

Module 3

ARV Treatments: planning and integration into health services

The following module provides guidance for planners, managers and HIV care providers in resource constraints settings who may be introducing antiretroviral (ARV) treatments in their services or in situations where ARV treatments are currently available, such as the private sector.

Before setting up ARV services key planning questions need to be addressed. A framework for these questions is provided in Table 1, which summarise decision options. The organisation of interventions with ARV treatments is discussed in section II, quality management in III, access to ARV treatment in IV, and the creation of information systems is discussed in section V. Section VI addresses the need for partnerships to ensure sustainability and section VII focuses on monitoring and reporting.

I. Introduction

The incorporation of ARVs into existing health care services, in a safe and effective manner, is challenging; as is securing sustainable financing of such interventions.

Key issues to be addressed before introducing ARV treatment into existing health systems include: establishing laboratory capacity, as well as mechanisms to control drug supply; assuring quality management; informing the public about the benefits and implications of ARV interventions; providing training and assuring an adequate number of health care and support staff.

Characteristics, specific to ARV interventions, require that these issues be resolved promptly:

- ARV drugs are particularly high-value items; therefore, regulatory mechanisms must be secured to avoid misuse or misappropriation.
- ARV treatments are complex to use and monitor.
- ARVs can easily be inappropriately prescribed or misused with little health gain and potentially adverse public health consequences, such as the development of drug resistance.
- Interruption of the drug supply may have serious repercussions for patient care and overall programme efficiency.
- Additional staff time and technical training is required for patient counselling on adherence to the complex tablet regimens.

When introducing ARV treatments into health care services the following approaches may be adopted:

1. Attach a new ARV treatment service, specially organised as a parallel or vertical programme, to private or public health services.
2. Develop a phased approach where existing health care services for people with HIV are adapted and strengthened to incorporate ARV treatments.
3. Integrate ARV treatments into general health services by training existing staff and modifying the current infrastructure for ARV intervention.

Decisions on the implementation of ARV interventions are dependent upon the local and regional context. Critical factors to consider include:

- Seroprevalence of HIV in the country/community
- Attitudes toward HIV in the country/community
- Existing health system and support services
- Commitment to ARV interventions
- Maturity of the epidemic and stages of development of associated support services
- Financing options

Effectively initiating ARV interventions require general health care system strengthening. However, specific programmes, such as the implementation of mother-to-child transmission of HIV (MTCT) prevention in antenatal care and maternity services, and providing antiretrovirals for post exposure prophylaxis (PEP) of health care staff may also need to be considered.

The decision to expand pilot initiatives to national programmes should only be taken following a careful analysis of the requirements for the intervention and an evaluation of pilot programmes on the clinical, operational and social effects. Sections of health service infrastructure may need to be improved before a larger scale intervention can begin. Assumptions made in the pilot phase with regard to support services will need to be analysed to ensure project feasibility.

Table 1: Questions options and criteria for decision making when considering planning an ARV intervention

Question	Options	Criteria for decision making
1. Is financing secure?	<ul style="list-style-type: none"> • Delay implementation if financing for sustained use is not guaranteed • Proceed if interim budget is sufficient for initial or pilot implementation phase(s) • Proceed if finances are secured 	<ul style="list-style-type: none"> • Sustained reliable govt and external funding • Audit • Accountability • Requirements for funding • Requirements for renewal of budget • Potential cost recovery
2. What methods of distribution and procurement will be used?	<ul style="list-style-type: none"> • Vertically developed and managed • Integrated within existing drug distribution form public or private sector • Phased approach 	<ul style="list-style-type: none"> • Management capacity • Quality assurance • Financial control • Access • Efficiency in use of resources • Distribution system which can respond rapidly
3. How will the intervention be introduced and where will it be based?	<ul style="list-style-type: none"> • Introduced as a pilot study • Services linked with existing public/NGO AIDS care centre • Delivered in approved specialist centres exclusively • Delivered in private sector 	<ul style="list-style-type: none"> • Location of pilot sites • Location of service delivery sites • Geographic accessibility • Financial equity • Distribution issues
4. How will the quality of the intervention be monitored?	<ul style="list-style-type: none"> • In depth quality assurance strategy • Medical audit 	<ul style="list-style-type: none"> • Staff and patient involvement • Sustainability of monitoring • Monitoring time-scale • Define process indicators
5. Who are the important partners in ARV management?	<ul style="list-style-type: none"> • PLHA support groups • Community based organisations • NGOs • Private sector • "Donor" community 	<ul style="list-style-type: none"> • Information process • Counselling services • Patient adherence • Provision of services • Regulate existing use of ARVs

