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**Scaling-up anti-retroviral treatment (ART)
& the health system in Southern Africa**

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Introduction

After field visits to several countries in Southern Africa, where I visited hospitals and health centres delivering ART, I have some impressions and thoughts to share. First, on the effect of ART for patients and families. Second, on the lessons learnt from pilot projects. Third, on the relation between ART scale-up and the health system.

I would like to stress that these impressions and thoughts apply to Southern Africa, where countries face a 12 to 40% adult HIV sero-prevalence, and a serious crisis in the field of human resources for health. One should be cautious not to extrapolate them to countries with much lower HIV sero-prevalence or different human resource situations. Southern Africa also covers a relatively wide range of situations with South-Africa & Botswana at one end (richer, better developed health system) and Malawi & Mozambique at the other end (much poorer, much weaker health systems). One should constantly bear in mind this diversity.

Initially, ART has mainly been delivered through a mixture of public and private provision, with NGO provision (e.g. by Médecins Sans Frontières) predominant in several countries of Southern Africa. However, NGOs mainly started pilot projects, and population coverage through such approach is likely to remain relatively limited. The main plans for scaling-up ART to a sizable proportion of the population, are largely based on public provision, often funded by the Global

Fund to fight AIDS, TB and Malaria, or the US President's Emergency Plan for AIDS Relief (PEPFAR).

Lessons learnt from pilot ART projects

Here we focus on lessons learnt (1) from the patients perspective, & (2) from the perspective of health services. We then discuss their implications for the scaling-up drive.

(1) From the patient perspective

There is no doubt that for most AIDS patients having access to anti-retroviral treatment (ART) has a very positive impact. Most people adhere well to their treatment, and most recover their health often in quite a spectacular way. As ART is relatively new, it is unknown how long people will remain well on ART. In Europe and the US, it is now estimated that people will be perhaps 20 years on ART. In South Africa the official estimate used for their treatment plan is that people will remain on average 4 years on ART, but it seems quite likely that this will be much longer. Ten years seems quite a realistic estimate for people who receive a correct combination of three drugs. This supposes that supply of these drugs is reliable, that preferably fixed-dose combinations are used (3-in-1 pills) and that provision is free, or almost free. If these conditions are met, outcomes for patients are really very good, with over 90% of patients surviving after one year. Recovering their health and resuming economic activity, it seems quite reasonable to assume that their households become less vulnerable, that they support their children and maintain them in school. For people already infected with HIV, provision of ART seems the most important strategy to improve their fate.

(2) From the perspective of the health services

Here I would like to comment on treatment regimen, on the need for laboratory monitoring, on the staffing needs, and on the cost.

On the treatment regimen and the need for laboratory monitoring:

The need for laboratory monitoring of patients is still a matter of intensive debate. From the diversity of opinions and experiences, I have a personal impression that it can be fully justified to limit laboratory monitoring to an absolute minimum, or even to abolish it (as many treatment centres in Malawi are doing). This is quite a technical discussion, in which I want just to mention two elements: (1) it is not proven in low-income countries that laboratory monitoring translates into better patient outcomes as compared to little or no laboratory monitoring; and (2) upgrading laboratories and training laboratory technicians is a huge challenge, and requiring improved laboratory monitoring for all patients will, without doubt, slow down considerably scale-up of ART. Most people remain well on first-line treatment. The need for second-line treatments has been overestimated. How many years this will last is unknown for the moment. I personally also think that potential problems of drug resistance are a bit overstated.

On staffing needs:

ART as it is delivered now in pilot projects is quite labour intensive. Doctors or clinical officers see patients periodically, with a variety of other health care workers also involved in the treatment. In South Africa it is estimated that for 500 patients on ART, they need as many as 10 permanent staff (1 doctor, 2 nurses, 5 counsellors, a lab technician, and others). Most pilot projects have indeed similar staff/patient ratios. It is quite obvious that most countries in Southern Africa simply do not have the human resources to provide these services in such a labour-intensive way.

