

A PUBLIC HEALTH APPROACH FOR SCALING UP ANTIRETROVIRAL (ARV) TREATMENT

A TOOLKIT FOR PROGRAMME MANAGERS

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GLOSSARY

AAI	Accelerating Access Initiative
AIDS	Acquired immune deficiency syndrome
ANC	Antenatal care
ARV	Antiretroviral
CBO	Community-based organization
DRA	Drug Regulatory Authority
EDM	Essential drugs and medicines
GAVI	Global AIDS Vaccine Initiative
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHSS	Global Health Sector Strategy for HIV/AIDS
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit
HAART	Highly active antiretroviral therapy
HAI	Health Action International
HIV	Human immunodeficiency virus
IEC	Information, education and communication
ICH	International Conference on Harmonization
ILO	International Labour Organization
INN	International non-proprietary name
IPR	Intellectual property rights
ITAC	International Treatment Access Coalition
MSF	Médecins sans frontières
MSH	Management Sciences for Health
NGO	Non-governmental organization
OI	Opportunistic infection
PAI	PharmAccess International
PEP	Post exposure prophylaxis
PLHA	Person/people living with HIV/AIDS
PMTCT	Prevention of mother-to-child transmission
STI	Sexually transmitted infections
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
UP	Universal precautions
VCT	Voluntary counselling and testing
WHO	World Health Organization
WTO	World Trade Organization

INTRODUCTION

Lack of access to antiretroviral (ARV) treatment has perpetuated HIV/AIDS-related stigma and discrimination in many countries. The cost of medicines, poor infrastructure and the lack of skilled healthcare workers are frequently cited as obstacles to scaling up ARV treatment in resource-limited settings. In the face of these challenges, many pilot projects have shown that safe and effective ARV treatment can be delivered in resource-limited settings. These pilot projects have also shown that the availability and accessibility of ARV treatment is accompanied by significant reduction in stigma and discrimination.

Financial resources available for provision of ARV treatment in resource-limited settings rose from \$300 million in 1999 to nearly \$3 thousand million in 2002. There are now fewer reasons for delay in setting up treatment programmes¹. Evident from the United Nations Declaration of Commitment on HIV/AIDS² and the World Health Organization's recent announcement declaring HIV/AIDS a global public health emergency, significant attention worldwide is being paid to the urgent need for scaling up ARV treatment in resource-limited settings. There is a growing consensus that a public health approach is the way forward for scaling up access to ARV treatment in resource-limited settings.

A successful ARV treatment programme involves far more than getting pills into the mouth of the patient. ARV treatment is not a cure; for optimal outcomes, ARV treatment must always be linked strongly with prevention and care efforts. This will include testing and counselling for prevention and adherence, systems for follow-up and referral, meaningful involvement of people with HIV and measures to address stigma and discrimination. Scaling up ARV treatment will also mean scaling up testing and counselling and prevention efforts.

Many health systems in resource-limited settings already have some capacity to commence rapid implementation of ARV treatment programmes. In many countries there are individuals or organizations with experience of ARV treatment, who are valuable resources for the scaling up process. A range of stakeholders must be mobilized and efforts made to be as inclusive as possible in planning and implementing ARV treatment programmes. This will be essential for the success of ARV treatment programmes.

The toolkit is based on **three key assumptions**:

- ▶ that a commitment to working towards universal access to ARV treatment has been made at a national level;
- ▶ that efforts to scale up access to ARV treatment will learn from and build on the existing experiences of providing ARV treatment at local, national or regional levels; and
- ▶ that a range of viable and valid approaches to scaling up ARV treatment is necessary for scaling up ARV treatment, particularly in resource-limited settings.

¹ A Commitment to Action for Expanded Access to HIV/AIDS Treatment. International HIV Treatment Access Coalition (ITAC). WHO/HIV/2002.24. December 2002.

² Declaration of Commitment on HIV/AIDS, United Nations General Assembly Special Session on AIDS (UNGASS), June 2001.

The **aim** of the toolkit is:

- 1) to address issues arising from planning and implementing ARV treatment programmes in resource-limited settings; and
- 2) to provide user-friendly technical guidance on planning and implementing ARV treatment programmes in resource-limited settings.

Who is the toolkit for?