I. Organisation of ARV Treatments into HIV Care and General Health Services

Methods of incorporating ARV interventions into existing HIV care services need to be determined before project onset. Questions regarding the implementation of ARV interventions need to be answered such as:

- Should the management of drugs, project monitoring, and follow up be created as a separate vertically organised and funded service or integrated within existing services?
- How will HIV/AIDS clinical care fit in with a district health service that is in the process of decentralisation or currently decentralised?

Integrating ARV treatments with other services

The method for introducing ARV into existing health services is dependent upon local resources. Although integration is likely to be the final goal, initially, vertical approaches may be more feasible. A national authoritative committee to guide ARV implementation should be established to serve as the key mechanism for achieving consensus on programme initiation.

Experience from other interventions and programmes, which initially began vertically, but are now being integrated in the general health services, may provide insight into effective programme implementation and management.

Management at the national level

The national committee should be specifically organised to guide ARV interventions. This may be either a new committee with sole responsibility for the ARV intervention and other HIV drugs, or an existing drug regulatory body. A multidisciplinary approach is best, and maintaining links with key partners including "care focal points" from HIV/AIDS programmes, experts (pharmacists, physicians, nurses and counsellors), consumer organisations (PLHA support groups) and drug control officers (pharmacists, administrators, private sector representatives) is critical. Progress of the ARV initiatives will ultimately depend on how well this central body performs its duties.

The tasks of the national committee should include the introduction, phasing, implementation and evaluation of this intervention, as well as the following:

- Arrangement of financing for the intervention, be it from public and/or private sources.
- Establishment of a regular distribution system for ARV drugs.
- Identification of sites for ARV interventions.
- Development of process indicators and evaluation tools.
- Provision or dissemination of public information on the advantages and implications of ARV treatments.

To generate broad consensus, immediate tasks for a national committee include:

1. National policy formulation on ARV, including financing, pricing mechanisms and phasing.
2. Development of country specific practical guidelines.
3. Capacity building for clinicians, counsellors and drug administrators at identified sites.
4. Estimation or assessment of realistic drug needs.
5. Strengthening and development of a storage and distribution system; ensuring regularity of supplies and distribution.
6. Selection of clinics/sites suitable for the provision of ARV treatment.

Organisational options for start up at site level

Most countries affected by the epidemic provide HIV/AIDS care in a variety of settings, such as:

- Special units in major hospitals (district, mission, provincial and national referral institutions) where HIV/AIDS clinical care is often linked to an NGO to assure comprehensive care needs (Patient Support Units and HIV clinics).
- Private physicians' clinics.
- Clinics within the workplace.

The decision as to which site should initiate ARV interventions should be based on site fulfilment of the minimal requirement standard, as described in Table 2.

It is best to first pilot the ARV intervention at one or a few sites meeting the eligibility criteria, and monitor the programme for information regarding effective ways of integrating ARV treatment into existing HIV care before expanding the initiative.

Limiting the intervention to sites that meet the minimum requirements will likely raise questions of equity and accessibility. Some physicians may complain that their professional integrity is being questioned if they cannot freely prescribe. Therefore, it is critical that the national committee develops a communication strategy with professionals to inform them of the reasons for selecting their approach, and include the private sector in programme initiation discussions.

