Seattle, Washington, USA became infamous for making judgments about patient selection that pointed to matters both of patient desert (church attendance) and patient contribution (family dependents and supports). Entertaining these considerations brought considerable discredit to this approach for establishing criteria based on some community values.

A second argument in favor of the requirement, pointing beyond better outcomes for patients with supports, rests on the risk that non-compliance with ART regimens can produce the public health threat of new drug-resistant HIV strains. Here there is relatively little direct empirical evidence of the risks imposed, but the view that there is a significant public health risk carries considerable force with many. The issue here is not producing best outcomes but avoiding worst case scenarios.

3.1.2 Two types of ethical theory

Within ethics, there is an important distinction between consequentialist and non-consequentialist theories. Consequentialists in general define what counts as right in terms that depend entirely on some view of what counts as good; in general what is right is a function of what maximizes goodness or net benefit from an action or policy. Utilitarianism is a specific form of such a maximizing approach. Non-consequentialists do not ignore the consequences of what we do, but they believe that right action involves restrictions on action that do not derive from simple calculations of net benefit. These different ethical theories underlie disagreements about health policy just as they do other matters.

There is some tendency in health contexts, for example, to assume that the right thing to do is to produce the greatest net health benefit (assuming we have some way of measuring it). In some cases, the measurement might seem simple: how many lives will be saved or extended to beyond some threshold amount. This tendency reflects a strong influence of consequentialism in public health and medicine. But non-consequentialists will argue that people may have claims on others for fair treatment, for example for treatment in a way that does not simply treat them as a means to the maximizing ends of others. This very general divide in ethical perspectives, that is between principles calling for the maximization of benefits and principles appealing to fairness or equity in different ways, is a source of persistent disagreement about many issues and gives rise to disagreement in our case at hand, the medical eligibility criteria.

3.1.3 Controversy about eligibility

Though the rationales for the more restrictive eligibility requirements are powerful they are not decisive. An argument against the more exclusive requirements comes from those patients

(14) Macklin 2003, Ethics and Equity.

who would derive some benefit from being included but are denied any chance at all at a benefit simply because they may be less likely to get full benefit or they may increase the risks to others. They might argue they deserve some chance—at benefit even if they do not belong to the group with the best expected payoff from treatment. Their complaint raises the ethical problem that is referred to in the philosophical literature as the “fair chances/best outcomes” problem. Similarly, unless there were no alternative to family support as a way of reducing risks of non-compliance, those excluded because they pose a risk to others could complain they are being labeled unfairly and penalized with a death sentence without direct evidence that treating them will produce the harm of resistant strains.

3.1.4 Need for fair process

My point in articulating the ethical controversy that surrounds medical selection criteria is not to insist that the existing criteria are unacceptable or unwarranted. Rather, it is to point out that they are not just technical. The controversy surrounding them deserves to be addressed by a fair deliberative process at the very high level of program development within WHO. That process should not just include technical experts, though it should also include them.

If the WHO process is itself one that can be seen as fair and appropriately deliberative about the ethical issues, then the eligibility criteria may later be defended in case they encounter opposition on ethical grounds at other levels of implementation in “3 by 5.” The same point applies to national implementation of those criteria and additions to them. For example, a community that had lost many people to AIDS and therefore could not provide family supports in many instances might object that continued exclusion from eligibility of victims of the AIDS epidemic was unjustifiable and they should not be further harmed in this way. That kind of objection has great force and may have to be entertained as grounds for reconsidering the exceptions that may be made to the general eligibility requirements.

This kind of objection might well mean that WHO must view the eligibility criteria it proposes as based on decisions that are revisable in light of new evidence and arguments, and its deliberative process should allow for that. Or it may be the case that the deliberation about this exception should take place at the country level or local level, and discretion about exceptions granted to the local decision-makers.

3.2 Siting of Treatment Facilities

3.2.1 Efficiency vs. Equity issues in siting

The location of ART treatment facilities, as well as the degree to which they are integrated into existing health systems, will have a great impact on who has good access to care. To reach rural populations, which traditionally have the worst access to care, rural sites will have to be developed. The same point can be made for vulnerable groups, such as ethnic minorities, who often have had worse access to care within the health system.

Health planners developing programs for scaling up ART, however, argue that locating initial ART sites in urban, tertiary care facilities, often a university hospital, where diagnostic equipment and better trained personnel already exist, is a more efficient way to reach large numbers of patients quickly. Moreover, as training permits and scaling up becomes possible, other sites at the provincial, district, and even peripheral levels can then be added. Thus, in Zambia, a phase 1 effort located sites in Lusaka and Ndola, but in the current phase 2, there are sites in all 9 provinces, with plans to extend these to district level treatment centers as scaling up proceeds.

If planners develop siting plans for scaling-up ART that follow this argument from efficiency, a path of least political resistance as well, then “3 by 5” efforts will replicate the existing inequities of facilities and personnel and resource allocation in those health systems, at least for

the time frame of the “3 by 5” and possibly for the foreseeable future beyond. The argument from efficiency that is invoked to justify this approach – more patients treatable within a short timeframe using fewer new resources—entrenches existing inequities in the system. It clearly risks leaving more rural areas and special groups with traditional vulnerabilities underserved in these programs, perhaps to be catered to in the distant future, if at all.

3.2.2 Taking equity seriously in siting

In a stirring argument for a different approach, David McCoy argues that an emphasis on distributional equity should carry the day in the siting debate, which takes place at national as well as provincial levels in each country. The opportunity presented by the flow of new resources from the Global Fund and elsewhere should be seized upon as a way of moving the health systems as a whole toward a sustainable, equitable distribution of care. Instead of focusing on the most resource-rich sites and areas, a special effort should be made to make the “3 by 5” and other programs reach out to rural and other underserved populations from the beginning, putting the resources necessary into training and infrastructure that can later mean better health for traditionally underserved populations.

3.2.3 Fair process again

Obviously, just how much balance should be reached between efficiency considerations (in the short run) and equity considerations is a matter for deliberation at the country and sub-national levels. This too is not just a technical issue, but a value-laden question. It involves tradeoffs between long and short term results, and between underserved and better served populations. There simply is no set of principles that tells us just what the proper balance point is in general or even in specific situations. Rather, the weight given to different considerations may vary from country to country and even from province to province. Ignoring either equity or efficiency considerations would probably prove an unacceptable extreme, but just where to find a balance is a matter for deliberation in a fair process that gives legitimacy to the result.

3.3 Priority to Special Groups

Macklin identifies a sizeable list of special groups that have been candidates for special priority, but in the discussion here I shall concentrate solely on granting special priority to health workers. I do so not because that group is more important to consider than others, or because the issues surrounding giving it priority are intrinsically more interesting or perplexing, but because the discussion well illustrates my central point. Reasonable people will disagree about whether to give priority to health workers and about when to do so, if at all, and the kinds of disagreement go to deep issues in moral theory that are unlikely to be resolved in the time allowed for action in “3 by 5.” That is, the case well illustrates the need for an account of fair process.

3.3.1 Why granting priority to health workers seems obviously acceptable to many

The argument in favor of granting priority to health workers is that an adequate number of such workers is essential to the sustainable delivery of ARTs to the target population. If the supply of such workers is low, or if it is threatened by the epidemic itself, as well as by international market forces draining trained personnel from developing countries with high HIV incidence, then granting priority for ART treatment to health workers may provide some measure of protection against increasing scarcity of needed health workers.

The pro-priority argument can be put in the form of a choice between two options. Suppose both options have the same resources initially available in terms of personnel and drugs. In the Priority Option, we grant priority to health workers who meet the medical eligibility requirements. In the No Priority Option, we take people on a first come, first served basis, pre-

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sumably barring favoritis m by health workers for other health workers. If granting priority means that the numbers of health workers are preserved better over time, then we may suppose that greater numbers of people will be saved by ARTs in this option over a period of time. Note that in the short run, the numbers of people treated and saved will be the same: favoring health workers does not itself mean saving more lives initially, only over time.\(^{19}\)

Of course, this claim rests on empirical assumptions. One such assumption is that the numbers of health workers could not have been adequately protected by other measures (e.g., through increased training). Similarly, it is assumed that any new funds made available for increased training would make the numbers of personnel available greater in the Priority Case than the No Priority case. Both assumptions are relevant if the numbers of health personnel is a direct determinant of numbers of patients treated. In a case where there was an adequate supply of personnel, or where the numbers of personnel were not a limiting factor on numbers of treatment possible, then the empirical assumptions in favor of the Priority case are not met and the argument for it is not sound. For example, in developed countries that are rich in personnel, arguments for giving priority to health workers would fail to satisfy the empirical assumptions their premises depend on.

### 3.3.2 Objections to the Priority Option

One argument against giving any priority to groups, like health workers (or teachers), who arguably provide an essential social service, including the additional saving of lives, is that doing so is unfair. There are several ways to argue for its unfairness. Suppose we think, as John Broome argues, that fairness involves claims people have on others, say as a result of some facts about them such as their degree of medical need.\(^{20}\) We may have other reasons for treating people differently — say health workers as compared to other people with AIDS — because of the additional effects of treating the health workers first, but doing so does ignore the claims the other people have by virtue of their need. It remains unfair to them that they be so treated and their claims ignored.

Another way to argue for the unfairness of granting priority to health workers is to claim it means we are not treating people with equal respect, or as being of equal moral worth.\(^{21}\) One way to give content to the idea of equal respect is the Kantian view that we should not treat people merely as a means to the ends of others but as ends in themselves. By not giving equal priority to non-health workers, we are treating them as a means to our social end of saving more lives.

Similarly, by looking to the indirect effects of treating the doctors first, we risk abandoning the view that people are of equal worth or should not be treated merely as means. If they are of equal worth, and that is the basis for equal treatment, then some people should not be judged of greater worth simply because they have some trait, such as training, that allows them to make an additional social contribution. Notice that in all of these arguments from fairness, whether from claims, from not treating people as means, or from equal worth, the rightness of what we do is not simply a matter of producing the best aggregate consequences, that is, the most lives saved over time. Here the divide between different moral views is deeply rooted.

Nevertheless, some philosophers and others who

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\(^{19}\) Macklin (2003, op. Cit.) refers to this as a utilitarian consideration, since it maximizes health benefits, but I note that maximizing the effectiveness of such workers might be in the service of an overall goal of reaching underserved parts of the population or of reducing inequalities in access to ARTs, rather than maximizing net health benefits. In this case, equity itself may be undercut by not giving such priority to health workers, at least under some conditions.


\(^{22}\) See Brock, D. 2003, Separate Spheres and Indirect Benefits, op. cit; see Kamm 1993, op cit.
respect non-consequentialist constraints might still favor support for the Priority Option.\(^\text{22}\) For example, Kamm might extend an argument she has given about a hypothetical case\(^\text{23}\) in this way: though we “do not do with our resource [ART drugs] whatever will result in as much good as possible...we [do] try to achieve the best outcome for which our resource was specifically designed.” Since the health worker and the extra patients they will give the drugs to all have equal needs for ARTs with the patients who fail to get priority, the drug is being allocated for the purpose it was designed to serve. Brock too would reach the same conclusion, though this is not the occasion for a full discussion of these philosophical controversies.\(^\text{24}\)

### 3.3.3 Fair process required

I rest my argument for fair process on a modest claim, not requiring the resolution of the philosophical controversies, nor insisting that they are insoluble. My claim is that reasonable people will disagree about acceptable policy in the Priority Case. More specifically, different people will give different weight to the empirical considerations, especially since they may give different weight or emphasis in their moral judgments to the principle of equal respect, which prohibits social worth judgments in medical context. Some may feel priority can be given only in the most dire conditions of scarcity, for only then will the social worth aspects of giving priority be framed by a very specific consequence of not granting it; others may be moved even when scarcity is less pressing. Some may also be troubled by the suggestion that health workers are generally better off than many of the patients they treat and so giving them priority may seem to be a matter of socioeconomic privilege, especially if it is health workers who grant the privilege of priority to themselves or even administer it.