The toolkit is for a target audience of programme managers, implementers and their partners in the public and private sectors, including non-governmental organizations (NGOs), community-based organizations (CBOs) and businesses.

This toolkit is a resource for those who are involved in setting up or scaling up ARV treatment programmes both at the beginning of the will process, and for existing programmes that are to be scaled up.

This toolkit is a practical starting point for thinking through programmatic and policy issues and developing a shared understanding of the issues of scaling up ARV treatment programmes.

What is in the toolkit?

The toolkit provides practical guidance on the process of planning and implementing ARV treatment programmes in resource-limited settings.

STRUCTURE

The toolkit is organized as follows:

Guiding principles

Components of ARV treatment programmes:

1. Planning
2. Enabling public policy environment
3. Involving and mobilizing stakeholders
4. Supply management of commodities
5. Service delivery
6. Human resources
7. Infrastructure
8. Costing and financing
9. Management systems
10. Information management and communication
11. Monitoring and evaluation

Style

The text of the toolkit highlights and discusses key issues. References include the following:

- ▶ **Information:** reports, articles etc.
- ▶ **Tools:** practical know-how, action-oriented guidance, skills-building
- ▶ **Examples:** documentation of experience (good practice, lessons learned, what hasn't worked, new and emerging experience, case studies, etc.)
- ▶ **Websites:** useful web sites containing related resources
- ▶ **Miscellaneous resources:** academic and other resources for additional information

The toolkit is intended to provide:

- ▶ a user-friendly approach;
- ▶ easy reference and access to its various components; and
- ▶ regular updates.

To ensure the broadest possible access and use, the toolkit will be available in several formats, including hard copy, CD-ROM and an Internet version.

To make it possible to learn from and contribute to rapidly evolving experiences of ARV treatment delivery, the toolkit is structured as a 'living document'. The toolkit's content will be updated regularly with the latest experience and developments in good practice and lessons learned. The World Health Organization (WHO) will manage the updating process. Selection of resources for inclusion will follow a vetting that will rely on the expertise of partner organizations of the International Treatment Access Coalition (ITAC).

The toolkit will have a user-feedback facility, which will enable regular monitoring of the use of the toolkit. Feedback will be utilized to make improvements to the toolkit and ensure that it continues to respond to emerging and changing needs.

Who developed this toolkit?

The toolkit has been developed by the **World Health Organization (WHO)**, the **International HIV/AIDS Alliance** and **PharmAccess International (PAI)** with support from **Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ)**.

WHO is the world's leading international public health agency. Its aim is to support the attainment by all peoples of the highest possible level of health—a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. WHO has declared HIV/AIDS a global public health emergency and is committed to working with its partners to support public health approaches for scaling up access to ARV treatment.

The **International HIV/AIDS Alliance** is an international NGO that supports community action on HIV/AIDS in developing countries. The International HIV/AIDS Alliance aims to:

- ▶ make a significant contribution to HIV/AIDS prevention, care and support to children affected by the epidemic, by working with communities in developing countries;
- ▶ promote the sustainability and scaling-up of effective community AIDS efforts, by building the capacity of CBOs, NGOs and NGO support programmes; and
- ▶ influence and improve HIV/AIDS policies and programmes of international agencies, donors and international NGOs, with particular emphasis on the role of community action.

The International HIV/AIDS Alliance is committed to working with its partners to meet the interim target set in the United Nations Declaration of Commitment on HIV/AIDS of having 3 million people in resource-limited settings on ARV treatment by 2005.

PharmAccess International (PAI) is a not-for-profit organization established in 2001. Its mission is to provide treatment for 100 000 patients in resource-limited settings by 2006. PAI focuses on organizations in Africa that have infrastructure and sustainable financing mechanisms in place to deliver highly active ARV therapy (HAART).

Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) is a government-owned corporation for international cooperation with worldwide operations. In more than 130 partner countries, GTZ is supporting 2700 development projects and programmes, chiefly under commission from the German Federal Government. GTZ has declared HIV/AIDS a cross-sectoral corporate task. It offers consultative services on HIV/AIDS prevention, treatment and care, and provides support on issues related to the social consequences of HIV/AIDS. The WHO/GTZ Initiative against AIDS was launched and supported by the GTZ BACKUP Initiative. This initiative includes technical and financial cooperation with WHO, UNAIDS, the International Labour Organization (ILO) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).