Table 2: Implementation steps to consider for ARV program introduction

Steps	Actions to be considered
<ul style="list-style-type: none"> • Design ARV implementation • Identify sites for pilot implementation 	<ul style="list-style-type: none"> • Set up national committee • Identify staff for ARV provision • Build on existing HIV care provision • Recruit new staff as necessary • Provide in-service training for staff
<ul style="list-style-type: none"> • Consider infrastructure viability for additional clinic requirements 	<ul style="list-style-type: none"> • Estimate patient population • Allocate necessary clinic space • Rehabilitate existing premises
<ul style="list-style-type: none"> • Review current VCT services and follow up counselling and care support 	<ul style="list-style-type: none"> • Identify access and quality of existing VCT services • Plan for follow-up counselling to ensure drug adherence • Recruit and train staff as necessary • Expand premises as necessary
<ul style="list-style-type: none"> • Plan linkages between ARV treatment and other clinic services such as family planning, TB, STI, home care, antenatal care, and general medicine 	<ul style="list-style-type: none"> • Identify services related to ARV interventions • Develop referral guidelines • Train staff on ARV interventions
<ul style="list-style-type: none"> • Set up necessary laboratory services for ARV intervention (see module 5) 	<ul style="list-style-type: none"> • Employ/train staff as necessary • Determine equipment needs, order, install and maintain • Build/rehabilitate laboratory premises as required • Set up supply system • Organise quality control system

<ul style="list-style-type: none"> • Establish or strengthen systems for drug clearance, stock control, drug storage, distributing and monitoring ARV use (see module 8) 	<ul style="list-style-type: none"> • Employ and train staff as necessary • Determine and attain equipment for safe drug storage • Develop an audit/accounting system • Build/rehabilitate pharmacy premises as necessary
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Organisational Requirements:

1. Training and support of health care staff

Training in ARV interventions is a prerequisite for staff at the unit where ARV will be implemented. Moreover, information sharing about ARVs must be made available to a wide cross-section of clinic staff. Continued training and updating of correct information/knowledge of health care workers should also be built into the system.

Health care staff undertaking new duties as a result of the ARV intervention may feel overworked and possibly suffer "burnout". Support for health care staff should be planned to minimise staff stress.

2. Motivation and time

A positive work environment is important in maintaining staff morale and commitment. Extra time should be allocated for staff to adequately explain to patients:

- Complex drug taking schedules, timing, and practice.
- Monitoring the effectiveness of ARV therapy, adverse effects and drug interactions.
- Counselling those who do not respond positively to therapy.
- Updating on new drug developments.

Staff who can effectively interact with and assist patients, their needs and reactions, and provide complex drug counselling should be recruited and supported.

1. Space

All programmes will require that suitable space be arranged for intensive drug counselling. Rooms where confidential sessions can be held and where local PLHA support groups can meet to provide peer support should be arranged. Space requirements for confidential counselling can be significant and should not be underestimated.

2. Laboratory support

In limited-resource settings, relatively inexpensive, simple methods for CD4 counts and standard methods for HIV diagnosis, as well as monitoring of ARV side effects, and diagnosis of opportunistic infections will require additional supplies, staff and space. This may be organised with the support of one central laboratory responsible for quality control and training. Where possible, facilities for monitoring ARV treatment response should include measurement of viral load. However, this may not be available in many developing countries. Laboratory requirements are discussed in detail in module 5.

From vertical to horizontal service delivery

ARV interventions initiated at specialised centres should be monitored, and if successful, included as part of an integrated follow-up service at peripheral clinics or primary health centres where adherence can be reinforced and other care and support requirements can be met. This continuum of care for patients receiving ARVs, as well as cross-referral between hospitals and the community is critical and will require extensive collaboration between clinic staff and care providers in the community.

