# Planning the incorporation of antiretroviral therapy into comprehensive care programmes

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Preliminary findings from the introduction of antiretroviral (ARV) therapy in district-based comprehensive HIV care services in highly affected countries in Africa suggest that such an approach is both acceptable and feasible. Results in adherence rates, for example, are comparable to what is found in Asia/Pacific, the Americas and Europe[1]. To date, ARV therapy interventions have been small scale, because only a very few people could afford the ARV drugs, because the particular project was targeted for a pre-determined catchment area of a health unit and was heavily subsidized, or because it was implemented in a low-prevalence country[1].

With the price of ARV drugs decreasing, thus making the drugs more affordable for programmes and clients, programme managers and health planners need to consider a number of planning questions in order to design scaled up services while ensuring sustainability and feasibility within current health systems. This paper responds to the following four questions:

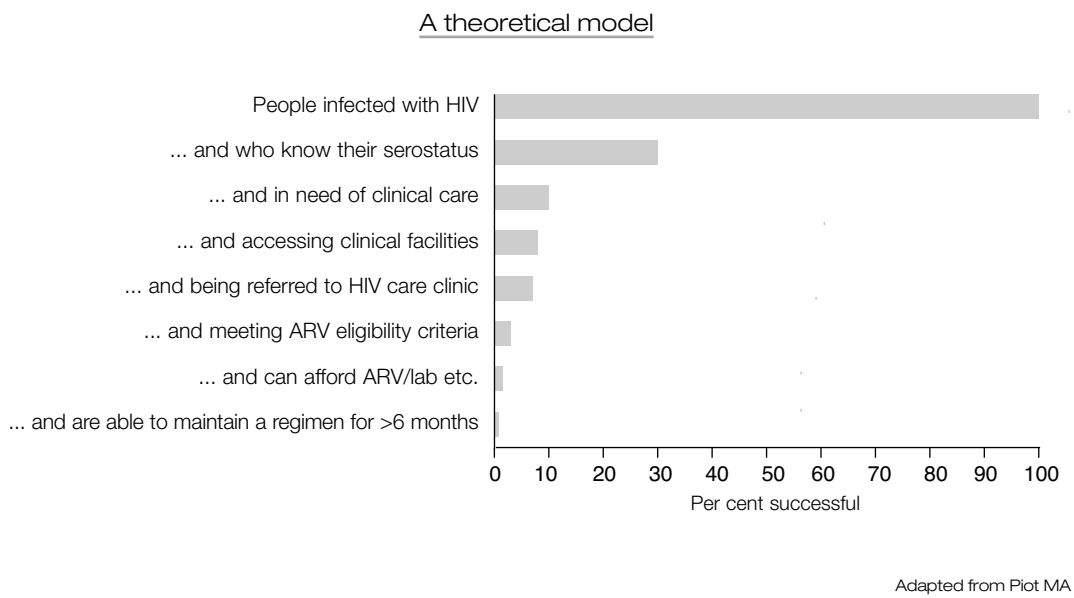
1. What are the expected numbers of patients to benefit from the interventions?
2. Will standardization of the interventions be able to obtain the minimally required resources (financial/technical/human) to meet current and expected demands?
3. What can be done to involve communities in the expansion and replication process?
4. How would a simple and sound monitoring and evaluation framework allow rapid learning from the interventions?

## Question 1

***What are the expected numbers of patients to benefit from the interventions?***

In order to plan adequately for the demands for HIV care when introducing ARV therapy (e.g. drug quantities, personnel, space, laboratory and other support services), the current and expected HIV care-seeking behaviour of the communities and the capacity and quality of current health care facilities must be considered. The following operational access-benefit model developed by MA Piot for tuberculosis (TB) in the 1980s (more recently it was also used extensively in regard to sexually transmitted infections (STIs)) looks at the cascade of coverage levels at the various stages of interaction between HIV-positive clients and the health system (Figure 1). Planning quality services will require addressing the barriers hindering access including stigma, costs and the current fragile state of public and not-for-profit health service provision. Other barriers are tied to public perceptions and require communication and education efforts at community levels. Finally, there are factors limiting coverage inherent to