GUIDING PRINCIPLES

Guiding principles are the foundation of a successful ARV treatment programme. They provide a basis for developing and promoting good practice in ARV treatment programmes. Promoting good practice in an ARV treatment programme will help to ensure good treatment and prevention outcomes. This section discusses the following:

- ▶ developing public health approaches to scaling up ARV treatment;
- ▶ mobilizing political commitment to working towards universal access to ARV treatment;
- ▶ implementing standardized counselling, testing and treatment protocols;
- ▶ involving and mobilizing a range of stakeholders;
- ▶ ensuring greater involvement of people with HIV ;
- ▶ situating ARV treatment programmes within existing health systems;
- ▶ developing a phased approach for scaling up ARV treatment; and
- ▶ equity.

The benefits of ARV treatment for patients are well documented. There is also evidence that ARV treatment generates benefits for households and society. Pilot ARV treatment programmes in resource-limited settings have shown that people with HIV can be successfully treated, achieving clinical outcomes that are similar to those seen in highly resourced settings. Progress has been made towards developing a **public health approach to ARV treatment**. This aims to provide treatment for as many people as possible, while working towards universal access to ARV treatment. More specifically, the public health approach is based on standardized first- and second-line treatment regimens with simplified laboratory monitoring. The public health approach for scaling up ARV treatment also calls for early involvement of a range of stakeholders, including people with HIV and other community members.

The following **guiding principles** form the basis of a successful ARV treatment programme:

1. **Political commitment to working towards universal access** is critical to the success of scaling up ARV treatment. All those involved in an ARV treatment programme must share commitment to working towards universal access to ARV treatment. This political commitment should be mobilized at all levels, including the implementation level, the community level and national policy level. Experience has shown that political commitment at any one level can catalyse political commitment at other levels. **Commitment to mobilizing resources on an ongoing basis** is also critical to a successful ARV treatment programme and scaling up for universal access to ARV treatment.
2. While countries are planning and implementing their ARV treatment programmes, they must **build on local experience and expertise** and make efforts to **involve and mobilize a range of stakeholders**, including the private sector, people with HIV and others. Community members and people with HIV must be involved in design, implementation and monitoring as well as patient care, especially for supporting adherence to treatment and prevention.

3. **Ensuring the greater involvement of PLHA** in all aspects of ARV treatment programmes will be critical to ensuring their success. By maintaining a rights-based approach towards increasing the participation of people with HIV in a meaningful and appropriate way, ARV treatment programmes will ensure better outcomes for treatment and prevention.
4. **ARV treatment should be planned and implemented as an integral component of the continuum of care, treatment and prevention.** Planning and implementing ARV treatment programmes must be based on a response to the community's care, treatment and prevention needs. ARV treatment programmes must be **situated within existing health systems**. Although most health systems in resource-limited settings tend to be underdeveloped and over-stretched, situating ARV treatment programmes within these health systems can be an opportunity to strengthen them.
5. **Standardized counselling, testing and treatment protocols** and **simplified laboratory monitoring** will greatly simplify decisions on HIV testing, counselling, treatment choice, procurement, dispensing, patient management and training needs. The treatment protocols should be based on WHO's Scaling Up Anti-retroviral Therapy in Resource-Limited Settings: Treatment Guidelines for a Public Health Approach 2003.
6. Working towards universal access and **scaling up ARV treatment** requires a **phased approach**. Resource limitations also require a phased approach to scaling up ARV treatment; it will not be possible to do everything at once. The phased approach will require:
 - ▮ strengthening of other service-delivery components, including counselling and testing, psycho-social support, and basic medical services that can identify and treat common HIV-related illnesses and facilitate referrals for further care, treatment and prevention;
 - ▮ reliable laboratory services;
 - ▮ reliable and affordable supplies of ARVs, other essential medicines and supplies;
 - ▮ trained healthcare workers; and
 - ▮ involvement of people with HIV and other members of the community.

As ARV treatment services are set up and lessons are learned, treatment can be scaled up and brought closer still to those clients who would otherwise be out of reach.