Boundaries between services are often difficult to define. For example, questions concerning limiting the role of counsellors to ARV-MTCT programmes (VCT, ARV follow up, infant feeding and family planning options) or incorporating counselling services for entire health facilities are often debated. Decisions regarding the role of counsellors should be determined in the local context. However, different solutions may be adopted at varying stages in the implementation process.

For ARV interventions to be safe and effective, they must be well resourced and staffed. Tensions between services in the same facility may result as disparities with other clinical services. Pressure to utilise ARV facilities for other equally compelling clinical problems may result. This type of operational difficulty has been witnessed with STI treatment kits, where broad-spectrum antibiotics are not otherwise available, but urgently required and administered to particularly sick patients.

I. Quality Management

Quality management and quality assurance are monitoring mechanisms used to ensure that minimal standards are met for the components of ARV interventions, including the inputs required for the intervention, the process of implementing the intervention, staff performance, job satisfaction and outcomes. The use of indicators for these various components is essential and must be incorporated into all ARV interventions or programmes from their initiation.

After the preconditions for the safe and effective use of ARV are met (see module 4), decisions regarding the implementation of the ARV intervention will be based on the assumption that a certain level of efficiency and efficacy will be delivered by the service. Staff performance, drug supply and clinical practical guidelines should all include quality control. The quality of the ARV service provided must be maintained and regularly reviewed to ensure that expected outputs are being delivered. Otherwise, failure to maintain efficient and effective services may jeopardise the future of ARV interventions

Standards setting and the monitoring of quality and performance for drug counselling services may be a new process in many settings. Simple process indicators can be easily set up for this purpose, including items such as:

- The number of patients recollecting drug dosage schemes
- Pill collection from the pharmacy
- The length and type of each counselling session
- The number of patients who returned to discuss drug related issues
- The number of patients able to involve a "significant other" or a family member in treatment issues

Clinical monitoring is similarly carried out by reviewing process indicators such as:

- Number of patients attended
- Number of patients found eligible for the intervention
- Number of patients accepting intervention
- Number of patients with reduced incidences of:

HIV-associated morbidity

opportunistic infections

hospital admissions

- Number of patients with adverse reactions
- Number of patients with drug interactions
- Patient mortality

Monitoring adherence is critical as problems of drug resistance may result if adherence is inadequate. Adherence may be monitored through semi-structured or qualitative interviewing of patients or "significant others" to explore difficulties in adherence of drug, or laboratory surveillance of drug resistance in the community.

Feedback from the results of the monitoring processes should be provided to health care staff, thus allowing early detection and rectification of problems in service provision. Staff discussions should be encouraged to address issues which may improve motivation and performance.

Quality assurance from the patient or "user" perspective is complex to define, assess and monitor. Interviewing patients as they exit the service may be subject to bias, although important breakdowns in the quality of the service can be quickly identified in this manner. More sophisticated methods of determining patient satisfaction include focus group discussions and household surveys. Although these are difficult and timely to conduct, they may provide critical process information. Partnerships with PLHA support groups or community-based organisations may prove helpful in assessing the quality of ARV services delivered, as perceived by the patient.

II. Access to ARV Treatment

Technical complexity and costs of ARV therapy make it likely that ARV programmes will be piloted before widespread implementation occurs. Often, the intervention will be introduced in a limited number of facilities with the capacity to deliver an effective service. However, it must be noted that in many settings, the prospect of offering universal coverage with ARV programmes is remote, even if the goal is to reduce MTCT.

The issue of who will benefit from "limited access programmes" may result in serious operational problems in ARV programme implementation. In many countries, access will be limited to those who can afford to pay for drugs, even if subsidised, or to those who live close to specialist centres or district referral points. A few middle-income countries such as Brazil, ensure universal access and free ARVs as a legal right, but in doing so face managerial, quality assurance and sustainability challenges.

An effective referral system, with set criteria for eligibility, will be required at the introduction of ARV treatments. These criteria will have to consider issues of equity in determining access. Deciding who will partake in designing these criteria, as well as making information about the services widely available, is central to ensuring that the referral system operates effectively.

