SPECIAL ARTICLE

The ART of rationing — the need for a new approach to rationing health interventions

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A key element in dealing with HIV/AIDS in South Africa depends on the resolution of the antiretroviral therapy (ART) paradox: while a universal First-World-style ART programme is unaffordable, a rationed treatment programme that includes ART is not only affordable but also vital for basic human rights reasons, to enhance prevention efforts and to keep the fabric of society together. Our recent paper on ART demonstrated how such a rationed programme would be both affordable and highly cost-effective. Traditional rationing mechanisms are unable to provide sufficient guidance as to how to go about this novel form of rationing. An alternative rationing mechanism is therefore proposed which seeks to balance ART in terms of three primary dimensions: total resource allocation to treatment, design of the treatment intervention, and setting targets on numbers to treat. Two secondary dimensions, related to total HIV and social spending, deserve equal attention. The current global context that precipitates and exacerbates the parallel contouring of disease burden and poverty should be constantly challenged.

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The current differential access to antiretrovirals (ARVs) may signal a new feature of the global political economy. For the first time, a whole class of drugs on the World Health Organisation (WHO) Essential Drugs list has been priced beyond the means of the majority of those afflicted by a mass condition.[1] This article argues that this change in the global context, together with the inevitability of explicitly limiting a new ARV treatment initiative in South Africa, necessitates a new approach to rationing health interventions.

Specific objectives of the discussion include: a review of contemporary public health decision making with respect to antiretroviral treatment (ART) in South Africa; a review of traditional approaches to priority setting and rationing more generally; the proposition of a pragmatic response to the unique challenge posed by ART in the current South African context; and an exploration of some of the issues resulting from this response, including how it reconciles with human rights approaches, and the societal value judgements that are required. Finally, a response to the challenges posed by ART is contextualised in terms of the changing global political economy.

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Contemporary public health decision making regarding ART

The current thinking around ART in South Africa has been polarised into two camps.

On the anti-side sit a coalition of government and public health officials who argue that ART is too expensive, too complex or too toxic for South Africa's health care infrastructure to implement.

The pro-side has been dominated by a growing coalition of treatment advocates such as the trade unions, religious organisations, health workers and political parties. The basis of this group's argument is essentially a human rights one — access to life-saving medication is a basic human right.

Unfortunately the public debate has been retarded by a focus on marginal issues, such as drug toxicity. There has been little constructive discussion between these opposing camps on the two key issues of cost and efficacy. Where the pro-camp has focused on efficacy and considered cost predominantly in relation to individual input costs, the anti-campaign has dwelt on total system costs under conditions of universal access and uptake.

The data showing the efficacy of ART in dramatically reducing rates of death, opportunistic infections and hospitalisations are incontrovertible.[2,3] One of the few valid counterarguments relates to the financing and infrastructure required to establish a treatment programme. It is undeniable that a 'First-World'-type ART treatment programme would be unaffordable to a country such as South Africa. A recent publication[4] calculated that providing ART to all stage III and IV AIDS patients would cost the country between R15 billion

and R70 billion per year by 2010 (which translates into roughly half to double the current health budget). Is it appropriate, then, to conclude on the basis of these and similar figures,[5] as was done in the abovementioned analysis, that ART, though effective, is unaffordable to less developed countries? This paper argues for an alternative response that seeks to balance considerations of cost with those of efficacy within the framework of a rationed ART programme.

Rationale for a limited ART programme

Our previous paper on this topic[5] showed that an adequately rationed treatment programme could cost the state a small fraction of the above figures (R407 million direct intervention costs in 2007). If one included direct savings the intervention could actually be cost saving to the health budget. Using such scaled-down costs and considering potential savings as a result of treatment, we have already seen how the individual cost-effectiveness of ART makes a strong case for its delivery. The population benefits, however, make the case particularly convincing.