- 6.1. Scaling up ARV treatment requires **the best possible use of resources—financial, material and human**. ARV treatment will be more affordable and more people can be treated if efficient systems for procurement and management of supplies (including assuring quality and value for money) are in place. Robust systems are important for scaling up ARV treatment. Such systems include financial management, information management, monitoring, evaluation and overall management and coordination. The best use of available human resources will be achieved by **ensuring teamwork and sharing aspects of patient care and follow-up among a range of healthcare workers**, including nurses, other cadres of healthcare workers and community or family members. Healthcare workers, people with HIV, family members and the community all have an important role to play in supporting patient adherence and protective behaviour, as well as in minimizing stigma and discrimination.

6.2. Issues of **equity, selection criteria and target-setting for the numbers of people to be treated** raise some critical concerns for which clear policy and guidelines should be articulated and applied. The numbers of patients who are started on treatment should be those for whom safe and effective ARV treatment can be provided on a continuous basis. It will also be important to ensure that treatment programmes are not concentrated only in better-resourced urban settings. While there are many ways of determining which patients should be selected for ARV treatment, a method should be chosen that is widely accepted as being the fairest and most medically appropriate. **The most equitable selection criteria for patient selection are based on clinical eligibility. Principles of promoting and protecting human rights, transparency and ensuring greater involvement of people with HIV should also inform the development of selection criteria.** In resource-limited settings, there will be many patients who qualify for treatment but cannot be offered treatment in the early stages of the programme. This should not deter providers from starting to implement ARV treatment programmes. The issue of equitable access to ARV treatment may be controversial but there must be a starting point. Members of the community and people with HIV should be involved in the often-challenging decisions about who should be offered treatment first. Only in starting the ARV treatment programmes can lessons be learned about scaling up ARV treatment. As the provision of ARV treatment expands and accelerates, more patients should be able to access ARV treatment.

Vulnerable populations such as sex workers, injecting drug users, men who have sex with men, and women and children typically have the poorest access to health services. In planning and implementing ARV treatment programmes, special attention will be required to ensure that these populations have equitable access to ARV treatment.

- Reference No. 1: *Scaling Up Antiretroviral Therapy: Experience in Uganda. Perspectives and Practice in ARV treatment, 2003.*
- Reference No. 2: *Antiretroviral therapy in primary health care. Experience of the Khayelitsha programme in South Africa. Perspectives and practice in ARV treatment, 2003.*
- Reference No. 3: *Voices from the Community - Report of a Community Consultation on Antiretroviral Treatment in Zambia, November 2002.*
- Reference No. 4: *From principle to practice: greater involvement of people living with or affected by HIV/AIDS (GIPA), September 1999.*
- Reference No. 5: *The Involvement of People Living with HIV/AIDS in the Delivery of Community Based Prevention, Care and Support Services, 2003.*
- Reference No. 6: *Antiretroviral treatment policy for Uganda (draft April 2003).*
- Reference No. 7: *Scaling up Anti-retroviral Therapy in Resource-Limited Settings: Guidelines for a Public Health approach, June 2002.*
- Reference No. 8: *Access to Antiretroviral Treatment and Care: Experience of the HIV Equity Initiative, Cange, Haiti. Perspectives and Practice in ARV Treatment, 2003.*
- Reference No. 9: *Partnership work: the health service – community interface for HIV/AIDS prevention, care and treatment. Report of a WHO consultation. (in press)*

COMPONENTS OF ARV TREATMENT PROGRAMMES

An ARV treatment programme's goals are to:

- ▶ reduce illness and death due to HIV/AIDS;
- ▶ provide safe and effective treatment (i.e. provide quality treatment and maintain people on treatment);
- ▶ work towards providing universal access to ARV treatment;
- ▶ make the best possible use of resources; and
- ▶ integrate ARV treatment with other public health services.