Equity in the provision of ARV treatments

The potential for ARV treatment services to be highly inequitable exists, particularly in high-prevalence countries with limited resources. In certain low-prevalence, middle-income countries, those in need may be able to access ARV treatment for all indications. Nonetheless, the rationing or subsidising of ARV treatment will need to be considered to avoid that the sole criteria for treatment access become financial.

Issues concerning equity of access to treatment and care for PLHA will differ for geographic regions and social groups. ARV provision within the public health system is likely to be centralised in cities, as this is where capacity is most likely to exist within the health system to implement quality ARV interventions. This places those patients from the periphery or from rural areas in a disadvantaged position. Referral arrangements for supporting patients from other areas will entail high familial costs, such as transport, loss of income, and accommodation.

Uptake will increase if services are more accessible, but if capacity and finances are limited, services may then be overloaded. Demand may exceed supply when ARV services are introduced and the initial need may often be to ration access rather than to broaden it, with the issues of distributive justice being important (see module 9). This will focus the ARV programme on the need to design "eligibility criteria", including clinical, psychological, economic and support criteria.

Guidelines for eligibility

National authorities must determine ways of obtaining broad consensus on ARV treatment interventions. Guidelines for eligibility will have to be drafted by national authorities based on these broad public consultations. Transparency in establishing criteria for entry into the ARV intervention programme is critical. These guidelines should also be made public and widely disseminated.

Guideline recommendations should be country and context specific, decided upon only after considerable debate. The debate itself, as a consultation exercise, is an important part of the ARV introduction process. It should be steered by the national committee guiding the ARV intervention programme, and will require that broad political support be obtained. It should be noted that this might prove to be a very time consuming process, therefore, this should be factored into the timetable of programme introduction.

Once these "guidelines for eligibility" have been determined, the process of implementation needs to be clearly delineated. Consistent monitoring of the intervention will be required.

V. Information Systems

There will be great public interest, expectation and confusion about any ARV programme as it is being planned. Many misunderstandings may result at the onset concerning ARV treatment. For example, it is often not understood that ARV does not cure HIV. It is critical that accurate and accessible information be regularly and widely disseminated about ARV interventions to ensure public knowledge. Messages should also be consistent with information provided from other HIV/AIDS activities.

Service provision and access

Clear and simple messages about ARV interventions must be prepared and widely disseminated once a final decision regarding ARV interventions has been determined. Public information campaigns should be released prior to programme implementation. A budget should be allocated for this purpose. The information should address:

- Who will be eligible for the interventions
- How ARV interventions may be accessed
- Advantages and disadvantages of ARVs
- ARV interactions with other common treatments
- Realistic expectations of ARV therapy (emphasising that ARV treatments are not curative)
- Specific services provided the benefits of:

Reducing the number of infants infected with HIV born to seropositive mothers

Protecting staff from accidents that may transmit HIV

Certain countries have established HIV treatment information services via the Internet. Information can continually be updated as new treatments and new drug interactions become known as adverse effects are discovered. Pharmaceutical companies may collaborate in this endeavour, although monitoring to prevent bias will be necessary.

It may also be important to inform the public about the costs and financing of ARV programmes. This may result in considerable debate about fund allocation. Nonetheless, this process should be encouraged particularly where large public subsidising has occurred.

Information regarding the involvement of partners should be shared with the public. In situations where the private sector is collaborating with ARV programmes, information on which private practitioners have been licensed to implement the intervention, as well as which NGOs have been sub-contracted should be disseminated to the public.

Regardless of whether ARVs are available through the public health service or not, accurate information must be provided to the public in order to avoid misuse and/or misunderstanding of ARVs.

Prevention messages: integration and reinforcement

The need to inform the public about ARV treatment and related care services affords the opportunity to reinforce HIV awareness and HIV preventive messages. Prevention messages must be widely and repeatedly stated to guard against the idea that one can be less careful. Safer sex practices should continue to be used by those on ARVs and widely promoted.