Because this is a contentious context in which reasonable people will disagree about when priority is warranted at all, as well as about how much priority, it requires a fair deliberative process. It is not a context in which principles we all agree on give us clear determinations about the right course of action. It is even clear that different groups of people deliberating about this kind of case may arrive at different conclusions, even when the facts of the situation are comparable. For various reasons, perhaps cultural, perhaps experiential, members of some social groups may tend to weight these factors differently. Fair process may then yield somewhat different answers depending on who the deliberators are. In different systems, such variation may itself be objectionable to different degrees.

Fair process is a way to produce agreement, or at least to narrow disagreement, among a group trying to justify decisions to each other. But that may not eliminate all conflicting results of deliberation across decision contexts. Later I return to comment on this important fact about fair process and to consider whether it involves a violation of a formal principle of justice, namely that we treat like cases similarly. I shall argue that it does not violate requirements of formal justice.

In her discussion of ethical principles that might bear on the issue of priorities among patient groups, Macklin notes that some groups may be viewed as more deserving in some way than others, or at least having a special claim of compensation compared to others.\(^\text{25}\) For exam-

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\(^{22}\) Kamm argues that saving a surgeon with a drug, because the surgeon can then use her skills to save others, would be unfair to anyone in need of the drug who is passed over in favor of the surgeon. But saving someone who could run fast to deliver a drug to save a second person in need would be fair because we are using the drug for the purpose for which it was designed. (18) Macklin, 2003, op. Cit.

\(^{24}\) Kamm and Brock both conclude that one does not violate a Kantian injunction against treating people as means in a case like our Priority Case, though for somewhat different reasons. This suggests that at least some non-consequentialists might agree with consequentialists about acceptability of the Priority Case, even if they would disagree about the reasoning underlying their conclusions. Brock’s and Kamm’s reasoning about health workers would not extend to teachers, however, though consequentialists might see the two issues similarly. Nothing emerges in the subtleties of this philosophical debate that challenges my claim that reasonable people will disagree on these cases.

\(^{25}\) Macklin 2003, op. Cit.
ple, people who became infected during vaccine trials might be thought to be special victims of that societal intervention, and though they were not promised any compensation, they are owed one in respect of the effort to contribute to society. Similarly, people who were infected by bad blood, or who are victims of rape, might be thought to be owed some special compensation because they are the victims of social neglect or negligence, or of a failure to provide basic security that is owed to all as a matter of human rights.

These too are important ethical considerations based on diverse appeals to concerns about equity or fairness. Everyone can recognize the relevance of these concerns about special desert or special compensation. Still, how much weight is given to them may depend on other moral views people hold and on the costs involved in giving them priority. My goal here is not to debate these issues but to suggest they require careful deliberation in the proper setting. For a decision-making process about setting priorities to be fair, it must encourage the kind of deliberation that allows these arguments to be considered, for that is the way in which communities tend to air and resolve moral disagreements, or, even if they cannot resolve them, to find a way to cooperate despite residual disagreements.

4.0 What are the central features of fair process?

4.1. An overview of key features, with some comments about their social function

A fair process for setting priorities about the distribution of ARTs has the following central requirements or features.26

- **Publicity Condition:** The process must be transparent and involve publicly available rationales for the priorities that are set;
- **Relevance Condition:** Stakeholders affected by these decisions must agree that the rationales rest on reasons, principles and evidence they view as relevant to making fair decisions about priorities; community and stakeholder participation and voice must vary in an appropriate way with institutional context;
- **Revisability and Appeals Condition:** The process allows for revisiting and revising decisions in light of new evidence and arguments, and allows for an appeals process that protects those who have legitimate reasons for being an exception to policies adopted.
- **Enforcement or Regulation Condition:** There is a mechanism in place that assures the previous three conditions are met.

In the remaining subsections of Section 4, I shall provide some explanation and rationale for each of these key conditions. I emphasize that none of these conditions is novel or surprising. Transparency and publicity are widely recognized features of good governance. Involvement of stakeholders in evaluating the rationales underlying a policy is also widely understood as a way to improve deliberation and assure people affected by decisions that their voice has played a role in it. Revisability is a way to assure due process to those who may be affected by decisions that are bad for them. Enforcement is an assurance condition for all. All of these features of fair process were abstracted from careful study of the context in which limit-setting and priority setting decisions were made in a broad range of health care institutions. Details about how these central features of fair process are realized will depend on the level within a system – national, provincial, local – at which the decision-making occurs, and I shall try to illustrate this in Section 5. First, however, I comment on how they function together to achieve accountability for the reasonableness of priority setting decisions and thus address the issue of legitimacy.

4.1.1 The legitimacy problem

The issue of moral legitimacy can be stated in this way: under what conditions do decision-makers who set priorities that fundamentally affect the well-being of others— in this case deciding who lives and who dies — have moral authority to make those decisions?

The question is best raised from the perspective of people most directly affected by it, that is, people living with AIDS who could benefit from ARTs. They will know that actual limits on resources (whether these limits are themselves ethically justifiable or not by domestic or international standards of justice) mean that not everyone who can medically benefit will receive ARTs. They will also know that they are winners or losers as a result of specific priority setting decisions about eligibility criteria, the siting treatment facilities, or the preference given to certain groups. What can persuade potential recipients that these decisions are reasonable and fair, at least in the sense that they resulted from a fair process?

It will matter to people what the rationales are for the priorities that are set. That demand for transparency is the basic justification for the publicity condition. As a matter of social justice, people should know why decisions that have a fundamental impact on their well-being are made the way they are. Similarly, people will want to know if the rationales are based on reasons that they would agree — as “fair-minded” people — are relevant to the kind of decision at issue. I am supposing that people in general are fair-minded in this sense: they want to be able to mutually justify to each other the terms of cooperation under which they interact. Basing decisions on reasons that people who are interested in such mutual justification can consider relevant is essential to treating them fairly. Finally, even decisions that are justified in light of evidence and arguments at one point may need revision in light of new evidence, including evidence that some people should be viewed as exceptions to the policy for reasons that were not anticipated.

4.1.2 Fair process and accountability for reasonable decisions

Together these conditions make decision-makers accountable to those affected by the decisions, and that accountability goes a long way toward establishing and sustaining moral legitimacy for the decisions. I am supposing that the decision-makers have a form of political and legal legitimacy already: they are part of a legitimate government structure or international structure. But actors in such institutions must still establish moral authority to make ethically sensitive decisions about the well being of people living in those societies, and that moral authority requires a special kind of accountability. People must be able to see that the decision-makers focused on relevant reasons, were willing to hear new or better arguments, and were willing to be public about their grounds for decisions so that the broader moral community could engage in the deliberation. Together the conditions establish what may be called accountability for the reasonableness of priorities or limits.

4.1.3 Effects of fair process

There are three general effects of implementing this fair process that deserve special comment. First, the account of fair process described here is not intended to apply only to the “3 by 5” problem of priority setting but to priority setting in health care (and perhaps other) institutions more generally. In many of the countries where “3 by 5” will be implemented, the goal of providing access to ARTs is intended to improve the capability of health systems to meet population needs more generally. Incorporating fair process for ARTs should be a step toward making that process part of the accountability needed in the health system more generally.

A second effect of implementing this form of accountability for reasonable priority setting is that it facilitates social learning about how to make decisions under conditions of relative scarcity. By publicly airing rationales and having to defend them against criticism, decision-makers and the clinicians and patients and broader public become more adept at deliberating
about relevant reasons and holding others to more thoughtful forms of deliberation. In this way, fair process contributes to social learning.

A third effect builds on the previous two: fair process of the sort described contributes to broader societal capacity to engage in democratic deliberation. When component institutions function in a way that makes them publicly accountable for the reasonableness of their resource allocation decisions, it becomes easier for broader social policies to be held to the same standard. Civic society becomes empowered to act in ways that demand that kind of accountability from government more generally, and the public itself becomes more able to make judgments based on what it has learned about relevant reasons.

I turn now to a more detailed discussion of the four conditions I have said are essential to fair process.

4.2 The Publicity Condition

In many countries, regardless of the form of organization and financing of their health system, resource allocation and priority setting decisions are often made out of sight, perhaps hidden behind budget decisions. This lack of transparency is true in the United States, where the grounds for many priority setting and resource allocation decisions made in both the public and private sectors are not public.27 It is also true for many specific decisions in publicly administered systems where there is universal coverage and where there may have been some public avowal of principles to govern resource allocation, as in Norway, Denmark, the Netherlands, Sweden, but also in Canada, the United Kingdom, and Germany.28 And, it is also true in many developing country systems. The goal of securing adequate publicity or transparency is thus an ambitious one, but not an infeasible one.

When decision-makers are public about the grounds of their resource allocation decisions, three important consequences follow. First, the rationales provided articulate a set of commitments, including ethical commitments, that can be subject to greater public scrutiny and discussion. In this way, publicity helps to empower the larger public to take democratic control over decisions that affect it in fundamental ways. This first effect has intrinsic value: people value knowing why decisions that fundamentally affect their well-being were made the way they were.

Second, the decision-makers are held to standards of argument and evidence that they are expected to adhere to in other decisions. A form of “case law” emerges that shapes the public debate about these issues and commits decision-makers to consistency over time. It is a way of providing public scrutiny of both horizontal and vertical issues about equity: are like cases treated similarly, and unlike ones treated in relevantly different ways.

The case law or precedents that emerge are not fully binding, since they can be revised in light of better arguments and evidence. This effect is both of intrinsic value, since justice requires some version of such consistency, and of instrumental value, since decision-makers are likely to find the guidance of previous decisions helpful to them. The first two effects combine to produce a third effect, largely of instrumental value: the quality of decision-making should improve if it must stand up to the public examination of it for appropriateness and coherence.

In the context of the “3 by 5” program, the publicity condition imposes some specific requirements on both international and national decision-making. For example, where WHO and others international agencies make recommendations about patient selection or eligibility criteria, there should be a publicly provided rationale about all elements of the decision. If the decision is weighted toward assuring that selected patients are most likely to enjoy better outcomes than excluded patients, then the criteria should be accompanied by a rationale for

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that decision. Similarly, siting decisions should articulate the grounds for making them: if initial efficiency is being emphasized, possibly at the expense of equity in access, a rationale should be offered for why the tradeoff is being made in the way that it is. Or if some groups are being given priority, such as health workers, then there should be an explicit rationale for doing that and the degree of scarcity of health workers that justifies that priority must be articulated. It may be the case, for example, that in some urban areas the scarcity of personnel falls below the threshold that would justify such priority, assuming it may sometimes be justifiable to decision-makers.

Attention will have to be paid to just what counts as meeting this publicity condition. Ideally, publicity requires the information be both widely accessible to the public and comprehensible by the public. In practice, only some groups may demand the information, and the actual mechanism for making it public must depend on some facts about local institutions. I return to these elements of the problem in Section 5.