Population-level benefits of ART

Treatment and prevention share effective synergies

There is a growing consensus that prevention and care are inextricably linked. Concentrating on prevention alone is particularly inadequate in countries with high prevalence epidemics. Programmes that only offer condoms or counsel abstinence generally fail to penetrate the denial, inertia and sense of hopelessness that accompanies death and dying.[6]

South Africa's response to the epidemic continues to be characterised by high population levels of denial. The extent of this problem is demonstrated by a survey done in 2001 which revealed that only 3% of South Africans believe that a family member or friend is HIV-positive.[7] This contrasts with countries such as Uganda where the leadership has been candid about the urgency of the problem and 87% of the populace are of the opinion that either a family member or friend is infected with HIV.[8]

One way of dealing with the denial/discrimination/stigmatisation cycle would be to provide treatment for HIV, thus transforming it from a condition which is perceived as a death sentence, to one which is seen as a manageable chronic illness. The offer of treatment also provides a direct incentive for persons to be counselled and tested — an intervention which has been shown to reduce risky behaviour and hence HIV transmission.[9]

The director of Brazil's HIV programme argues that the provision of treatment in general, and ARVs in particular, has been vital to creating the openness around HIV necessary to slow its spread.[10] Brazil's epidemic in 1990 was at a similar stage to South Africa's. Twelve years later, we have an adult seroprevalence 15 times that of Brazil.[11,12]

Two important conclusion arise.

1. Firstly, a seemingly expensive treatment intervention can be cost saving in the long term if it significantly reduces levels of population denial, encourages counselling and testing and thereby significantly reduces the number of new infections.

2. Secondly, these population-level benefits of an ARV treatment programme occur even if the ARV programme itself is significantly rationed. Thus the state sector does not need to promise to provide unlimited access to ARVs. Rather, it is only necessary that the state is seen to be doing all it can, within its constraints, to provide treatment in order to change the way people see both the illness and the risk-benefit balance of HIV testing.

Beyond all or nothing — a new rationing mechanism

The evidence presented so far should enable consensus on two crucial points. Firstly, an ART programme with unlimited access and no consideration of programme design (and most especially input costs) is unaffordable to a developing country such as South Africa. Secondly, an adequately rationed and pragmatically designed ART programme would not only be cost-effective at an individual level, but vital to the success of long-term prevention efforts. The central question this raises is how we should determine what this 'adequate rationing' entails.

An overview of traditional rationing mechanisms

Traditional rationing and priority-setting mechanisms such as those proposed by the WHO[13] or standard health planning texts,[14] propose the evaluation of new interventions in terms of certain entrenched criteria, the chief of which are cost effectiveness and considerations of equity (Table I). The result of applying these criteria is the creation of a package of

Table I. Green's criteria for prioritising health care interventions[14]

1. Cost benefit/effectiveness analysis
2. Technical, administrative and legal feasibility
3. Knock-on effects
4. Financial and resource availability
5. Long-term sustainability
6. Acceptability
7. Social, economic and political effects
8. Impact on equity
9. Gender effects
10. Environmental effects
11. Other developmental objectives
12. Ease of expansion from a pilot activity or project

essential interventions that should be accessible to all inhabitants of a country. This basket of interventions should expand in accordance with national wealth. Thus, as far as AIDS treatment is concerned, the WHO has divided interventions into three categories for low-, medium- and high-income countries.[13] According to this schema, ART is only regarded as appropriate for high-income countries. As already discussed, this all-or-nothing approach is no longer a sufficiently nuanced approach to rationing. Public health decision-making requires a methodology which is able to vary input and total costs of new interventions to see if there is a configuration of the intervention which would confer a net benefit to the country concerned. Before examining one such methodology let us first look at the contextual changes that have necessitated a new approach.

Changes in global context necessitate a new approach to rationing

ART, at an annual cost of $11 000 per person,[15] is clearly unaffordable to the majority of the world's population who live on under $2 per day.[16] This represents the first time that a highly efficacious treatment for a mass condition, and one for which there is no substitute, is unaffordable to the majority of those afflicted by the condition. How did this situation arise?

This state of affairs could be attributed to the conjunction of three processes embedded in the new global political economy: the rapid increase in intra- and international income inequalities, the increasing power of transnational pharmaceutical companies, and the extraordinary strength of intellectual property rights as determined by the World Trade Organisation.