VI. Partnerships for providing ARV services

The advantages of collaboration between various care providers at the institutional level (counsellors, physicians, social workers and nurses), welfare and community based organisations, social and spiritual services, and support groups has been witnessed in the provision of care for PLHA. Examples of successful continuum of care initiatives exist in several sub-Saharan African countries and Thailand. The introduction of ARVs allows for the opportunity to build on existing networks as well as expand or initiate comprehensive support services. Methods for collaborating with the private sector and NGOs have been discussed in module 2.

Table 6: Partners in ARV interventions

Partners	Roles
PLHA support groups	<ul style="list-style-type: none">• Disseminate information• Develop support and counselling services• Maintain drug adherence
Community based organisations	<ul style="list-style-type: none">• Disseminate information• Social, emotional, spiritual support• Home care
NGOs	<ul style="list-style-type: none">• Disseminate information• Counselling and clinical support
Private sector	<ul style="list-style-type: none">• Disseminate information• Regulate existing use of ARV & referrals
Pharmacies	<ul style="list-style-type: none">• Correct information provision• Follow up dispensing and early referrals

PLHA support groups

PLHA groups can be involved in the introduction of ARV treatments in a variety of ways. Furthermore, experience from several countries have shown that prevention and care is enhanced by including input from PLHA. Several ARV planning steps could benefit from input from PLHA groups including:

- Representation in the formation of the national committee guiding ARV interventions
- Guidelines for eligibility criteria
- Advocacy to increase access to ARVs
- Peer advocates for prevention and general HIV care
- Peer counselling and support to improve adherence to ARVs
- Evaluation of patient assessment of service quality

Community based organisations (CBO) and NGO

Many CBOs are active in HIV prevention and care. Moreover, /AIDS field, and a significant number have a particular focus on the care and support of PLHA people living with the disease. Like PLHA support groups, These CBOs play an very important advocacy role on behalf of their clients and patients. Therefore, they will need to be represented in the national debate on eligibility and entry.

; and hopefully will have some firm and robust ideas to promote.

CBOs often focus on counselling and social support services that can be attached to HIV care units in institutions such as "Patient Support Units" to ensure comprehensive care and necessary linkages with community structures and homes to ensure continuum care.

Community focus of these organisations is extremely beneficial as strengths they can provide realistic information about ARV interventions and ensure that a clear understanding of what is involved in the intervention: how to access it; what the programme involves; the likely benefits; and, possible problems that may exist, and so on. Counselling provided by CBOs may also have the benefit of strengthening monitoring adherence to ARV drug regimens. , a very important possible problem in many countries where compliance for something like tuberculosis chemotherapy is often very low. However because relatively few have significant clinical capacity they are unlikely to be able to assist in ARV distribution.

CBOs may be able to help in reducing certain access barriers and, thus, minimising the inequity of most programmes for those living in rural areas or in the periphery of large cities, a long way away from ARV treatment centres. CBOs may also be able to provide transport services to individuals to access the ARV intervention programmes.

Either through providing bus-fares or even by making available local accommodation. This sort of initiative needs to be discussed because a successful project to increase access may end up recruiting too many patients and clients for the ARV intervention to cope with.

CBOs and religious groups often provide emotional and social support for PLHA and their families. close to home. If As ARVs are not a cure for HIV, services must include comprehensive treatment of opportunistic and associated infections. If ARV interventions are not adhered to, or are not effective, palliative and supportive care will be particularly necessary. Establishing links between CBOs and ARV services is critical for ensuring that PLHA are provided a continuum of care should treatment be unsuccessful. Often, CBOs also involved in TB care (, the DOTS approach) and care for other chronic illnesses; therefore, there is great potential that HIV/AIDS may begin to be or can be de-stigmatised at the community level.