4.3 The Relevance Condition and Stakeholder Participation

4.3.1 Relevance as a restriction on allowable reasons

The Publicity conditions requires that whatever rationales are the basis for priority setting decisions, they be made public and exposed to the scrutiny that involves. The Relevance condition actually involves some restriction on the kinds of rationales that are permitted to serve as a basis for priority and limit setting decisions. The acceptable rationales must be seen by appropriate stakeholders as relevant to meeting needs for ART in a fair way.

Presumably, some discriminatory rationales for priority setting are therefore excluded just by this presumption of relevance. For example, as a matter of human rights, and as a presumption of any plausible view of social justice, traits of individuals or groups that have no bearing on needs — such as membership in some ethnic minority or religious group — should never be permitted as a basis for excluding people from access to ARTs or other medical needs. However, to rectify past wrongs or to meet existing inequitable distributions of needs, it may sometimes be relevant to give some priority to historically excluded or vulnerable groups that are clearly worse off than other groups. Here the relevant reason for granting such priority is to meet the greater needs of those who are worse off, not to exclude or discriminate against those who are better off because of who they are.

In this section, I first return to expand on a remark I made about the reasons for focusing on relevant reasons within a fair, deliberative process rather than relying on simple, familiar democratic procedures, such as voting, to resolve moral disputes. I then turn to the selection of relevant reasons and the role of stakeholders in doing that.

4.3.2 Majority rule and fair process: why deliberation and agreement on relevant reasons?

4.3.2.1 Procedural vs. deliberative democracy

What underlies the remark I made earlier that “majority rule does not make right” any more than “might makes right”? After all, citizens use democratic procedures and majority rule — directly or indirectly — to resolve other policy disputes. Why not the same simple solution to selecting patient groups for ARTs?

Democratic process should be the ultimate authority for settling disputes about limit setting in health care, but we must understand that process in a particular way if it is to have legitimacy as a way of resolving moral disputes about the distribution of health care. The need to select relevant reasons emphasizes the deliberative component of democratic process, not merely a

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(29) Macklin 2003 suggests that the requirements of fair process rule out discrimination and requires inclusiveness. Human rights and social justice constraints achieve the former because of the implications for what count as relevant reasons, as I note above, without singling nondiscrimination out as a distinct condition of fair process. I address aspects of inclusiveness when I talk about stakeholder involvement in achieving agreement on relevant reasons.
procedural appeal to majority rule. What gives majority (or plurality) rule, its legitimacy as a procedure for resolving moral disputes about public policy and the design of institutions? One prominent answer, sometimes referred to as the “aggregative” conception of democracy, holds that the procedure is fair and acquires legitimacy simply because it counts everyone’s interests equally in the voting process: each counts for one, not more or less. Adult persons are presumed to be the best judges of their own interests and can present and advance them in the political process.

Something important seems to be left out of this proceduralist view of the virtues of aggregation through voting. It allows us to compel people to abide by a majority rule, even where there are matters of fundamental moral disagreement, simply by aggregating the preferences of the voters, whatever they happen to be. If we had a large group and the option of buying only one flavor of ice cream, vanilla or chocolate, we might settle the dispute by voting. We might think that aggregating preferences through the mechanism of voting was a way to achieve the greatest net satisfaction of preferences. If most people prefer chocolate, then we get the greatest aggregate satisfaction of preferences by buying chocolate. Everyone’s interests are counted, including those who prefer vanilla, since the frustration of the vanilla lovers is offset by the greater pleasure of the chocolate lovers.

Abiding by a majority decision that compels people to act in ways that counter their fundamental beliefs about what is morally right is not simply like frustrating a taste for vanilla ice cream, however. Even a craving for vanilla is not to be assimilated to a moral conviction. Settling moral disputes simply by aggregating preferences seems to ignore some fundamental differences between the nature of values and commitments to them and tastes or preferences.

The aggregative conception seems insensitive to how we ideally would like to resolve moral disputes, namely through argument and deliberation. We expect people to offer reasons and arguments for their moral views, and we hope that the better arguments will prove persuasive. We want to be shown what is right by appeal to reasons that we consider convincing. If a good moral argument persuades us that our original belief about what is right is incorrect, we may be chagrined, but we are (or should be) grateful as well. We have been spared doing what is (or what we come to believe is) wrong. It is more important to end up knowing what is right and doing it, given our motivation to act in ways that we can justify morally, than it is to get our way.

This observation helps to explain why we are not satisfied in cases of moral disagreement simply to be told, “a majority of people think otherwise.” The problem is not that the majority will simply keep us from getting our way (as it would be if we preferred vanilla), but that majorities can be morally wrong and may make us do the wrong thing. In addition, they may be moved by reasons that minorities cannot even accept as relevant to resolving the dispute.

The aggregative account fails as an account of the legitimacy of a democratic procedure because it ignores the way reasons play a role in our deliberations about what is right. An alter-


(32) Cohen notes that an aggregative view might arguably be extended to give some protection against outcomes that involved discrimination against those who are targets of stereotyping or hostility, e.g., against people with disabilities or racial minorities. A process that allowed simple aggregation of those preferences arguably does not give people equal consideration and so violates its own rationale. Cohen, J. 1996. Deliberative democracy, unpublished ms, p.15.
native account of how a procedure such as majority rule acquires legitimacy depends on emphasizing the deliberative process that may conclude in a vote. Specifically, it imposes some constraints on the kinds of reasons that can play a role in that deliberation. Not just any reasons will do.

Reasons must reflect the fact that all parties to a decision are viewed as seeking terms of fair cooperation that all can accept as reasonable. Where their well-being or fundamental liberties or other matters of fundamental value are involved and at risk, people should not be expected to accept binding terms of cooperation that rest on reasons they cannot view as acceptable types of reasons. For example, reasons that rest on matters of religious faith will not meet this condition. Reasonable people differ in their religious, philosophical, and moral views, and yet we must seek terms of fair cooperation that rest on justifications acceptable to all.

4.3.2.2 Deliberation and not ignoring minority views

Suppose that a deliberation appeals only to reasons that all can recognize as acceptable or relevant kinds of reasons, but that consensus about an outcome is still not achieved. To settle the practical matter, we rely on a majority vote. What can be said in favor of reliance on this voting procedure that could not be said on the purely proceduralist view -- a vote not preceded by a comparable deliberation?

Relying on a majority vote to settle the matter has this advantage over the purely proceduralist (or aggregative) account. The minority is not being compelled to do something for reasons it thinks irrelevant or inappropriate -- even if it does not accept the weight or balance given to various considerations by the majority. On the aggregative view, the minority has to accept that it loses only because more people prefer an alternative, for whatever reasons. On the deliberative democracy view, the minority can at least assure itself that the preference of the majority rests on the kind of reason that even the minority must acknowledge appropriately plays a role in the deliberation. The majority does not exercise brute power of preference, but is constrained by having to seek reasons for its view that are justifiable to all who seek mutually justifiable terms of cooperation.

4.3.2.3 “Fair minded people” further explained

Earlier I referred to people who seek mutually justifiable terms of cooperation as “fair-minded” people. A simple analogy would hold to games. In games, fair-minded people abide by the rules of the game: such rules establish terms of cooperation in the game, and they are rules all sign on to in playing the game. Only “poor sports” -- clearly not fair-minded people -- would break the rules of the game deliberately.

Scaling up ARTs to reach millions of untreated people with AIDS is a game with very high stakes: what are the rules of selection that fair-minded people would accept? What reasons and rationales are relevant to the goal of the game, meeting medical needs fairly when not all can be met. The basic idea behind the search for relevant reasons is that these are reasons fair-minded people can accept, given their shared goal. It is crucial that fair-minded people would accept them as relevant because restrictions on liberty or fundamental limits on well-being must be based on reasons and principles that all can agree to.

(33) In earlier work on fair process (Sabin and Daniels 2002), I emphasized the importance of stakeholder involvement, including community or consumer participation, but held back from saying this was a strict requirement of fair process because I wanted to describe a process that was achievable even in a fully private provider, such as a for-profit U.S. managed care organization. Such stakeholder involvement could improve deliberation and enhance accountability, were it introduced, but there seemed no way institutionally to mandate it in that for-profit climate. Because we did not want to rule out legitimacy at all in that sector, we did not make stakeholder participation an explicit requirement of fair process. In contrast, in the context of programs to scale up ARTs, however, cooperation between private and public sector providers, including NGOs, is necessary, and in that setting, stakeholder voice and participation and empowerment are arguably strict requirements of fair process. Exactly what form this involvement takes -- for example, how democratic selection must be of participants -- depends on institutional structures.
4.3.3 Selecting relevant reasons:

How can relevant reasons be selected? What is the role of stakeholders in the decision in making that selection?33

4.3.3.1 Many candidates for relevance

If we think about the controversies reviewed in Section B, we find many plausible candidates for relevant reasons or principles, and we saw how important conflicts might arise among them. With reference to the siting problem, for example, reasons that focused on equity of access were in conflict with reasons that emphasized efficiency, especially in the early phases of scaling up. Similarly, in selecting the medical eligibility criterion, concerns about producing best outcomes with scarce resources were in conflict with concerns about giving all people with AIDS some fair chance at a benefit. In the debate about giving priority to some groups, such as health workers, or insisting that all patients with AIDS be given similar access, reasons focused on the maximizing sustainable delivery to target populations were in conflict with principles calling for equal respect or equal treatment. In debates about selecting other special groups for priorities, such as patients who participated in vaccine or clinical trials, reasons that focused on compensation for harms done or that emphasized desert were in conflict with concerns about equal treatment for all.

My contention is that all sides of these debates invoked reasons and principle that have a strong claim to being relevant to making fair decisions. Reasonable people will disagree about how to resolve those conflicts, but all will recognize that there is some force to arguments that invoke them, even if they may think the force is less than for their preferred principle or reason. Another debate that involves conflicting but relevant reasons concerns the sale of the drugs involved in ARTs. Some will argue that sustainability requires cost recovery, and that even partial cost recovery will mean more patients can be reached. This view is clearly in conflict with equity considerations, for even low fees for drugs will put them out of reach for some people unless those unable to pay at all are exempted. Administering exemption policies, however, proves to be difficult.

All of these reasons are clearly different from reasons that focused on “irrelevant” features of patients, such as their religion or ethnicity or gender, as a basis for exclusion or insisting on lower priority. If religion or ethnicity or gender had been the basis for past or ongoing unjust social policies, some additional priority might justifiably be given to members of those groups as a way of meeting the needs of those who are worse off. For example, in a situation where women have much worse access to health services and men are favored, giving priority to reaching women with ARTs would be a defensible view resting on a relevant reason, the fact that their equivalent or sometimes greater needs would otherwise be neglected.

4.3.3.2 Stakeholder role in vetting relevant reasons

But what kind of evidence can we have that reasons are generally accepted as relevant? Perhaps some people would challenge my view about relevance in the previous two paragraphs. One crucial piece of evidence is that the reasons have been judged relevant by the range of stakeholders who are affected by a decision. Do such stakeholders believe that these or other reasons are indeed relevant? Do they defend their claims with arguments or evidence? If they do, then that is some reason to think we are indeed grappling with relevant reasons, though ones different people may consider of different levels of importance.