The widening income inequalities have meant that a large majority of the pharmaceutical industry's profits arise in the First World and the prices of ARVs were therefore set relative to the benefit they confer to this market. The 20-year patent protection afforded by TRIPS (Trade-Related Intellectual Property Rights) frees these companies from the threat of competition and thereby enables them to charge exorbitant prices. Even at these prices, ART remains considerably more cost-effective than common therapies such as beta-blockers for hypertension in rich countries.[17,18]

If the public health community had merely accepted these high prices, then ART would certainly have remained unaffordable for the many high-prevalence and poor countries. A key part of rationing in the new era is therefore exposing the unfair pricing system and campaigning for alternative systems. So far this pressure has yielded a crucial amendment to TRIPS[19] which enables countries such as South Africa to import or manufacture cheap generic ARVs at one-thirtieth of the price. There is every reason to expect that generic prices could drop considerably further once economies of scale develop.[20] The chosen planning approach would therefore anticipate reasonable estimates of these price decreases. It would also be important to ensure that the new rationing mechanism takes adequate notice of the global inequalities which have given rise to the difficulty for Third-World countries to fund ART. One way to do this would be to negotiate with international bodies such as the Global Fund for AIDS, Tuberculosis and Malaria (GFATM) in such a way that the international body would match the funding put in by the national government.

How could this planning approach work in practice?

The three interdependent dimensions of ART rationing

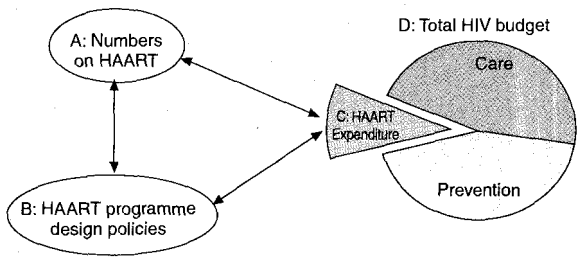
We propose a system that would ration ART by simultaneous consideration of five dimensions (Fig. 1).

Primary dimensions would be:

- A: numbers of persons who receive ART
- B: type (and hence unit cost) of ART offered
- C: total budget allocated to ART.

Secondary dimensions would be:

- D: the total spending on HIV care and prevention
- E: other health and social spending, i.e. allocative implications of the spending.



Key: The constituent variables of A, B and C

A) Rationing in terms of the numbers of clients on ARVs
- ARVs would only be available to the following clients
- Knowledge of HIV status
- In stage IV
- Live in a specified catchment area around one of the facilities offering ARVs
- Regularly attend infectious diseases clinic
- Meet clinical and biological criteria
- Meet social and adherence criteria

B) Rationing in terms of streamlining the type of ART programme offered
- The cost of ART could be limited via:
  - i. Use of generics
  - ii. Only offering first line
  - iii. Cut cost-ineffective tests
  - iv. Nurse driven

C) Rationing in terms of budgetary restraints
- Limit total cost to national fiscus according to what is affordable
- Aim for matched funding from business, global funding, etc.

In addition

D) Balancing HIV/AIDS spending with other health spending

E) Balancing health spending with other social spending

Fig. 1. Dimensions of rationing in designing an ART programme.

Each of these dimensions is a vital determinant of the ART programme's size and shape. We argue that the key to the successful rationing of ART lies in balancing these dimensions. A successful balance cannot be accomplished by simply calculating an optimal solution in one dimension and imposing this solution onto the others. Thus we cannot start, as traditional rationing systems would, by working out the optimal ART treatment package (such as three tiers of triple therapy) at conventional prices and then multiply this cost by the total number of persons in stage III and IV. As already demonstrated this produces an unaffordable figure. Instead, the dimensions should be simultaneously optimised and, in an iterative fashion, the calculation adjusted until an optimal equilibrium is found. This rationed form of the intervention can then be appraised for inclusion into the national health service.

Numbers on treatment (A)

Part I of this series applies this process to South Africa in 2002. It was proposed that initially, the central constraint would be infrastructural rather than financial. Each province should, however, be able to start two pilot ART programmes in 2002, covering 1% of patients developing AIDS. This could be gradually increased to cover close to 10% of patients developing AIDS by 2007.

Resource allocation (C), total HIV spending (D), and total social spending (E)

An upper limit should be placed on C to ensure that ART does not have a disproportionate impact on D and E. Dimensions D and E are particularly important when dealing with a disease such as HIV where consideration of both behaviour modification and poverty relief are crucial components of a successful response. ART should not swamp out other vital health sector expenditure such as primary health care or key social programmes aimed at poverty alleviation (e.g. a basic income grant). Green's[14] criteria might assist in determining the acceptability of the primary and secondary balance points chosen between these different spending options.