On cost:

Economic evaluations of pilot projects reveal that ART remains relatively expensive. In most estimations the cost of medicines is the most important cost item, even after the steep falls in prices of antiretroviral medicines (from US\$10,000 per person per year, to now US\$120 per person per year for the simplest triple combination treatment from generic producers in India). There are conflicting interpretations of how prices will, or will not, move in the future. Some

people predict a further fall to US\$50-60, others claim that prices are unrealistically low, and will rather increase. The cost for laboratory monitoring varies enormously, depending on the number of tests, and the type of equipment.

In its most simplified version at US\$200 or \$300 per patient per year, ART is considerably more expensive than any other medical treatment being delivered at a large scale in developing countries (as a comparison: medicines for tuberculosis cost approximately US\$10 to 15 for a 6 month course). For Malawi or Mozambique, an ART program reaching 30 or 50 % of coverage, will cost tens of millions of dollars per year (which translates in several dollars per inhabitant per year); thus considerably increasing total health expenditure in these countries. Currently, almost the totality of these costs is funded by Global Fund, PEPFAR, World Bank, and other ODA sources. There is little or no prospect that this will change in the foreseeable future.

Further observations

Growing caseloads are under-estimated. The enormous build up of people who will need periodic contact with health services is still underestimated and needs consideration.

E.g. in Malawi, there are approximately 1,000,000 HIV + people; approximately 10 %, or 100,000 of them, will need to be started on ART annually. Malawi's national plan aims at including half of these or 50,000 per year, in the nationwide ART program. Within 10 years, if good adherence and good outcomes are confirmed, between 300,000 and 400,000 will be on ART; and in need of regular follow-up, with caseload still growing.

Such huge caseload is totally unprecedented for health systems in developing countries. All scenarios presently discussed seem to be considerably under estimating the size of the job to be faced in the medium term.

Providing a new technology (ARV drugs or ARVs) in weak and unregulated environments. ARVs are expensive and could 'leak' out of the standard health system. ARVs are unlikely to be used in the right way without an organised system, and would then be ineffective. There are also fears that fake, substandard or expired ARVs may become available in the private market. ('Production sites' of ARVs are mushrooming in a number of countries with weak regulatory systems, while there are real quality issues with ARVs).

How to deal with this? Three measures seem most promising:

- (1) Use as much as possible 3-in-1 pills (fixed-dose combinations, FDCs), which are much easier to use well;
- (2) Large-scale availability of ARVs through public provision at no cost would considerably reduce attractiveness of parallel markets; and
- (3) Treatment literacy campaigns, so people understand the issues. Here there is great potential, which is little used, for using patients on life-long treatment as experts.

Human Resources for Health (HRH) crisis. Most countries in Southern Africa are currently facing real HRH challenges. In countries such as Zambia, Swaziland and Malawi attrition rates among health workers in the public sector are increasing, due to the combined effects of brain drain and AIDS, and some sources fear that the total number of health workers in public service is actually decreasing in these countries. And this anticipated decrease comes at the very moment that the very ambitious ART scale-up is being planned. 'Who will do the job?'

Implications of lessons learnt for scaling-up drive:

We distinguish the implications of these lessons (1) for financing of ART scale-up; (2) for human resource issues in the health sector (HRH); & (3) for ART delivery models.

- (1) Financing of ART scale-up. The costs of ART scale-up will continue to rise over many years to come, mainly due to the growing caseloads of people on ART. Foreign aid seems the only realistic funding source for the poorest countries. Countries as South Africa and Botswana can pay a large share of the cost themselves.

- (2) HRH issues will need more attention. Better retention and more intake in training institutions, will have to be combined to reverse the present situation. However, this seems to be quite complicated, as many forces converge to weaken the attractiveness of the public sector, as compared to other employment opportunities.
- (3) ART delivery models will have to be adapted to the HRH situation and the growing caseloads. This may involve delegating tasks from doctors to clinical officers and nurses (task shifting), combined with further simplification of treatment models. This may also involve the creation of new cadres of staff, such as counsellors. What is still little explored is the potential for a larger role of patients themselves. Maybe lessons could be learnt from the UK experience of expert patients in chronic diseases, such as diabetes.