FIGURE 1: Estimating the current coverage for ARV therapy

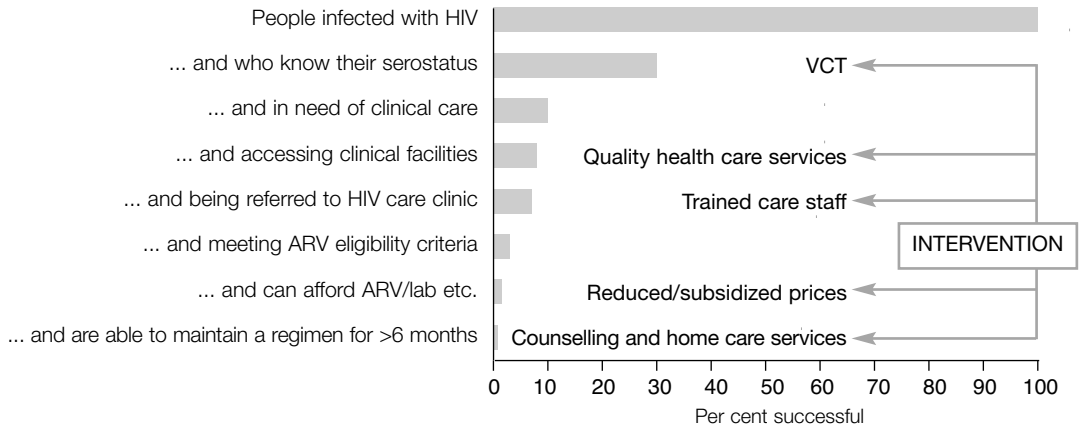



Adapted from Piot MA

the natural history of HIV infection and to the pharmacological profile of the currently available drugs. For example, few HIV-infected people have access to services where they can learn their serostatus, and an estimated one third of those infected are symptomatic in countries with advanced epidemics[2]. A proportion of them have access to medical care and a smaller proportion to HIV skilled care. Only a small proportion of HIV-infected persons will meet clinical and laboratory eligibility criteria for ARV therapy[3], and only some of the "eligible" HIV-infected will be able to afford the current prices of drugs and laboratory services. Of those, a proportion will be able to tolerate and adhere to a given regimen during a minimum period of drug-taking to fully benefit from the intervention.

To address the decreasing access between the different functional stages of the model, effective and feasible interventions within HIV care programmes have been developed over the last ten years in Africa (Figure 2). Comprehensive HIV care and support services are essential to enhance access to ARV therapy and ensure that those eligible and those non-eligible for whatever reason can benefit from care and support. For example, those not fulfilling eligibility criteria for ARV therapy, such as those with concurrent opportunistic infections requiring treatment for opportunistic infections prior to ARV therapy (e.g. TB and meningitis), those who cannot tolerate or are not able to maintain ARV therapy, those with terminal illness or those who no longer respond to the available regimen, will all need HIV care and support. ARV therapy thus can only complement ongoing HIV care and support services and will not replace the need to prevent and manage opportunistic infections or provide home care. The package of these comprehensive HIV care elements (voluntary testing and counselling (VCT), strengthened HIV medical and nursing management, preventive therapies, TB prevention and control, nutritional support, follow-up psychological and social support, palliative care, home care) has been recognized as essential by many national HIV

FIGURE 2: Estimating the coverage for ARV therapy




strategies in Africa. Nonetheless, there is still a long way to go to reach all those in need. For example, service coverage and access at all stages of the model are much lower for women and children[4]. There remains an urgent need to implement a comprehensive strategy and HIV care programmes that ensure benefits to all those in need.

## Question 2

***Will standardization of the interventions be able to obtain the minimally required resources (financial/technical/human) to meet current and expected demands?***

Meeting current demands and scaling up for a nationwide coverage require a systematic planning approach where as many care providers as possible can rapidly and safely acquire the skills to implement these interventions in a safe and effective way. Lessons have been learned from effective implementation of nationwide TB control programmes using standardized approaches. For ARV therapy this will require that some national standards should be set on what a first- or second-line regimen should be, on the eligibility criteria for starting ARV therapy and on what criteria to use for patient monitoring. Only through the setting of national standards, can public or institutional health planners and administrators negotiate better price deals through, for example, bulk purchases, more rapid training of mid-level clinical personnel using standard clinical management protocols, and a more consistent and easier monitoring and evaluation system to quickly learn from what is being practised, so as to effectively plan for the future.

Setting norms and national standards for HIV care are also necessary for testing and counselling, for good clinical practices, standard operational procedures for infection control, for home care and for the safe and effective use of ARV therapy. This may involve the creation of regulations which may not be immediately accepted, in particular by the private sector

where the bulk of ARV prescriptions currently take place. Hence the need for continuous advocacy and explanation of the benefits that will result from such implementation still exists. At the institutional level, standardizing clinical and nursing practices is also essential to assist in planning the mobilization of local resources as well as for coordination between different partners involved in HIV care and ARV therapy.