C was set at R500 million, both because this would allow the most cost-effective form of ART (B) to be given to a feasible number of clients (A) and because this would be affordable within the constraints of current public health spending. Current HIV expenditure is R5 - 8 billion per annum.[21]

Programme design (B)

In order for this budget to provide treatment to as many as possible, B was configured in such a way as to minimise the cost-ineffective components of ART. Expensive laboratory tests were foregone, generic drugs were used instead of patent drugs and in the baseline scenario, ART was limited to a single tier of triple therapy. This brought the costs per patient per year down to R5 700. ART was also offered only to those in stage IV. Many of these choices are very difficult to make. Both limiting ART to a single tier of therapy and limiting it to persons entering stage IV means offering each person with AIDS a less than optimal form of ART. These steps do, however, go a long way to ensuring that the limited budget can provide ART to enough persons to make the programme feasible.

Most existing ART programmes are designed in such a way that applicants for ART must pass through a selection process. In the Medisins Sans Frontieres (MSF) Khayelitsha project for example, biological and social criteria are used to select patients. Despite being able to provide ART to just 4% of the persons with AIDS in Khayelitsha, the programme is not massively oversubscribed. The determination of how stringent these criteria are, therefore, offers a further way of controlling A (numbers on treatment). This is just one further example of the importance of balancing these different dimensions using an iterative approach.

Issues emerging from a pragmatic iterative approach to rationing ART

Human rights response to rationing

The proposed approach to rationing must comply with the imperatives of the South African Constitution, and in particular the right of access to health care services. The latter right is expressly qualified by the availability of resources and subject to progressive realisation. This provision has been applied by the courts in the Soobramoney and Treatment Action Campaign cases. The court's reasoning in these cases indicates that the scarcity of resources as well as the context within which health care services are rendered necessitates some form of rationing. The court did note that the way the state rations services must address the needs of the most marginalised. In addition, it has interpreted the right to health to mean progressive realisation over time. The rationing mechanisms proposed in this paper are likely to accord with this standard.

Importance of broader societal acceptance of value judgements

It would be misleading to suggest that such a complex question as the makeup of a national AIDS programme could be solved by a technocratic rationing mechanism alone. Many of the decisions involve difficult value and technical judgements. An example of such value judgements is the choice between treating a smaller number of persons with a two-tier arsenal of therapy and treating a greater number of persons with a single tier of ARVs (where the total benefit per person would be less). The latter option was ultimately favoured as this would benefit more persons (and hence confer greater equity) and was more cost-effective (i.e. resulted in a greater number of life-years gained per amount spent) than the two-tier option. Many of the value judgements implicit in these

assumptions may however be at odds with those of the general populace. A central element of the decision-making process should therefore be ensuring that all role players participate in the process.

Conclusion — to accept that ART is unaffordable to poor countries is to accept the deepening of the system of global apartheid

ART has been proved to be highly effective in prolonging the lives of persons with AIDS. It is in addition a vital component of the treatment programme so necessary to affect the population level shifts in how this disease is perceived. At First-World prices, however, it remains too expensive for general roll-out in developing countries. Public health needs to develop a new methodology for rationing in resource-poor settings which allows for a comprehensive response (including ART) to challenges such as the one illustrated by HIV/AIDS in many poor countries, while taking cognisance of the global changes that have brought this situation about. The tentative outline of one such methodology has been presented here in response to the all-or-nothing approaches that have characterised debates on ART.

The relevance of developing novel approaches to resource allocation mechanism is unlikely to be limited to ART. HIV is but one of 30 infectious diseases that have emerged in the last 25 years, the majority of which place their greatest burden on the poor.[22] Our response to ART could therefore be crucial in determining how we allow the global political economy to unfold with regard to differential access to new therapies.

The differential access to ART is a marker of the enormity of the inequalities that have built up. Promoting access to ART should therefore not be limited to wringing price concessions out of pharmaceutical companies, but should be done in a way that highlights the shortcomings of a system that has placed such a large proportion of the global populace in a position of extreme vulnerability to the human immunodeficiency virus and cut them off from access to treatment. ART provides us with an opportunity to expose the effects of this system to those with the power to change it. To accept that drug companies should be able to set the prices of life-saving medications as they see fit and the consequent view that ART is unaffordable to poor countries is to accept the deepening of the system of global apartheid.

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