What is likely going to happen? Impact on health systems

We distinguish four possible scenarios: two are rather pessimistic and two are more optimistic. In scenario 1, no fundamental changes occur in either the field of HRH or in the ART delivery models, or in the wider health system. In scenario 2, no fundamental changes occur neither, but ART monopolises a growing share of HRH thus weakening the non-ART part of the health system. In scenario 3, enough resources can be mobilised and they are used to strengthen the entire health system. In scenario 4, ART is scaled up but using radically different ART delivery models, using mainly new specially created cadres. Each of these options is worked out in some more detail.

Scenario 1: No fundamental changes.

The current doctor-intensive ART delivery models remain the dominant ART delivery model and no fundamental changes occur in the number of HRH available. In such scenario, the number of slots for ART available will remain quite limited. The existing ‘pilot’ projects may be replicated here and there, but the number of people under treatment at each site will remain relatively limited, as the HRH constraints will not allow doing otherwise. Through experience the staff delivering ART may make some gains in efficiency, and doctors may be able to see more patients per month. However, this may not result in larger numbers of new treatment slots, because of the build-up of an ever growing caseload of patients on ART needing long-term follow-up. In such scenario, the coverage of ART is likely to stall at 10% or 20%, far below the ‘3 by 5’ targets in countries with limited stocks of highly skilled HRH (such as Mozambique, Malawi and Zambia). In such environment, it is likely that implicit rationing systems, such as queuing will be the dominant mode of selection between those getting access to ART and those deprived of ART. It also seems likely that large numbers of people needing ART, but not able to access ART through the formal health system, will create opportunities for unregulated markets in ARVs to emerge.

Scenario 2: ART gets priority, but within existing frames.

Also in this scenario there is neither fundamental change to the ART delivery models, nor to the HRH base. But, ART scale up gets increased funding and priority. Extra money will become available, but this money will be earmarked for AIDS, and ART delivery will be expanded. This may lead to a situation where ART will attract most of the new doctors and nurses being graduated, or even attract HRH away from other programmes. As the HRH turn-over in the rest of the health system will continue, this could effectively lead to weaken the rest of the health system. (Although it would be difficult to distinguish between the very impact of AIDS, that definitely is weakening health systems in countries with the highest HIV prevalence, and the possible additional impact of AIDS programmes). Fears that ART scale-up may effectively monopolise not only financial resources, but also HRH, has been voiced already. These effects are then variably called that ART “may divert resources”, or “create distortions” in the health system.

Scenario 3: ART scale-up strengthens overall health system.

A more optimistic scenario is that scaling-up ART will reveal the weaknesses in the health systems, and that the increased resources becoming available will allow for fundamentally tackling bottlenecks in the wider health system. HRH will get sufficient attention, and the national HRH base will be strengthened, not only for ART, but for all essential services. Drug supply will become more reliable, not only for ARV drugs, but for all essential commodities. For such changes to happen, it is essential that a health systems view becomes dominant in ART scale-up, and this with a long-term vision.

Seen the enormous needs being created by all aspects of ART and the sheer scale of the challenge, including the enormous build-up of patients on ART needing lifelong follow-up, this would require very considerable investment over a long period of time. Such investment in the health system would require both domestic resources and donor resources. It would also require that IMF and World Bank ease their ceilings on public spending, especially for the health sector. This would necessarily lead to a fast growth in health care expenditure, much faster than growth in the overall economy. Health sector expenditure, as percentage of gross domestic product would thus increase. It seems likely that such increases would need to be substantial; not just a few percentage-points, but in the poorest countries, such as Malawi or Mozambique, at least a doubling or tripling of health budgets would be needed. Under such scenario countries of Southern Africa would soon be spending 10%, 15%, or even more of their GDP for their health sector.

Scenario 4: Radical change in ART delivery model

A last scenario is that countries hardest hit, with the weakest HRH base, wanting to scale up ART and to maintain large cohorts of people on ART, will realise that a more radical rethink of ART delivery models is needed. Within such scenario, we can think of two relatively different options. A first option, involving a high degree of standardisation and codification; and a second option, using a new approach centred around expert patients.