This point about evidence needs qualification. Suppose, for example, in some contexts, some people would openly argue that women should be given lower priority than men, and suppose further that this view is taken seriously by vari-
ous stakeholders. Human rights considerations would clearly weigh against this view, as would arguments from social justice more generally. The fact that a local group takes a factor that is “irrelevant” for allocation according to international standards (gender, ethnicity, race, religion) should not then count as strong or conclusive evidence in favor of it counting as a relevant reason. Nevertheless, some weight should be given to the fact that stakeholders view the consideration as relevant and take arguments about it seriously.

4.3.3.3 Who are the appropriate stakeholders?

Who are the stakeholders who should be considered? In the case of scaling up ARTs, the obvious stakeholders include health providers, health planners, people with HIV or AIDS, and people at risk of infection from HIV, such as sexual partners of people with HIV. But others are also stakeholders: family members on whom falls the burden of raising orphaned children, or of caring for ill relatives. In many high incidence countries, this group at risk of infection or of having to shoulder the social and economic burden of the illness or relatives includes the whole public.34

Can such a broad range of stakeholders play a role in vetting reasons for their relevance? Just how such broader participation or input into decision-making can be arranged depends on institutional arrangements. I take up some of these issues with illustrations in Section 5, but in the remainder of this subsection, I address the issue in more general terms.

4.3.3.4 Level of decision-making and relevant stakeholders

We need to divide the problem into different decision-making levels and contexts. Let us start at the periphery of many health systems, where clinics at the village or health area (defined by population) level operate, and then work our way up. In some countries facing significant AIDS epidemics, for example, Cameroon, health units are each partly governed or advised by representative community groups called “Dialogue Structures.” Analogous governance arrangements exist, at least in theory if not always in practice, in other countries, an effect of earlier health sector reforms emphasizing community involvement in primary health care.

Where such community structures exist and have an official role in health unit governance, there is an existing, natural way to involve representative stakeholders in vetting the rationales that play a role in selection. For example, suppose at a higher level in the system there was a decision that health workers could be given some priority provided the level of personnel shortage reached some critical dimension. Then it might be a task of the dialogue structure or its equivalent to deliberate about the reasonableness of granting priority of that sort under the local conditions. It is possible that variations in scarcity of personnel would lead different local health units to want to modify or apply recommendations about priorities differently, and it is arguably reasonable to allow them to do so.

4.3.3.5 Conflicts between levels

The problem for a local level decision arises if decisions made at higher levels in the system preclude certain options that seem locally reasonable. For example, a siting decision made more centrally that gave poor access to people in certain regions and that seemed to favor other areas at their expense would seem unfair to local units with less access. We would need to distinguish two kinds of cases of this sort. Suppose a siting decision is made more centrally. In one case, deliberators about that decision had to make a trade-off between reduced access for some districts in order to deliver significantly greater access to others, and, although there were winners and losers, the terms of the trade-off seemed acceptable to a broad, representative group of stakeholders. Call this the Pure Trade-off Case. In the other case, a trade-off was also made, but it was apparent to all that political favoritism was the basis for the actual

(34) See Dhalwal et al, August 2003 (draft), A Public Health Approach for Scaling up ARV Treatment: A Toolkit for Program Managers, pp. 28-34.
siting decisions. Call this the Political Favoritism Case. In both cases, some groups are losers and some winners.

In the Pure Trade-off Case, losers are disadvantaged, but if, by assumption, some groups had to be disadvantaged in order to benefit many more people, and there was no basis for the distribution of advantage other than considerations all thought relevant to it, then losers cannot complain of being treated unfairly, even though they remain clearly worse off than others and could have been better off than an alternative set of losers if some other siting pattern had been chosen. (They are, however, no worse off than anyone need be under the conditions.) Pleading unfairness here does seem simply self-serving, since someone or other would have to be worse off than others given the assumptions of the case.

In the Political Favoritism Case, the situation is clearly different. Although there may have been a condition that required a trade-off, the actual siting decisions were not made on the basis of that trade but on grounds not defensible as relevant to achieving the gains the trade-off permits as acceptable. The specific decisions are made on irrelevant grounds and will clearly be seen by losers to be unfair. It is not the mere fact of there being winners and losers that is unfair, but the actual details of what determines the grounds for distribution. Political support is not a relevant reason for the distribution of medical services, let alone life-saving ones.

The example has implications for the kind of stakeholder involvement that ought to play a role at the higher levels of decision-making. It is not easy to set up structures that have the legitimacy of local community governance units. Hand-picked representatives could turn out to be favorites of those doing the selecting and could open the door to problems like that posed by the Political Favoritism example. Where civic society lacks robust, independent community organizations and groups who can play a role of supplying participants, there is clearly a problem facing the plausible selection of stakeholders in deliberations about relevant reasons.

This difficulty is present for public institutions and for private ones that work together with public institutions in scaling up ARTs. In the United States, where many of the decentralized decision-makers about health care resource allocation are private, including for-profit institutions, it is legally and politically difficult to imagine compelling proper stakeholder involvement, such as “consumer voice” in decisions. But similar problems face some NGOs who establish private hospitals that will serve as plausible sites for ARTs in some countries. In many cases, these NGOs have good community relations and establish roles for input from community groups. It is not impossible, only difficult, to establish some expectation that such stakeholder involvement in priority setting be part of the framework for any scale-up activities that get external donor support. In effect, this is a regulatory issue that must be dealt with at the international and national levels if fair process is to become part of the priority setting process at all levels of the “3 by 5” program.

4.3.3.6 Stakeholders and legitimacy

Stakeholder “voice” in accepting reasons as relevant is widely perceived as adding legitimacy to decision-making processes. The exact theoretical framework for that fact is not as clear as it might be, given its wide endorsement. In many contexts, stakeholders are not democratically elected representatives (as they might be in some local dialogue or community governance structures). So their involvement cannot simply be called a form of representative democracy in general. Similarly, those who do play this role are not “proxy consenters” in any legal or formal way: they do not have a defined fiduciary relationship to the people on behalf of whom they may appear to give proxy consent. Despite these theoretical limits, many see them as adding legitimacy.

Some of that enhanced legitimacy may come from instrumental contributions they make to
meeting the conditions on fair process I have been describing. They make decisions more transparent and public, since their participation is a way of opening up the process and giving it more vehicles for communication to others. They improve deliberation about relevant reasons, potentially adding to the range of considerations and the perspectives from which they are evaluated. By being involved, they take some ownership of the results, and through their potential roles as public critics or advocates, they can help explain and defend decisions they have come to take ownership for.

### 4.3.3.7 Making the best of imperfection

Stakeholder inclusion is an imperfect process, fraught with risks of cooptation and even corruption. But it may be the best we can do to broaden deliberation to include a full range of values and perspectives from those affected by decisions, whether they implement them, as providers do, or are beneficiaries of them, as patients are. The practical task is to try to make their inclusion work at different institutional levels, even where there are strong traditions of exclusion of the public from scrutiny of what goes on.

Since the scaling up of ARTs has been coupled with assurances that the new resources will be used to reinforce capabilities of national health systems to meet population needs and will not become a competing silo that drains away strength from health systems, it is important to see the introduction of fair process in resource allocation decisions as part of ongoing health sector improvement. Practices developed for stakeholder involvement should be ones that can also transfer to health systems as a whole and strengthen their transparency, accountability, and legitimacy – as well as the commitment to pursuing equity in distribution.

In Section 6, I return to the issue of how we can learn more about making imperfect processes, including those involving stakeholder participation, work better.

### 4.4 Provision for revisability and due process

How may a selection priority for ARTs be challenged by those affected by it? More generally, how can a faulty policy be improved?

#### 4.4.1 Revisability, quality improvement, and appeals procedures

The concern expressed in this condition on fair process is aimed at producing better decisions — a form of quality improvement — including ones that give patients some recourse to correct unfair practices, a needed form of "due process" protection for individuals. Institutional provisions for appeals from decisions, including coverage decisions in public or private insurance schemes, are well developed in some countries. In the United States, in response to consumer backlash in the 1990s against managed care organizations, 42 states have mandated independent review procedures for insurance coverage denials. In Michigan, for example, blinded cases are even published on a webpage, giving the grounds for appeals and rulings on them a very public face. These mechanisms are not well connected, however, to quality improvement procedures within insurance plans.

In many systems, however, there is little provision for appeals at all. More generally, there is little institutional provision for a process of revisiting prior decisions in light of new evidence and arguments, including those raised by appeals, so that better decisions can emerge. Fair process requires this provision for reconsideration. Provisions to meet this condition should be part of implementation of fair process, and what is accomplished with regard to decisions about ARTs can then be transferred to more general use in health system.

#### 4.4.2 Internal and external functions of appeals procedures

Dispute resolution procedures in health play two distinctive roles. Internally, within the health plan

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(36) See the Guiding Principles for Scaling Up in Dhaliwal, op.cit 4-9.

or agency, these procedures give members and clinicians an opportunity to voice their perspectives. The procedures create the potential for altered and improved decisions. Externally, these procedures contribute to a wider societal learning curve about the need for limits and the ways in which limits can be set fairly.

Internally, the Revision and Appeals Condition closes the loop between decision-makers and those who are affected by their policies. Done well it engages a broader segment of stakeholders in the process of deliberation. Through these mechanisms parties that may not have participated in the original decision-making process and whose views may not have been clearly heard or understood find a voice, even if after the original fact.

Because the reasons involved in the original decision are publicly accessible (the Publicity Condition), and because decisions are constrained to focus in a reasonable way on meeting the health needs of the insured population under resource constraints (the Relevance Condition), people using the Revision and Appeals Condition to challenge a decision are able to understand the basis on which the decision was made. Even if they did not participate in the original deliberation the Publicity and Relevance Conditions empower them to reopen the process in the most effective manner.

Of course this does not mean that every challenge leads to a reconsideration of the decision by the original group responsible for it. It does, however, mean that good arguments that plausibly challenge the original decision are provided a visible and public route back into the policy formulation process. The decision making process is thus enriched by the new resources for argument that the grievance process brings to bear. Conversely, those affected adversely by the original decision are compelled to engage in the process of constrained reason giving that informed the original decision. Whether specific decisions are actually changed or not, if the arguments raised by these appeals lead to honest reconsideration of the original decision on its merits, they have an important effect on the overall legitimacy of the decision making process and on its likelihood of achieving fair outcomes. This task plays an educative role for all involved. That is, the appeals and reconsiderations become part of the process through which the broader social deliberation about the problem of limits takes place. The mechanism enables and enhances that broader social process and contributes to the improvement of quality.

Externally, the Revision and Appeals Condition contribute to a broader social deliberation about the problem of limits and ultimately to democratic governance of health care itself. Even if enrollees and clinicians do not participate in the original decision-making about limits, the Revision and Appeals Condition empowers them to play a more effective role in the larger societal deliberation about the issues. If stakeholders are not satisfied by the internal process they can turn in a better informed way to public institutions that play a role in regulating health plans. By creating the potential for connecting the deliberation that occurs within health plans to wider societal oversight of the limit setting process, the four conditions described in this section play a role in assuring broader accountability of private organizations to those who are affected by limit-setting decisions.

4.5 Regulation and assurance that the publicity, relevance, and revisability conditions are met

Fair process requires compliance with the Publicity, Relevant Reasons, and Revisability and Appeals conditions. How can such compliance be assured? Clearly the details of any answer will vary from country to country, depending on its legal system and regulatory capability and practices. It is unlikely that reliance on voluntary compliance will work in complex systems. Compliance with the three conditions is often a challenge in systems that have long traditions of lack of transparency, lack of consultation with parties affected by decisions, and reliance on weak institutions in civic society to challenge practices and improve accountability.
Against that background, it will probably be necessary to try to assure compliance through regulation. Assurances that fair procedures will be implemented may have to be made a condition of scaling-up where external agencies have any discretion. Ideally, winning governments at all levels to comply with the conditions is the only approach likely to succeed in the long run. It may even achieve the broader goal of helping extend institutional practices regarding fair process more broadly in the governance of health systems.