The private for profit sector

In many countries of both the developing and industrialised world, the private sector will play an increasingly important role in promoting and prescribing ARVs. An important The main initial issue in issue in developing a partnership between the national ARV initiative andwith the private sector will probably be to regulate the existing use and delivery of ARV drugstreatments. ARVs are often widely available through legitimate sources and/or donations from abroad. It is important to develop a partnership between the national ARV initiative and the private sector to regulate the existing use and delivery of ARV drugs to avoid inadequate prescription and/or patient care., and some form of could beis thought to be a

widespread practice now in many resource-poor countries One worry is exploitation of poorly informed patients; the other is limited value for money - and the ever present spectre of poor use leading to high drug resistance rates.

Regulation and licencing can be promoted by having the government services running a series of training workshops (free or at subsidised rates) after which a certificate of training is issued. These could then be used by the private practitioner to show to the public his/her competence as opposed to competitors down the road wh did not have the certificate. Voucher schemes are also a possibility. The need is somehow to control or at least regulate the private market for ARVs to limit improper use and exploitation.

Partnerships rather than sanctions will be more likely to work.

There is a possibility of organising an extensive network of private practitioners across most countries for the delivery of ARV therapies. This model has already been implemented in some middle income countries. However this seems a limited option at least initially in many countries. Although maMnyost private practitioners maywill not have access to the necessary counselling, monitoring and laboratory facilities needed rigorously to supervise ARV treatment To set them up has considerable cost implications and this may generate significant duplication of equipment and resources., strengthening links with hospitals where counselling and laboratory services could complement the private practice may be feasible.

There are several advantages of usingHowever i the private sector in the delivery of do quality-controlled ARV services, then, particularly if the public sector health service capacity itself is somewhat limited. Several possible ways can be envisaged whereby private firms or companies contract a private health care worker to provide ARV services with drug procurement from the public sector at an agreed price.

Caution is needed in some partnerships with the private for profit sector. It is of great importance that all those who can afford private ARV treatment (usually out of the pocket rather than any insurance programme) end up paying for it and liberating the subsidised space in the government services for those most in need. Or that those organisations who can afford to pay for their employees to receive treatment contribute fully to the drug and treatment costs.

The private not for profit NGO clinical services

In many countries a significant proportion of the population have access to, and use, NGO-managed clinical services. It therefore is obvious that iIf ARVs are to be scaled up in implementation beyond just a few specialist clinics in the capital city, then NGO-run/supported hospitals maywill be important sites in which to incorporate an expanded programme. With financial and technicaloverseas support from various sourcesand links, these NGO-run hospitals (including "mission hospitals") often have better infrastructureinfrasutucture, drug supplies and even resources than their government equivalent; and can be relied upon to provide relatively good-quality service. It is assumed that aAudit processes are becoming standard practice in NGO services; therefore,and the expected quality assuranceand audit components may also needs to be carried out.

The advantages of this are similar to any partnership with the private for profit sector. Government need not to be involved in the day-to-day management and supervision of such an intervention ; and can take advantage of the extensive NGO clinical capacity. Indeed f In terms of increasing access and equity, incorporating NGOs is vital as they may be the sole provider of services in a particular locality.

VII. Monitoring and Monitoring and reporting

7. evaluation of the intervention

1. Data collection

Given the cost and complexity of any ARV intervention, and the often marginal(likely) tight cost-benefit and cost-effectiveness profiles, it is important that services are provided as effectively and efficiently as possible. SFrom the outset special attention must needs be given to the monitoring and evaluation process, and. Important considerations include:

- in particular what data needs regularly to be collected
- ; what system of reporting and sending data to a central surveillancesurveillance/monitoring unit will be utilised
- ; how will data be analysed;
- and
- what use will be made of the summary results .
- Routine methods for collecting monitoring data shouldregularly must be established and properly implemented. A standard report form for , usable by all centres delivering the ARV intervention shouldshould be designed and piloted. This can then be modified for more wide-spread use., and then scaled up for general use. Pro-formas should be used in different settings and clinics for comprehensive evaluation. Staff will likely require ust have been properly trained and prepared training for the regular auditauditing purposes. Evaluation and audit need require active promotion promotion and ownership with staff, as the staff may initially find the process threatening.