The first option is to break with the current patient-centred ART delivery model, heavily relying on counselling and individualised follow-up. Many elements of AIDS care, from VCT over staging of patients and ART follow-up should then be standardised and codified in simple protocols. Many staff will then have to be trained for executing specific tasks, with strict supervision and quality control. Such approach could take inspiration from the current approach in many TB treatment programmes. In its early years, TB treatment was in the hands of specialised TB physicians, but progressively it was realised that case-finding and treatment could be standardised to a great extent and subsequently delegated to auxiliary staff who are trained to strictly adhere to guidelines. Auxiliary staff is regularly supervised, or inspected, to check whether they comply with guidelines. Patients are supposed to adhere strictly to the instructions. More recently this approach was brought still a step further with directly observed treatment, where adherence to treatment is strictly controlled by staff. One could imagine ART following a similar track. But ART involves many more steps and tasks than TB treatment. Important differences are that (i) not all HIV+ people need treatment yet, but need regular follow-up before the threshold for treatment is reached; and (ii) that ART can not be reduced to a short course, but is life-long.

Such more mechanistic approach would require a fundamental change in mentality in ART programmes. It would require a huge 'army' of ART staff, but most of them could be relatively low skilled. Such approach would also require acceptance that although a majority of AIDS patients may fit in, others may not. Indeed, while tasks for 'simple' or 'standard' patients can readily be standardised, this seems much more difficult for patients with very advanced disease and/or complicated opportunistic infections, patients with prior use of non-standard ARV regimens, or patients with apparent treatment failure under ART. Such patients may still need non-standardised medical care, which may still require highly qualified HRH. Alternatively it could be decided to prioritise the patients that fit in the standard approach, and accept that the others have to forego treatment. Similar choices have been made in TB treatment, where smear-negative patients have not been prioritised (or neglected, in other words).

The second option builds on the potential of ART delivery models based in the community and centred around the HIV positive people themselves with minimal reliance on medical professionals. Such patient-centred approach would also go much further in task-shifting, but without the strict standardisation and mechanisation of the previous option. It would make extensive use of lay providers or expert patients; and this not only in support functions but also for tasks up to now reserved for doctors and nurses. The concept of expert patients is being promoted for chronic diseases in the UK, and in some other countries. One of the basic ideas behind this concept is that among all the patients living with a chronic disease, a number of them can be trained to function as health care providers for their peers. It is thought that through his or her personal experience of living with the disease, the peer provider, or expert patient, has an added value as compared to a doctor or nurse, who are mainly experts in the medical-technical dimensions of the disease. Till now, relatively little evidence exists on the use of this approach in AIDS patients, and this despite almost a decade-long call for “Greater Involvement of People living with AIDS” (GIPA). But, as AIDS is a chronic life-long disease affecting large numbers of patients, it seems *a priori* that such approach may have real relevance and potential.

Both options have in common that they entail a de-professionalisation, or at least a de-medicalisation, of ART. This would fundamentally change the doctor-patient relationship. In the first option, the bulk of the work would be done by armies of relatively low qualified ART staff, trained to execute standard instructions, with a minimum of flexibility and creativity. In the second option, lay providers or expert patients would take on most of the work. Such approaches are relatively radical departures from the current models, and would require fundamental changes in the way the medical professions are seen and regulated.

Which scenario? Where?

It seems that decisive action to turn the tide in AIDS will need fundamental changes in the health systems of the countries of Southern Africa. Whether no effective large-scale ART programmes will be created (scenario 1); or ART programmes will monopolise resources and weaken the wider health system (scenario 2); or current health systems will be enormously strengthened, requiring a far larger share of society’s resources (scenario 3); or radically new ART delivery models will be rolled-out on a large scale (scenario 4); will occur, will depend on the complex interplay of transitions ongoing in the local context and on reforms being introduced. Most likely is that in every country an idiosyncratic mix with elements from the different scenarios will operate, depending on the resource constraints, strategies within pilot projects, role of policy makers, professional bodies, regulatory frames, funding and market forces. But what is most unlikely is that “business as usual” will continue and reach the ambitious objectives of universal access to ART.