A number of international agencies, such as the World Bank and USAID, have in recent years made governance issues in health sector reform a prominent concern. The implementation of fair process as here described falls directly into that category of concern. Experience with improving governance more generally may provide some more specific insights into how compliance with the conditions defining fair process may be achieved. Enforcement through regulation may be the soft under-belly of the problem of fair process, and that may be true because enforcement in this context is part of a much larger problem of assuring enforcement in the governance of the health sector more generally and of other sectors as well. This is not a special problem raised by the need for fair process; if it were, its solution might be easier.

4.6 Divergent results in fair process

Can there be more than one just or fair way of deciding an issue? If we are governed by clear principles, it might seem this is implausible. The fine-grained principles should lead to a specific answer when they are reconciled with each other and all the facts of a case. But in a fair process, different decisions about similar cases may arise. Suppose for example, that one district or province grants special priority to health workers, but another does not. It could be that the difference is based on a difference in scarcity of personnel, in which case, the conflict is only apparent, since conditions differ. But suppose that conditions are the same. Can patients given priority lower than health workers in one district complain they are being treated unfairly compared to those in the other?

One basis for that claim might be that a fundamental principle of justice has been violated, the formal principle that like cases be treated similarly. If the conditions of scarcity are the same, the low priority patient might claim, then they should either both get the same lower priority or neither should have lower priority than health workers. The formal principle does not tell us how both should be treated, only that they should be treated similarly for the same reasons apply to both.

This complaint that a formal principle of justice is violated actually turns on there being a substantive reason or principle that grounds the decision to give priority to health workers. To see this point, consider this variation on the case. In both districts, a coin is flipped to determine whether priority is to be given health workers or not. Suppose this is the notion of fair process employed. When the patients with HIV/ AIDS who have lower priority now complains that like cases are being treated dissimilarly, we can say to them, "The cases are unlike: there was a coin toss, and you lost and others won." There is no violation of the formal principle if there is a non-reason-based procedure used to distinguish the cases, as there is in the case of a coin toss. Alternatively, we can construe this as a case in which a principle is appealed to and uniformly applied, namely the principle that winners but not losers of coin-tosses (or other random processes) will get the treatment.

Neither district flips coins, however; that is not the fair, deliberative process we have described. Within their different procedures, each encourages the giving of reasons and the deliberation about cases in light of reasons. We presuppose that the difference in their procedures for managing these cases rests on a difference in the weights the two districts give to certain values, i.e., the values of preserving equal respect for all patients vs hoping to save more patients over time. Suppose further that we are right to claim there is no argument that we all
can accept that shows that one weighting of these values (and thus one procedure) is clearly morally more justifiable than the other. That weighting, and thus the choice of fair procedure, is itself the focus of reasonable disagreement.

Generally, when there is a violation of the formal principle of justice, we are challenged to evaluate the weight attributed to a reason or principle that was applied in one case but not the other. We are asked to find a difference in the cases, that is, to show that they were not really similar in all relevant ways, or to affirm the uniform application of that reason or principle or of some alternative principle. But in the condition of moral pluralism we face, we have no candidate principle that enjoys "our" endorsement independently of the fair procedure we are employing. A reason that may seem compelling or decisive in one process may not have that force in another. To be sure, decision-makers are not flipping coins in either case. They are deliberating carefully in a reason-driven and reason-giving way. But the weight given reasons in each setting is a reasonable reflection of other moral disagreements and moral uncertainty -- the very uncertainty about what counts as a just outcome that compels us to adopt a procedural approach to fair outcomes. Patients with lower priority than health workers can be told this: patients with AIDS in the other district were given higher priority than you because in their district, decision-makers reasoned about the issue differently than in your district, and both ways of reasoning are relevant and arguably fair.

How acceptable differential treatment would be seems to depend, then, on whether a persuasive political rationale for uniformity can be developed. In a decentralized system, the political rationale would have to be sufficient to override the presumption that "private" insurers or different states have the authority to select from among a set of comparably fair procedures. Of course, the political rationale might simply be that the legal system would not allow differential treatment; but that too remains to be seen.

In a national health care system, the political rationale for uniformity would have to show that differential treatment among districts was less acceptable than giving them the autonomy to select their own procedures. If meaningful political units, like districts, felt strongly enough about their choices of procedures, the costs of uniformity might be too high. For the problem we are facing, then, it remains unclear how unacceptable it would be for similar patients in different districts to have different levels of priority for
5.0 Illustrations of Fair Process

My intention in this section is to illustrate how elements of fair process might be introduced into some decision-making settings at different institutional levels. Some qualifications are needed to introduce the discussion. First, the illustrations are theoretical. They are not intended to capture the specifics of any particular country, but my intention is to make them typical enough so that key elements of them will transfer to actual settings in a way that guides implementation of scaling up efforts. Second, I vary the topic of the decision in each hypothetical illustration, though I do not intend to suggest that the topic addressed in each example is one that should be addressed only at or even primarily at that institutional level. Third, we should see the introduction of fair process for priority setting decisions as a learning process, one that is taking place under great urgency. We must develop a research agenda that helps us all learn from initial experiments in this area, a point I return to in the concluding section 6.

Fourth, I suggest that the very briefly described illustrations provided here could be turned into teaching materials in the form of developed case studies. These materials could then be used in training workshops that explore in more detail, including through role playing and problem solving, the issues raised by them. Developing those case studies would clearly take me beyond the assigned task in this paper, but I recommend provision for developing them be made.

Finally, I want to emphasize that decisions made at higher levels, including those by external agencies such as WHO or external funders such as GFATM, or by the Ministry of Health, or even by provincial authorities, put constraints on decisions made at lower levels. The idea of fair process that I propose requires there be room for lower institutional levels to challenge decisions coming from above in a way that urges reconsideration and reevaluation if the deliberation at lower levels raises new evidence or arguments that should be addressed. Legitimacy is the result of iterative decision-making with different levels of decision-makers respecting the deliberative force of those working at other levels. External and more central national decision-makers must listen carefully to how their judgments are received at more peripheral levels within a country, and peripheral decision-makers must feel they are not simply ‘carrying out orders’ but are empowered to convey their more detailed and possibly more accurate perception of conditions at local levels, including the perceived legitimacy and fairness of the constraints placed on their own implementation decisions by those above them.

No doubt this picture of interactive exercise of authority against a mutually respectful background of deliberation at all levels is an ideal picture, hard to achieve. But without seeing it as a requirement of fair process that all should strive to achieve, then there will be a threat to the legitimacy of decisions that are made. People affected by them will not end up feeling their voice has been listened to with respect and the process itself will be open to serious challenge.

In the illustrations that follow, I do not intend to review in detail all elements of the moral controversy surrounding each topic, relying on the review in Section B to provide background for the process-focused discussion that follows. I focus on what kinds of information, evidence and arguments are needed, who should be involved, what should be revealed publicly about the deliberation that takes place, and what kind of openness to reconsideration is necessary.

5.1 Decision-making about medical eligibility: external agency recommendations and national acceptance

In section 3.1, I noted that medical eligibility criteria may appear to be purely technical, but they often embed some value judgments. Specifically, the medical eligibility criteria currently recommended by WHO include (a) a restriction to those with CD4 counts below 200, or to people clinically diagnosed with AIDS, given the low capacity in many places for measuring CD4
counts. Some other discussions have considered restricting eligibility to (b) those with some form of family or community support that is intended to make compliance with the drug regimen more likely.

With regard to (a), the scarcity of the drugs may have inclined decision-makers to restrict their use to those most urgently in need: those most likely to die sooner if they do not receive the drugs. It may also be true that the expected benefit of giving the drug to sicker patients may be thought higher. These are distinct reasons with different ethical rationales.

With regard to (b), the concerns are of two types. One concern is to maximize health benefits (b1): people who are less likely to comply are less likely to derive benefit, so there is a concern about selecting patients in whom best outcomes are more likely. Another concern is to minimize health risks to others (b2): people less likely to comply increase the risk of drug-resistant strains emerging that will threaten effective treatment of others. These three issues each involve moral considerations that are controversial, as I noted earlier.

5.1.1 Gathering relevant empirical evidence

One component of fair process is that the evidence and arguments bearing on each issue be fully discussed by both experts and relevant stakeholders, including representatives of groups providing the care under the restrictions that are set as well as of groups in need of the care. What kinds of evidence are needed?

With regard to the restrictions on CD4 counts, these questions seem relevant: What do we know about the benefits people receive at different levels of CD4 counts? Will people with higher counts also benefit significantly, or are they at risk of developing resistance that does not extend their lives as long as they would be extended by waiting to administer ARTs? There is some disagreement about this issue in resource rich countries that do not ration ARVs.

What do we know about the scarcity of resources that obtains? Is the scarcity of resources permanent or temporary? If scarcity is permanent, then simply waiting to treat more urgently ill patients may mean treating patients less likely to benefit and leaving patients more likely to benefit at risk of dying anyway. That is, the assumption that number of lives saved is maximized by treating the more urgently ill may be false under conditions of permanent scarcity. If the scarcity is temporary, however, then giving priority to the more urgently ill might save more lives since more resources would be available later to save those passed over initially.

Deliberators need to be familiar with the argument that urgency is a relevant consideration, but it is also relevant to know what kind of scarcity is present and what real effects it has. They must also have some evidence that bears on the expected benefit to the different groups they are selecting, especially if the selection is driven, at least in part, by a concern to maximize health benefits: it must be apparent that the maximization calculation works out in just the way that is supposed and does not rest on false assumptions.

With regard to the considerations in b1 and b2, which focus on family support, a range of empirical issues also needs to be addressed. What is the actual evidence about compliance in resource poor settings? Is there empirical evidence that people who are ill and without family supports are less likely to comply with ARTs? Is there another community based way to monitor compliance, and is there evidence of its effectiveness when family supports are not present? Decisions that are made should be evidence-based and not driven by assumptions about how things might work. What do we know about the actual risks of drug resistant strains of HIV emerging if compliance is compromised? How well can we extrapolate from TB to HIV?

5.1.2 Ethical arguments

The ethical issues that need to be brought out with regard to the restriction on CD4 counts are
these: How much increase in risk do we impose on people with higher cell counts by delaying treatment until they meet lower CD4 count requirements? When are gains in expected lives saved by respecting urgency outweighed by increasing the risk to those with higher counts? The point is not academic since not all people meeting cell count requirements will end up treated. Who among the participants in setting requirements is prepared to engage the ethical arguments that might be made about these factors?

The ethical issues surrounding the requirement that people have family or other supports to monitor drug compliance divide into two cases. Suppose the primary concern is getting the best outcome from treatment. Then it may seem that how important getting a best outcome is will vary with judgments for the lack of family supports. For example, a goal of seeking best outcomes may seem less compelling so some people if the reason some people have no family supports is that they have already lost those supports to the AIDS epidemic.