The following interventions benefit from such standardization and need to be operational in order to allow rapid scaling up to ensure optimal benefits for clients in need of HIV care and ARV therapy.

- VCT, including for diagnostic purposes.
- Primary care and home care services with functional referral networks.
- Comprehensive HIV care, including opportunistic infections management (prevention and treatment), TB directly observed therapies (DOTs), palliation and nursing care (e.g. nutrition, universal precautions, support).
- Capacity for ARV therapy management: trained staff, drugs and commodity management, space and appropriate laboratory support.
- Client follow-up systems and other adherence-enhancing measures (e.g. counselling, DOTs, family members, etc.)

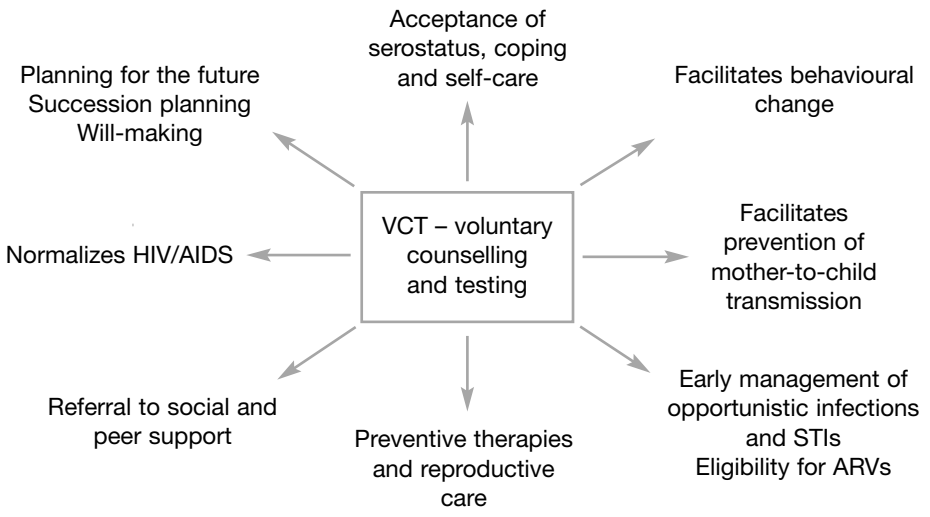
This does not mean that all of these interventions are prerequisites before starting ARV therapy, as this would be both unrealistic and lead to unacceptable delays. Indeed, it simply means that these interventions need to be strengthened, or developed at the same time as ARV drugs are introduced. As Jonathan Mann said while establishing the Global Programme on AIDS in the World Health Organization (WHO) in 1986, "One builds the ship while sailing".

*VCT for HIV and follow-up counselling for coping, disclosure and drug adherence*

Counselling and testing is not only an effective prevention, care and support intervention aimed at the public in general, but an essential first step in the diagnostic process for people with suspected HIV-related illness (Figure 3). Therefore, collaboration is needed between those who diagnose and manage HIV-related illnesses and those who manage VCT services. Patient consent and involvement as part of the diagnostic process ensures better coping and results in increased HIV clinic attendance in both sophisticated and non-sophisticated settings[5]. Good collaboration between counsellors and clinicians creates efficiency and enables diagnosis at an earlier stage of disease, allowing more people living with HIV/AIDS to access screening for eligibility to start ARV therapy. Follow-up counselling to address coping and the client/patient's readiness to disclose serostatus to a significant other is crucial in order to enhance adherence. It is here where the lessons learned from the directly observed therapy model for TB could be adapted and made applicable to the specific challenges of ARV therapy drug adherence. The extensive demands of the regimen, more than once a day treatment for life, will also need to be addressed by client, pharmacist and care provider. Observed treatment at intervals and/or support by a relative or a community member chosen by the client are suggestions of modalities to be examined.

A small but increasing number of countries now have national VCT programmes and standardized HIV testing regimens. The number of sites where VCT services are available either as stand-alone centres, or integrated into health and clinical services, is rapidly growing.

FIGURE 3: VCT – an important entry point for HIV prevention and care




Adapted from WHO (2000)

For example, in Kenya in 1998 there were only four established VCT sites, yet in mid-2002, 49 sites are operating, both in the public and not-for-profit sectors[6]. Manuals and guidelines on how to plan and scale up VCT services are available from numerous organizations including WHO, the Centers for Disease Control and Prevention (CDC) and Family Health International (FHI).