and intimidating.

clinical efficacy as defined by outcome (eg reduction in vertical transmission; improvement in surrogate disease markers like viral load and CD4 count; etc)

amount of drug supplied and prescribed

integrity of drug supply

rates of HIV drug resistance (where appropriate)

behavioural aspects, especially HIV prevention activities

in-service training and refresher courses provided

specific problems which have arisen and affected service delivery (eg lack of drugs, problems in the laboratory; personnell issues)

Routine ways to collect such data regularly must be set up and properly implemented. A standard report form, usable by all centres delivering the ARV intervention, should be designed and piloted, and then scaled up for general use. Pro-formas The same forms should be used in different settings and clinics for comprehensive evaluation. Staff must have been properly trained and prepared for the regular audit, otherwise this task will be poorly carried out - and thus lose much of its impact. Evaluation and audit It may be important to require active promotion with the value of audit and evaluation as some staff as they may initially find the process threatening and intimidating.

2. Reporting to a central unit

Once collected, Monitoring data need regularly to be sent to a central unit which will process and analyse the information. It is probably best if Data should be routinely reported every few months to the central unit. A clear chain must be set up, and when reports do not appear, a tracking device and default procedure organised in place to ensure that the problem can be identified, the data collected, and steps taken to rectify the difficulties immediately implemented. It is best if p

, so they can be held accountable for delays and lack of data - or be rewarded for regular and efficient performance.

Such a The central unit may best be located at the national level, perhaps within the Ministry of Health. This to some extent However, this decision depends on whether a vertically or horizontally managed service is implemented. Although, even within a decentralised health service managed at the district level, a necessary role for central monitoring remains, particularly because of the cost and central purchasing and supply of ARVs.

Table 7: Data for monitoring ARV interventions

<i>The necessary data for monitoring and service audit</i>
<ul style="list-style-type: none"> Economic and pharmaco-economic
Amount of drug supplied and prescribed Integrity of drug supply
<ul style="list-style-type: none"> Logistic
Number of patients undergoing voluntary counselling and testing Number of patients referred and counselled for ARV interventions In-service training and refresher courses provided Specific problems affecting service delivery
<ul style="list-style-type: none"> Clinical
Side-effects of treatments Laboratory quality control results Clinical efficacy as defined by outcome
<ul style="list-style-type: none"> Epidemiological
Rates of HIV drug resistance Proportion of patients who are HIV-seropositive
<ul style="list-style-type: none"> Social and behavioural
Numbers entering and remaining in the programme Adherence/compliance to specified ARV treatment regimen Impact of psycho-social support Behavioural aspects, particularly HIV prevention activities
<ul style="list-style-type: none"> Summary of information from quality assurance and/or medical audit

3. Acting on the data received

The final step in monitoring and evaluation is the use to which the data, analyses and results are put to. It is not enough just to collect the information, however efficiently this is done. The data must be regularly processed and analysed. It may be best if a particular officer is identified for this responsibility. for the speed and accuracy with which such analysis is carried out and the appropriate evaluation and monitoring results are generated.

After this regular Regular review needs to be carried out of both the aggregated national and the local results. Regular audit should identify any problems with the integrity of drug supply. Cost-effectiveness and cost-benefit data could also regularly be generatedgenerated if economic analysis and review is available.

Problems identified by "front-line" staffFrom the point of view of the staff at the local care facility, must be attended in the "front-line" as it were, it is very important that any problems identified - or generally recognised and reported upwards for some sort of action - toare actual speedily and effectivelyy dealt with in a speedy fashion, otherwise. If not confidence in the system will deteriorate, and possible negative repercussions may include minimal effort being exerted into collecting the data, in the first place, further undermining the process.