Suppose, however, that the primary concern underlying seeking family or other supports for monitoring compliance is avoiding the risks to others posed by encouraging drug resistant strains. Then we need some evidence, not mere speculation, about what risk is really posed. We would also need some deliberation about whether individuals who would comply despite the lack of family supports should be penalized by simply being included among a group at greater risk of non-compliance. Perhaps some key features of personality are better predictors of compliance than family supports, and some might then think that the broad notion of family supports is not as relevant a consideration as might have been supposed.

5.1.3 Who should deliberate about these issues?

Different international agencies making recommendations about medical eligibility criteria will have their own governance structures. In general, however, the sub-agency or division within an international organization that is responsible for recommendations will have been delegated that task through its standard governance procedures. Typically, in the development of medical guidelines, the assumption is that people with technical expertise and familiarity with the relevant evidence should be the sole decision-makers, or advisors to decision-makers. The argument presented here is that medical eligibility criteria needed for the selection of patients for ART are not purely technical and reflect values and ethical assumptions. Accordingly, a special effort will have to be made to broaden the group of experts to include the kind of consultations noted above.

A broad range of other stakeholders are important to the process, and some form of their involvement, through consultation or full participation in deliberation, is needed to address the interaction between relevant evidence and relevant reasons. An international agency should, for example, consider including a range of health workers from various countries in its deliberation. They will be charged with implementing the decisions and people like them will have to take ownership of the recommendations if they are to be perceived as relevant. Similarly, representatives of populations of people with AIDS from different countries should be included. Ideally, the process might include field discussions with people who do and do not have family supports. This input is not the same as social science inputs about the effect of family supports on related problems, such as DOT-TB programs, but it may prove relevant since there is likely to be a dearth of social science evidence, perhaps combined with too much expert confidence in what will happen.

5.1.4 How should participation of stakeholders be organized?

Consultation could be achieved through a form of publicly accessible hearings, including the presentation of evidence and arguments. This would require the selection of presenters and deliberators, and there is a great range of possible scenarios all of which would arguably involve adequate or sufficient inclusiveness among
relevant stakeholders for a relevant cross-section of countries. Where direct participation is not possible, it may be possible to conduct focus groups so the views of relevant groups are properly aired and understood by those stakeholders who do directly participate.

Including this kind of consultative process, or involving a range of selected stakeholders in the deliberation about criteria, would help in the presentation of the resulting medical eligibility criteria to countries for their guidance and acceptance. Once these recommendations are seen to contain morally contentious elements, rather than purely technical, value free decisions, then countries will want to know why the recommendations should be followed by them. They will, or should, insist that there be a publicly accessible rationale that elaborates the grounds for the recommendations. They will, or should, insist that they or countries like them have been consulted on the ethical issues. Part of the information made available to them will be the process for selecting those stakeholders who were consulted?

5.1.5 Relationship between levels of decision-making

Fair process in the external international agencies will set the tone for deliberation at the national level. How fair the process at international agencies is perceived to be by national authorities will affect what happens when the recommendations are presented for acceptance. National authorities may, and probably should, feel the need to review these issues through their own version of a fair process, including more extensive review and consultation on the recommendations about eligibility requirements that includes a broader range of stakeholders at the national and sub-national level.

Rather than repeat the elements of fair process that would involve, I consider in the next section another decision that would clearly have to be made at a national and provincial level. From it, we can derive recommendations as well for what national-level fair process should be like for the acceptance of medical eligibility requirements.

5.1.6 Revisability at international levels of decision-making

Before turning to that illustration of national-level fair process, it is worth noting an implication of the account for international recommendations about selection criteria. If countries embark on a deliberative process that meets the conditions described here, and some of them reject international recommendations, that should count as strong grounds for revisiting the international recommendation within the agencies that made them. In effect, this would be a demand for revisability in light of new arguments or evidence, or fair “due process” in recognizing the complaint from an affected party, in this case a country, complaining that the general recommendation does not fit their circumstances or is in other ways not fair to them.

5.1.7 A checklist for fair process

The following are key elements of fair process illustrated in the case of decisions by international agencies regarding medical eligibility criteria for scaling up ARTs.

Publicity:

Does the international agency (and national decision-maker considering such recommendations):

- Provide public access to the full rationale for its decision about medical eligibility criteria?
- Hold public hearings during the process of arriving at its recommendations?
- Make sure what is made public is comprehensible to a wide audience?

Relevant Reasons:

Does the international agency (or national level decision-maker):

- Undertake a careful, comprehensive gathering of relevant evidence that bears on the empirical background to the various
ethical issues that must be addressed?

- Distinguish empirical from ethical issues so that values are not submerged within technical conclusions by a narrow range of experts?
- Consult with and welcome to the deliberation a broad range of stakeholders affected by the decision?
- Support stakeholders during the deliberative process with access to information, an opportunity to understand the evidence, interact with others in the deliberative process?
- Treat disagreements with respect and patience, looking for grounds for reconciliation of views?

**Revisability:**

Does the international agency:

- Invite disagreements raised by national and sub-national level decision-makers and revisit policies in light of these complaints?
- View decisions as best achieved through an iterative process in which new evidence and arguments are welcomed as a chance to improve quality?

**Enforcement:**

Is the international agency:

- Accountable to national decision-makers for having carried out a fair process in its deliberations?
- Willing to challenge decisions made in response to its recommendations on the grounds that these decisions were not made in accord with fair process?
- Seek international agreements on the elements of fair process that should be involved in such priority setting decisions?

The checklist at 5.4 provides a summary of features of fair process illustrated in this case of international recommendations regarding medical eligibility, as well as the other illustrative cases that follow this one. It may be possible to convert these illustrations and checklists, with improvements, into case studies for teaching and training purposes.

### 5.2 Siting decisions at national and provincial levels

Decisions about the siting of treatment centers for ARTs will primarily be made by countries and their subdivisions (provinces, districts), though external funding may actually be tied to approval for siting plans. In that case external agencies may have in mind some general guidelines that involve a mix of concerns about equity of access and efficiency of delivery. For example, at a very general level, the “guiding principles” for scaling up ARTs suggests a “political commitment to working towards a universal access to ARV treatments” and “situating ARV treatment programmes within existing health systems” albeit with a “phased approach for scaling up ARV treatment” in ways that preserve “equity.”

If these general points are made more specific as recommendations to national and sub-national decision-makers, then the points made in the illustration at 5.1 would apply here as well: the more specific recommendations will have to be based on the kind of consultative, deliberative process involving various stakeholders that is appropriate for the medical eligibility criteria.

In the illustration that follows, let us suppose that only a very general directive about siting is issued to countries by external agencies. Suppose the guidelines from external funders say that goals should include equitable access, with full respect for international agreements about human rights. Funders then allow countries to make specific siting decisions that take into account sustainability and the capacity of the system to carry out the training of personnel in a phased effort at scaling up. In the discussion of siting at 3.2, it was clear that the trade-offs involved here reflect underlying value judg-

ments about which people will likely disagree. Like the medical eligibility criteria, these too are not simply technical decisions on which the usual experts have access to the relevant empirical evidence and make straightforward evidence-based judgments.

5.2.1 What kinds of evidence?

Though values and facts are both involved, empirical background must be taken into account. Appropriate evidence must be gathered, and experts who know how to present and evaluate it, regarding the capacity of the system to undertake ARV treatments, integrated with appropriate preventive measures in a setting that does not undermine the rest of the system. Capacity must be evaluated at different sites for monitoring CD4 counts and for train personnel of various sorts to deliver standardized first and second line treatments must be assessed. Knowledge of surrounding communities must be good, for planners must know about the ability to develop family and community supports for sustaining regimens in different settings. An assessment must be made of how these measures can be integrated with other components of the health system in ways that strengthen it rather than pull resources away from it. A clear assessment of the needs of different subpopulations must be made, including clarity about what kinds of access to different potential treatment centers those populations have.

This information base provides a background for the ethical deliberation about how to prioritize among goals, it does not determine that set of priorities.

5.2.2 Ethical deliberation and going beyond traditional planning experts

Knowing that certain existing centers, say some tertiary care facilities connected with universities in large cities, have the capacity to scale up treatment to patients, if drugs were available, is a matter of fact that the evidence gathering can make clear. What is not a simple matter of fact is how one should use that fact to phase in broader access to ARTs. If one leaves the existing inequalities in access in place to start with, siting treatment where the highest capacity already is, then better served populations will again benefit more and the populations least well served will have to wait for much later phases of the scaling up effort, assuming they ever actually materialize.

Should priorities be changed to correct existing inequities, even if that means slower scaling up to start with and fewer patients reached immediately (with more dying) in order to save more people from underserved groups where the need may be greater sooner? This kind of trade-off in planning must reflect deliberation about values. It is not simply a matter for experts but for all stakeholders affected by the decision—people with HIV/AIDS in the various communities, clinicians who must treat them or turn them away, planners whose facilities are affected by the decisions, communities whose children are being orphaned and whose survivors are driven deeper into poverty. All are affected by the priorities that are set.

To illustrate the problem of these tradeoffs, note what happens if traditional inequalities in the system are taken as a given. The rationale for building on existing strengths is that resources are already in place for beginning the delivery in certain central, tertiary care facilities. Scaling up will be more efficient, some then conclude, if those strengths are utilized. In Zimbabwe, for example, the Ministry of Health and University of Zimbabwe “are directing the setting up of treatment initiatives in the main cities, away from the areas of greatest need,” presumably because those are the sites where scaling up poses less logistical and personnel problems. But it is “district hospitals, including mission hospitals that have already developed the infrastructure required for community based VCT, home based care and prevention of PTCT...[these are] preferable sites...closer to areas of greatest need...” Unless the recommendation to focus on district level centers is followed, Zimbabwe risks replicating in its ART

effort a common pattern of inequity in health services, namely that richer parts of the population, often located in cities, derive disproportionately more benefit from public sector services than the poor.\(^{42}\)

So far in this section, we have focused primarily on location when talking about siting decisions. It is crucial to note that there is another dimension to the problem of siting decisions: are treatment sites well integrated into the delivery system or do they function as silos that are separated from efforts to improve equity more generally in the system? The problem is well illustrated in the case of Malawi.\(^{43}\)

In a national plan to improve equity in health services, an Essential Health Package (EHP) was developed by the Ministry of Health in 1999. The siting issue here turns on whether ARTs will be included in an expanded EHP and their delivery tied to developing the infrastructure needed to assure universal coverage for the EHP, or will ART treatment efforts be promoted in ways that actually give some incentives to health workers to abandon the effort at EHP and to follow the new resources into ART treatment centers, thus weakening an already fragile system with inadequate personnel? There is considerable fear that funding coming from the GFATM, with its targeted goals of patients reached for ART, may undermine, rather than help to build, the effort at EHP. As a matter of fairness, we must avoid the dangers of AIDS exceptionalism here as elsewhere.

This aspect of the siting decision also is not merely technical but involves value based trade-offs. It should be given as careful attention in deliberations about fair process as the issue of urban versus rural siting. Unless the decision-making process includes the deliberative, inclusive process described here, the result will be to disguise value issues as merely organizational and technical ones, with results that will leave losers feeling they have been treated unfairly. In this instance, the losers will not just be those who would benefit from ART but do not receive it, but also those who need access to EHP but do not get it.