*Strengthen primary care services to recognize and manage early HIV-related illnesses*

Late recognition of HIV-related illness by clinicians at peripheral care levels is a very common complaint made by district health managers in many countries. Lack of clinical skills in HIV management, the reluctance of clinicians to go through the diagnostic process, and the late care-seeking and initial unpreparedness of patients to cope with an HIV diagnosis, are all issues that need to be addressed. Stigmatization is particularly pervasive and needs to be explicitly addressed in both health institutions and communities in order to maximize the scaling up of services. Addressing stigma has proven to be difficult even in areas with readily available and free ARV drugs[5]. Attitudes and practices of health care providers in general care need to be improved through appropriate policies, peer pressure, peer example-setting, support for staff burn-out, training and addressing fears among providers. In-service training as well as basic training at the current medical, nursing and paramedical schools is an intervention that should be considered immediately. Furthermore, adhering to infectious control principles, regular supplies of protective materials and provision of post-exposure prophylaxis can be organized and managed relatively easily. Providing psychosocial support for people with chronic illnesses as a routine service in an institution is another way to normalize HIV. So far these approaches are still relatively rare.

*Training staff and organizing the health and laboratory services for ARV therapy management: standard procedures, drug management and regulation*

HIV management with ARV drugs is not simple but is feasible at mid-level district hospitals in resource-poor settings, as has been shown in South Africa, Kenya, Uganda and Senegal. The rapidly evolving research and expertise in ARV therapy, clinical and laboratory monitoring require continuous learning. Ease of administration, drug tolerance, side-effects and the development of antiviral resistance are issues well known in the use of antibiotics in general, but are more complex for the currently available ARV drugs. Training materials are rapidly becoming available for resource-constrained settings[7]. National ARV therapy specific guidelines, or HIV clinical management guidelines including ARV therapy, are being developed rapidly in most countries in sub-Saharan Africa, although these guidelines often reflect the individual and non-standardized clinical use of ARV drug regimens in the United States or Europe. Since they cannot be directly applied to resource-limited settings and situations with different clinical presentation and health care management of HIV disease, attention should be given to their appropriate adaptation in the local circumstances of developing countries.

Reliable laboratory support to diagnose HIV and common opportunistic infections, to determine biological eligibility for ARV therapy, to monitor side-effects and effectiveness, is another essential function of an HIV clinic. Building the necessary laboratory infrastructure and capacity will require substantial financial and technical resources. This may be based on the example of Brazil's experience of rapidly building a capacity of 44 laboratories nationwide to provide additional virological monitoring. Furthermore, alternatives do exist which focus on more cost-effective approaches that may speed scaling up without losing effectiveness. For example, restricting viral load testing to national academic sites for research purposes and implementing CD4 alternatives using light microscopy will allow many more eligible patients to afford ARV therapy. Many experts in HIV research and care are now supporting simplified monitoring procedures and developing mechanisms to rapidly avail these techniques to resource-poor settings[8].

Presently, the management of drug selection, supplies, storage and distribution, together with the development of necessary regulations to avoid stock-outs, spoilage and unauthorized use, is being pinpointed as critical by health care managers in considering the incorporation of ARV therapy in HIV care. Guidance in drug management in these areas has been developed[9] but experiences in applying and scaling up these particular activities in resource-poor settings is still limited.

## Question 3

***What can be done to involve communities in the expansion and replication process?***

The growing availability of affordable ARV drugs raises public expectations of a cure far beyond the current ability to substantially reduce morbidity and mortality. A quick look through the common daily newspapers in Anglophone and Francophone Africa makes the reader believe that a cure is nearby for all those infected. This perception will affect any HIV care site offering ARV therapy, as inevitably the clinics will have to refuse this treatment to patients who do not meet ARV therapy eligibility criteria. Addressing a sense of realism is required, while at the same time ensuring a steady increase in the safe and effective use of ARV therapy, as well as joint decision-making at the individual (i.e. the care team, including the patient) and community levels. Providers of traditional health care (e.g. healers, herbalists and

others) have a key role in community care-seeking behaviour and also need to be involved in information programmes. Similarly, the private clinics and laboratories often already involved in prescribing ARV therapy need to be involved in communicating to communities realistic expectations of ARV therapy. Here the role of people living with HIV/AIDS (PLWHA) becomes paramount. In Uganda, PLWHA involvement has guided and assisted ARV therapy projects, which has been well appreciated. PLWHA groups have worked with individuals seeking diagnosis or disclosing their serostatus, have provided clients with referral to numerous support groups, and have worked on advocating and educating PLWHA and the public in setting realistic expectations about what comprehensive care and ARV therapy can achieve. Furthermore, working with the media, in particular local radio stations and daily newspapers, and working in national and local languages is an essential element in any programme where ARVs are being introduced or scaled up. Mechanisms for this exist within National AIDS Control Programmes and Councils insofar as media training is incorporated in most national HIV/AIDS strategies.