Clearly the ethical debate about siting must be reflected at the level of national plans. In Zambia, the process is planned to proceed in phases. Scaling up of ARTs began with two pilot projects for delivering ARTs in Lusaka and Ndola, which were then extended into all 9 provincial hospitals and two faith based hospitals; the plan now calls for reaching all district hospitals during the period ending 2005.\(^{44}\) In Malawi, as in the other countries, a central obstacle to equitable scaling up is the dire scarcity of health care personnel. This is a factor that must be addressed in scaling up plans; it is not a fixed determinant of them.\(^{45}\)

5.2.3 What stakeholders to include?

Deliberation is needed to arrive at an acceptable valuation of the trade-offs involved against this factual background. A key issue then is what stakeholders are invited into the national and provincial decision-making process about siting? Siting does not just mean location, but also the kind of integration with existing facilities. The implication of the claim that the decision has broad effects is that the involvement of stakeholders must be similarly inclusive.

A basic guiding principle in scaling up, noted earlier, is the inclusion of stakeholders and the community generally in planning. But this inclusion must extend to the process of setting priorities around which the planning occurs. The point of such involvement is to broaden the deliberative process and to ensure that value questions are addressed and not submerged as merely technical issues about “capacity” in the existing system.

(44) WHO 3 by 5 Mission to Zambia on Scaling Up, 2003, p.5.
In many countries, an effective scaling up will require a coordinated effort with the public sector and key components of the private sector, including NGOs of various sorts. This fact implies some broadening of official consultation and planning. This broadening should be extended to include a full range of stakeholders affected by the siting plan: providers of different types from different levels of the public system and from appropriate components of the private sector, advocacy groups, and representatives of diverse community groups. The intention is not to stimulate lobbying, but to provide a context in which arguments about needs and the consequences of different siting arrangements can be assessed.

Uganda’s effort at scaling up involved establishing a National Advisory Board that was to make various recommendations based on an assessment of needs for ARTs. It was also to recommend “objective” criteria for people who should participate and suggest how the scaling up effort could improve the health care infrastructure. Key to this approach was the fact that the Board included a range of specialists and stakeholders, including representatives of people living with HIV/AIDS. In addition, the Ministry of Health appointed a National Committee on Access to ARV Therapy; it was multidisciplinary, including representatives of various international and bilateral agencies, faith based and other NGOs, and people living with HIV/AIDS. One of its tasks was to oversee the development of “technical guidelines” for ARV therapy. With some elaboration of its consultative activities, this kind of commission could play a role in making some priority setting decisions regarding siting and other issues in ART scaling up. Think of it as involving practical first steps toward what is elaborated as the elements of fair process in what follows.

5.2.4 What forms of stakeholder involvement?

The inclusion of various stakeholders can take different forms, provided that some avenues for doing so do not become labeled or perceived as tokenism. It may be necessary to conduct focus groups in some cases since involving some types of stakeholders in the more centralized process may be infeasible. But this kind of consultation should not be seen as a process in which the “experts” talk to “consumers” but are not really bound to listen to what they say.

There is no one formal structure or institutional arrangement that must be implemented to achieve a deliberative, fair process. Various institutional structures can be integrated to work: public hearings, testimony from various groups to a commission, focus group or other community and other stakeholder investigative approaches. Local traditions may make some forms easier and more acceptable than others. The central conditions described earlier – publicity, involving stakeholders to seek agreement on relevant reasons, allowing for revisability, enforcement of the process – are general enough to be compatible with many arrangements.

Siting decisions may be made at various levels in a health system: national, provincial, district. It may be necessary to carry out the deliberative process with different degrees and formats of stakeholder involvement at different levels. But the rationales for all decisions must be publicly accessible, regardless of the level, and each must be constrained by agreement on relevant reasons. Each must be revisable in light of better evidence and arguments from other levels that impact it.

Some countries have previously implemented community structures that can be adapted to playing the role described here; others have begun to build them into scaling up proposals. For example, I noted earlier that in Cameroon there are “dialogue structures” which involve community representatives (in theory and sometimes in practice) in the governance of local health units. Such structures can supply representatives for both local and more provincial or national efforts at deliberation. In Zambia, a multidisciplinary Task Force on ART in the Central Board of Health (CBOH) includes

people from different disciplinary backgrounds who work part-time on ART program development, but the Task Force does not include a broader set of stakeholders needed for the kind of deliberation here proposed. Each province in Zambia has an ART Selection Committee “comprised of a physician, a social worker, a counselor, a religious representative and a psychologist (where one exists). Inclusion of a representative of people living with HIV/AIDS has been suggested and is being considered. It is responsible for selection of patients to be put on treatment, following set criteria.”

5.2.5 Stakeholder participation and accountability

As Loewenson argues in his excellent discussion of the relationship between participation and equity, there is a strong connection between stakeholder involvement – various forms or types of participation in the priority setting process – and accountability. Participation builds understanding of what has to be done and encourages a sense of control. Encouraging the emergence of that understanding and sense of control in civic groups creates an organized pressure to keep decision-makers and providers on track for doing what they have agreed to do. This relationship does not require that stakeholders, including community organizations, actually have control or exercise a delegated power, though such strong forms of empowerment may exist at very peripheral levels. Those very strong forms of participation may be desirable and feasible in some settings, but they are unlikely to be achievable without very strong political forces working both from above and below, a relatively rare event. Nevertheless, joint planning and advising in a formalized way, rather than simply being consulted on occasion or receiving information after the fact, are forms of participation that generate accountability. They are also the forms that are essential to establishing fair process in which relevant reasons can be agreed to by affected parties.

It is also important to recognize that participation can be encouraged in theory and on paper without the reality matching theory. The Zimbabwe health Review Commission (2000) points to various factors that undercut official positions supporting participation. They include poor health worker appreciation of the value of participation, poor health worker skills in facilitating community involvement, weak methods for improving that appreciation and the needed skills, weak political commitment toward the goal of participation, and lack of stable planning structures for joint planning between communities and health services.

5.2.6 Provision for revisability and appeals

An important feature of fair process includes the provision of opportunity for revision in light of new evidence and arguments, and especially for reconsideration of cases that are based on complaints of unfair treatment. A national and provincial decision-making process for determining appropriate ART sites must be open to complaints by areas that consider themselves underserved by the siting decisions. What has to be in place is a process open and sensitive enough to...

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(50) Loewenson’s Figure 1 notes these levels of participation. See Loewenson, 2007 Op. Cit. P.5, citing Community participation for health for all. London, Community Participation Group of the United Kingdom for All Network, 1991.
distinguish cases of (temporarily) unavoidable inequality from ones that involve unjustifiable inequity.

Specifically, rationing decisions will generally have “losers” – people put at some disadvantage in priority relative to others. But not every such case is a case of inequity. It matters what the grounds were for establishing the priority and what the process was as well. Every rationing decision may leave some groups of people relatively disadvantaged, but if the decision is made in accord with due consideration of all ethical issues, there may be no way to eliminate the disadvantage without equally disadvantaging others. (As before, if no one is worse off than others would be or than anyone need by under the conditions, the complaint about equity may be unfounded.) The goal is to eliminate all patterns of inequity, but where not all needs can be met, there is no way to eliminate inequality in the meeting of needs.

What is crucial is that lower levels of a system must have a way to raise complaints and higher levels must be willing to listen to those complaints to see if there is an inequity that must be addressed. Decision-makers at higher levels must then address it. They must consider revising the recommended siting pattern accordingly.

5.2.7 An opportunity to be taken

The challenging point is that many of these arrangements – especially the proposals about fair process that extend these preliminary versions -- are novel to most health systems and even to most forms of public deliberation in any government structure. The striking ethical challenge of distributing ARTs fairly provides an opportunity to undertake an effort an introducing accountability for the reasonableness of priority setting and other allocation decisions into systems more generally. Just as the argument supporting the scaling up effort makes the point that this is not a silo program but an effort to improve the functioning of health systems beyond the use of ARTs, so too the deliberative, fair process that equitable scaling up requires should be translated into ongoing procedures in the system as a whole.

5.2.8 Summary of points and checklist

Publicity:

Do the national and provincial decision-makers about siting:

- Provide public access to the **full rationale** for their decisions about siting and integration of treatment sites into the health system?
- Hold public hearings during the process of arriving at its recommendations?
- Make sure what is made public is comprehensible to a wide audience?

Relevant Reasons:

Do national and sub-national decision-makers:

- Undertake a careful, comprehensive gathering of relevant evidence that bears on the empirical background to the various ethical issues about location and integration that must be addressed?
- Distinguish empirical from ethical issues so that values are not submerged within technical conclusions by a narrow range of experts?
- Consult with and welcome to the deliberative process a broad range of stakeholders affected by the decision?
- Support stakeholders during the deliberative process with access to information, given them an opportunity to understand the evidence, and to interact with others in the deliberative process?
- Treat disagreements with respect and patience, looking for grounds for reconciliation of views?
- Clarify decisions that impose unavoidable delays or disadvantages from those that involve replicating existing inequalities that must be challenged?
Revisability:
Do the different levels of national and sub-national decision-makers:

- Invite disagreements raised by lower level decision-makers or communities and revisit policies in light of these complaints?
- Develop an iterative process in which new evidence and arguments are welcomed as a chance to improve quality?

Enforcement:
Are the national and sub-national deliberators:

- Accountable to lower level decision-makers and civic society for having carried out a fair process in its deliberations?
- Willing to challenge decisions made at other levels that depart from its recommendations when those decisions are not made in accord with fair process?
- Seek national regulation requiring elements of fair process be involved in such priority setting decisions?

The checklist at 5.4 provides a summary of features of fair process illustrated in this case of international recommendations regarding medical eligibility, as well as the other illustrative cases that follow this one. It may be possible to convert these illustrations and checklists, with improvements, into case studies for teaching and training purposes.

5.3 Decisions about priority to special groups, such as health workers, at national and local levels

In this subsection, we again discuss fair process at the national and sub-national levels, including local decisions at or below the district level, but we focus on the question of what priority, if any, should be given to special groups of patients. Macklin identifies the claims that might be made about a significant range of special groups, and she suggests that these decisions should be addressed at a local level. I view these decisions as appropriate to consider at various national and sub-national levels, but I narrow the discussion, as in Section 3.3, to a discussion of giving priority to health workers, aiming to be illustrative of process, not exhaustive of substantive issues.

Specifically, it will be important to address the degree to which national priority-setting recommendations must leave room for local discretion in implementation, since there may be circumstances or value judgments that differ across local settings. We shall also have to reconsider some aspects of enforcement and regulation of fair process: enforcement is crucial if we want to avoid people agreeing to the importance of fair process but expecting that local authorities and providers will distribute resources as they see fit, regardless of what decisions are made. At the same time, I want in this illustration to highlight some different issues in process, not repeating points emphasized in 5.1 and 5.2, and so the discussion will be briefer.

5.3.1 Distinguishing empirical and ethical issues (again)

In Section 3.3, we saw that there was a general tension between believing, on one set of related views, that equity or fairness required treating all patients with equal respect, or as being of equal worth, or as having equal claims depending on their needs, and believing, on the basis of other considerations that some special groups, such as health workers, should be given priority for reasons that are arguably relevant. The various ethical views are each accompanied by empirical assumptions that need to be distinguished. Evidence must then be gathered to see if these assumptions are truly met. Empirical claims are unlikely to resolve underlying ethical disagreements, so there must be opportunity for proponents of these views to make out their arguments in a climate of mutual respect.

What kinds of evidence should gathered as part of the fair process of decision-making? Minimally, the process, whether it occurs at national or sub-national levels, must have good evidence about manpower availability and
5.3.2 At what level should this decision be made?

Instead, I want to consider the question of the level at which this decision about priority to special groups should be made and the resulting discretionary authority and interaction that must then follow.

Consider first why one might think that giving priority to health care workers should primarily be a national level decision about priorities. The availability or scarcity of personnel needed to reach the 3 by 5 targets is itself a matter of national policy. The evidence needed to decide how vulnerable plans are to personnel loss from AIDS if no priority is given health workers needs to be assembled nationally, though it must reflect facts at the local level. Further, it may appear arbitrary if some provinces or districts give priority to health workers and others do not. Departing from an “equal respect means equal access” principle to allow priority to special groups is such a weighty decision that, some will argue, it should have the legitimacy that derives from national legislative and administrative authority.

These considerations suggest there should be a national policy on this issue. Nevertheless, there are counter-considerations. The facts about scarcity of personnel will vary with local. In addition, there may be different views in different regions about the threshold that must be reached before priority is acceptable to local stakeholders. In any case, there is some considerable uncertainty about how to specify that kind of threshold and that contributes to variation in acceptability.

Putting the two positions together, some points become clear. Whatever national priority setting is done, including a general recommendation about a threshold of scarcity that justifies priority, the policy arrived at may have to be one that permits sub-national authorities considerable discretion in complying with it. This flexibility is especially important because of in many systems, health reforms over a period of time have emphasized the importance of decentralization of authority in order to make systems...
more responsive at the local level. Whether or not that decentralization has had its intended effect, it is an important feature of the political culture that must be respected, especially when issues of legitimacy are at stake, as they are in priority setting.

5.3.4 Fair process all the more important where discretion is allowed

The discretion allowed to sub-national authorities is, however, dependent on their conducting their own deliberations through the same type of approved fair process that the national level decision-makers used. Local authorities should be held accountable nationally and to local civic groups for abiding by elements of fair process. If this form of enforcement is not imposed, there is a risk of discrediting the local variations in policy that arise.

The risk of loss of legitimacy, whether at national or local levels of decision-making, is particularly high when some groups are explicitly given priority over others, in some ways a more visible form of explicit rationing than medical eligibility or siting decisions. The extra threat is that the singling out of any group for special priority may lead to lobbying or pressure by other groups making out claims for themselves. A fair process must be robust enough to entertain such challenges, or it will collapse under the pressure, perhaps unjustifiably opening the door to other priorities or perhaps simply dogmatically insisting it will not entertain other arguments. Either way it risks discrediting the effort at fair process.

Consider what happens if efforts to establish arguably relevant priorities for certain groups fail and local authorities are simply left retreating to a “first come first served” selection principle. Remember from our discussion in section 2.3 that this approach might seem to be an approximation to random selection among equally worthy candidates for a benefit, a view that we noted is sometimes taken to represent a paradigm of fair process. In reality, the results of “first come, first served” are likely to replicate a pattern of existing inequalities in access to services. In Malawi, for example, Kemp et al argue that first come, first served will predictably mean that richer, better educated, better connected people with HIV/AIDS will receive treatments before poorer, more vulnerable populations will. Since existing patterns of service delivery already favor those better-off populations, who derive more benefit from public services than the poor do, there is good reason to think that “first come, first serve” is equitable only in appearance and not in reality.

5.3.5 The importance of enforcement and assurance

The political difficulty of adhering to a decision made as a result of fair process, especially when some groups or individuals vigorously protest their being losers and portray their loss as unfair, means that fair process must be public and must have involved stakeholders most likely to want and need their voice heard from the beginning. But more than that, it requires that there be enforcement of the elements of fair process and enforcement of implementation of decisions made according to fair process. Without enforcement of the former – assurance that fair process is sought and achieved – people will doubt its decisions from the start. Without enforcement of implementation, people will end up thinking that people with power locally, including doctors and local authorities, will do what they wanted to, including what was simply in their interest, and fair process was just window dressing, not aimed at the real thing.

The challenge regarding governance is key.

5.3.6 Summary

The importance of developing a policy that allows for sub-national authorities to exercise discretion, based on their own deliberations under conditions of fair process, comes from noting three points: a) conditions of scarcity may vary by region, so thresholds that are crossed in one place are not crossed in another; b) values involved in setting thresholds may vary by regions, and since legitimacy will by judged lo-

(53) Kemp et al. 2003, op. Cit.
cally and not just nationally, there is room for
discretion is setting thresholds; and c) inviting
local authorities to reaffirm priority-setting deci-
sions through their own deliberation under con-
ditions of fair process improves local account-
ability and strengthens local civic groups.

By making local efforts at fair process more
visible, it undercuts the cynical (but often realis-
tic view) that people in authority will just do
what they want, whatever the more distant cen-
tral gestures at fair process.

A checklist for the novel points raised in this
illustration:

**Relevant Reasons:**

Does the international agency or national or
sub-national decision-maker

- Make recommendations about priorities
  and rationales for them that are appropri-
  ately respectful of local discretion and
  authority?

- Do stakeholders involved at each level of
decision-making pay careful attention to
fair process in deliberation at other levels
and consider arguments and resulting ra-
 tionales in their own deliberations?

- Where priorities among special groups are
the issue, have deliberators refined their
rationales so that they guard against
charges of “favoritism” and concentrate on
arguments that all stakeholders can see as
relevant?

**Revisability and Appeals:**

- Where discretion is allowed at different
levels, arguments made at each level lead
should be viewed as relevant to revisabil-
ity at other levels.

**Enforcement:**

- Agreements about components of fair
process should be sought among decision-
makers at each level so that standards are
clear and departures from them can be
challenged.

- Accountability for abiding by fair process
is crucial when decisions about giving prior-
ity to some groups are involved in order to
ward off perceptions of favoritism.

**5.4 A summary checklist for fair process, based
on three illustrations**

**Publicity:**

Does the international agency or national or
sub-national decision-maker considering such
recommendations:

- Provide public access to the full rationale
for its decision about medical eligibility or
siting or group priority criteria and not
simply to its recommendations?

- Hold public hearings during the process of
arriving at its recommendations?

- Are the rationales as accessible as the rec-
ommended requirements?

- Are rationales presented in ways compre-
hensible to people who are interested in
understanding them?

- Are stakeholders involved in deliberation
about these rationales free to discuss their
arguments outside the deliberative proc-
ess?

- Are complaints that are brought by deci-
sion-makers from national and sub-national
levels made public so that the responses to
the proposals are also publicly accessible?

**Relevant Reasons:**

Does the international agency or national or
sub-national decision-maker

- Undertake a careful, comprehensive gath-
ering of relevant evidence that bears on
the empirical background to the various
ethical issues that must be addressed? Ex-
pand the relevant evidence that is gath-
ered as new arguments are raised that
involve empirical assumptions?
• Distinguish empirical from ethical issues so that values are not submerged within technical conclusions by a narrow range of experts?

• Consult with and welcome to the deliberation a broad range of stakeholders affected by the decision? Are they from all relevant groups? Are they from appropriate levels (national, regional, local) at which the effects of recommendations will be felt?

• Support stakeholders during the deliberative process with access to information, an opportunity to understand the evidence, interact with others in the deliberative process?

• Treat disagreements with respect and patience, looking for grounds for reconciliation of views?

• Empower stakeholders to feel like true participants rather than just tokens? Is their involvement valued by other experts, or merely tolerated?

• Make to organize the results of stakeholder deliberation, so that all can see the framework for different positions as clearly as possible and understand what is at issue in cases of disagreement?

• Discuss and deliberate about the process for resolving disagreements, so that people feel the process is fair to them and genuine in its intentions to respect them?

• Develop rationales that are inclusive of points of disagreement, so that others can see the careful nature of the deliberation?

• Make recommendations about priorities and rationales for them that are appropriately respectful of local discretion and authority?

• Do stakeholders involved at each level of decision-making pay careful attention to fair process in deliberation at other levels and consider arguments and resulting rationales in their own deliberations?

• Where priorities among special groups are the issue, have deliberators refined their rationales so that they guard against charges of “favoritism” and concentrate on arguments that all stakeholders can see as relevant?

Revisability:

Does the international agency or national or sub-national decision-maker:

• Invite disagreements raised by national and sub-national level decision-makers and revisit policies in light of these complaints?

• View decisions as best achieved through an iterative process in which new evidence and arguments are welcomed as a chance to improve quality?

• Assure decision-makers at other levels that they have an opportunity and responsibility to raise objections to other levels, requesting reconsideration?

• Assure that appropriate stakeholder are involved in the careful deliberation about revision and that they are treated and supported in the ways described earlier?

• Is there a mechanism for making appeals of decisions, including the grounds for the complaint, a matter of public record as well as the decisions themselves?

• Is the responsiveness to appeals and other complaints seen as part of a quality improvement process, or is it dismissed as rebelliousness or obstructionism?

Enforcement:

• Does the international agency or national or sub-national decision-maker:

• Make itself accountable to lower levels of decision-making for having carried out a fair process in its deliberations?
• Challenge decisions made in response to its recommendations on the grounds that these decisions were not made in accord with fair process?

• Seek international agreements or national regulations on the elements of fair process that should be involved in such priority setting decisions?

• Seek agreements about components of fair process among decision-makers at each level so that standards are clear and departures from them can be challenged.
6.0 Improving Fair Process Over Time

6.1 The importance of training

I earlier suggested that the illustrations in Section 5 could be converted into a set of case studies for teaching and training purposes at various levels within national health systems. Developing an understanding of and commitment to abiding by fair process is something that emerges over time and through experience. Training sessions in which ideas can be explored and shared, for example at regional and national and sub-national levels of decision-making is a good first step. Institutional and cultural variations among countries mean that the ideas proposed here must be examined and adapted for use in local settings. Developing the details will take some experimentation.

6.2 The importance of research

I conclude with a plea for further research into fair process. If the “3 by 5” consultation we are engaged in stimulates various decision-makers at different levels to try to implement versions of fair process, as they understand it, a laboratory for studying fair process will have been created. It should be possible for WHO and other international agencies to then engage in a coordinated research effort to examine the experiments at fair process, to seek examples of best practices, to make comparisons across contexts, and to make better recommendations about how to make fair selection and other decisions about priorities in the future.

If the commitment to this research program is taken seriously, the following steps should be put into place.

- A descriptive record of processes put into practice should be developed.
- A set of research questions should be developed to test the compliance with recommended components of fair process.
- A set of research questions should be developed to examine the effects of fair process on outcomes, including the perceived legitimacy and acceptability of the decisions made. The research questions should identify and try to measure the “value added” of abiding by fair process. Typical questions might be these:
  - Is there less resistance to recommendations when process is perceived to be legitimate and fair?
  - Are more consistent and coherent decisions made when a body of “case law” emerges to frame those decisions?
  - Is there an increased perception of fairness in the system when central elements of fair process are used and made visible?
- Appropriate research techniques should be supported for answering those questions.
- A timeframe for this research agenda should be set so that efforts to extend the “3 by 5” effort into the future with new targets are guided by results learned from the current efforts.
- International support should be gathered for this kind of monitoring and evaluation and research effort. It is just as important a type of research as that aimed at examining the effectiveness of operations put in place or the other outcomes of those operations.

6.3 A learning curve

Finally, I caution that we are early in the process of learning how to implement fair process in priority setting and limit setting activities in health systems. What is described here will need improvement and revision in light of further experience. The training and research proposed here are intended to yield those improvements. If the recommendations of this section are followed, a path will be set toward global learning about fair process.
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For further information on the Department of MDGs, Health and Development Policy (SDE/HDP) and the Pro-Poor Health Policy Team, visit:
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