### Question 4

***How would a simple and sound monitoring and evaluation framework allow rapid learning from the interventions?***

Moving from small to larger-scale programmes can only be successful if lessons are learnt quickly from the immediate results of such an implementation. Hence, there is a crucial need for careful monitoring and evaluation to identify and correct inefficiencies, obstacles and adverse effects from programmes in the field. Monitoring and evaluation should also address feasibility, costs and the role the programme has within a comprehensive care approach, while operational studies could address various modalities in implementing drug adherence approaches. Specific studies may be needed to provide a greater insight about the effects and impact on prevention and on the health services in general. The primary aim of this kind of operational or intervention development research is to assist programme implementers and care teams (carers and patients) to do a more efficient job in a more cost-effective way. Therefore, there is a need to involve programme managers, clinicians and clients, combined with rapid data analysis, in order to develop specific plans to use evaluation results in modifying the programme implementation.

Checklists for monitoring, tabulation and rapid analysis, as well as indicators to determine trends over time, need to be developed to measure progress. Complementary quantitative and qualitative operational studies also need to be put in place to fully understand what is happening and why. There is a challenge for ARV therapy programmes to balance monitoring through a strengthened ongoing health information management system and meeting the need for careful and specific monitoring and evaluation of the ARV therapy intervention in order to learn quickly and scale up HIV-related care activities.

## Intervention-linked research

Following the planning process by addressing the above questions, some important operational research questions will evolve which need to be incorporated in the design of a scaled up ARV therapy programme. These questions may include the following:

1 What will the trends in demand be over time for the different infection/disease stages in accessing testing, VCT and care services?

2 How will an ARV therapy programme affect stigmatization?
3 What will the effect of HIV care with ARV therapy be on the health institutions and community in regard to prevention practices and programmes?
4 What are the determinants of adherence to ARV therapy and what is necessary to develop sustainable adherence practices?
5 What community and home care models are relevant in order to support HIV care/ARV therapy programmes?
6 Which entry points (or combination of) for HIV care/ARV therapy are most efficient, acceptable, effective and feasible (e.g. mother-to-child transmission, VCT, STI, TB, general outpatient and HIV clinics, etc.)?
7 What models of VCT for accessing ARV therapy will ensure normalization and respect confidentiality, while being feasible within current health systems?
8 How will ARV drug management affect essential TB, STI and other drug management programmes at site level?
9 How will workload and time flows be affected at various clinical service points?
10 What is the balance between integrated and vertical ARV therapy services vis-à-vis quality, sustainability, ownership and acceptance?
11 How can national standards evolve as new drugs, diagnostics and other information become available?
12 What is an affordable household expenditure for HIV care with ARV therapy?
13 How can HIV care/ARV therapy programmes be made accessible to children given the various specific requirements: drug formulations, eligibility, adherence and disclosure, clinical monitoring, etc.?

**NOTES AND REFERENCES**

1 This has been shown in Médicins Sans Frontières (MSF) projects in seven countries, including Homa Bay, Kenya and Khayelitsha, South Africa; the national ARV programme in Senegal and the UNAIDS access to ARV pilot projects in Uganda and Côte d'Ivoire.

2 WHO/UNAIDS (2001) AIDS epidemic update, December 2001. Geneva.

3 See the MSF eligibility social criteria for Homa Bay, Kenya and Khayelitsha, South Africa in MSF Guidelines for ART, access@geneva.msf.org and the US and European criteria in "Panel on clinical practice for treatment of HIV infection, US Department of Health and Human Services" and the Henry J Kaiser Foundation (2000) www.hivatis.org; Recommendations of the International AIDS Society (IAS) (2000) *Journal of the American Medical Association*, 283, no.3.

4 To illustrate the possible uptake for ARV therapy at antenatal clinic sites in heavily affected Rakai district in Uganda, it was found that among the HIV-positive pregnant women only 14.6% had more than 55 000 viral RNA cps/ul and would have met the US standard viral load criteria to be eligible for ARV therapy (Rosenfield, Columbia University, personal communication).

5 Friedland GH (1997) Adherence: the Achilles' heel of HAART, improving the management of HIV disease. *Newsletter of the International AIDS Society* 5: 13-15 and: Friedland GH, Williams A (1999) Attaining higher goals in HIV treatment: the central importance of adherence. *AIDS*, 13(Suppl 1):S61-72; Katabira E, Uganda, personal communication; HRSA-Whitman Walker clinics USA; Paris HIV clinics, Agence Nationale de Recherche sur le SIDA, ANRS.

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