An ARV treatment programme will have the following **components**:

1. Planning
2. Enabling public policy environment
3. Involving and mobilizing stakeholders
4. Supply management of commodities
5. Service delivery
6. Human resources
7. Infrastructure
8. Costing and financing
9. Management systems
10. Information management and communication
11. Monitoring and evaluation

1. PLANNING

Planning is an important component in efforts to scale up ARV treatment and must have the participation of all relevant stakeholders. Planning provides a framework for bringing together the different components of an ARV treatment programme that are addressed in this toolkit. Planning should be informed by a situation analysis that gives qualitative and quantitative feedback on the components of an ARV treatment programme. Expansion of ARV treatment is best planned in a step-wise or phased approach. The issues discussed in the planning section include:

- ▶ a plan for ARV treatment;
- ▶ leadership and stewardship for scaling up ARV treatment nationally;
- ▶ conducting a situation analysis in preparation for scaling up an ARV treatment programme; and
- ▶ planning for establishment and expansion of an ARV treatment programme.

An ARV treatment plan

It is useful to develop a specific ARV treatment plan that outlines how the programme should be implemented. Many governments already have some framework for managing aspects of the HIV/AIDS epidemic in their health plans. An ARV treatment plan should complement any national strategic plan on HIV/AIDS. The plan to provide ARV treatment should assess the current status, identify targets, outline strategies and processes for the delivery of services, and define mechanisms for monitoring and evaluation.

Determining leadership and stewardship roles

Political commitment is needed to start planning a national ARV treatment programme. Wherever possible, national authorities should lead the process of planning. By the time planning activities start, it should be clear that a range of stakeholders, including those at national level, have committed to supporting the process of scaling up ARV treatment provision. All stakeholders must also commit to achieving targets and mobilizing the necessary resources. Roles and processes to enable action should be clearly defined.

A national advisory body should be involved in planning and decision-making and should drive the planning activities. The national advisory body should also ensure the full involvement of a range of stakeholders, especially those who will be involved in implementation.

A national advisory body should include representatives from the following:

- ▶ health ministry, and any other relevant ministries such as planning and finance;
- ▶ health professionals knowledgeable in HIV/AIDS, essential medicines and clinical management of HIV infection;
- ▶ people with HIV, vulnerable groups and communities;
- ▶ academic and research institutions;
- ▶ national AIDS Programme/Commission/Council;
- ▶ NGOs and CBOs involved in HIV/AIDS care;
- ▶ business community and private sector; and
- ▶ donors and multilateral agencies.

In scaling up ARV treatment, the greatest effort should be made to plan for success by setting ambitious targets for the numbers of people to be treated. It will also be important to integrate treatment, care and prevention into existing healthcare structures and to develop linkages with a range of stakeholders. WHO's Global Health-Sector Strategy for HIV/AIDS (GHSS) states that many of the goals, targets and commitments in the Declaration of Commitment on HIV/AIDS adopted by the United Nations General Assembly (UNGASS Declaration) can best be met with a comprehensive contribution by the health sector. It lists action points for health ministries that include developing mechanisms for formal involvement of stakeholders to identify priorities and implement interventions (see Guiding principles section).

- Reference No. 1.1: *Nine guidance modules on antiretroviral treatments, Module 3, 1998.*
- Reference No. 1.2: *Report of the meeting on the evaluation of the UNAIDS HIV drug access initiative, May 2000.*
- Reference No. 1.3: *Scaling up antiretroviral therapy: experience in Uganda. Perspectives and practice in ARV treatment, 2003.*
- Reference No. 1.4: *Global health-sector strategy for HIV/AIDS: 2003-2007. Providing a framework for partnership and action, 2003.*

Situation analysis

A situation analysis is an important step in planning for scaling up ARV treatment. It is a critical first step for gathering data for the planning process. It can serve the dual purpose of collecting baseline data on the current situation and providing an evidence base for building further commitment and catalysing action.

The situation analysis should aim to answer the following questions:

- What is the extent of current treatment requirements?
- What treatment facilities and capacities currently exist?
- What is currently being done and by whom?
- What do we know about what is going well, and could be expanded?
- What do we know about what is not going well, and could be changed?
- What opportunities exist for expansion?

It may not be possible to carry out a highly detailed situation analysis because of limited funds or a potential time delay, or both. Initial assessments can at least begin with the collection of data that currently exist. The analysis should be both qualitative and quantitative and should include existing capacities in the private and public sectors as well as other players in health service delivery. It will help to map the available resources and the scope of the ARV treatment programme. The situation analysis should also look at linkages between communities, NGOs, CBOs, and private and public sectors. Finally, there should be a review of the current levels of availability and provision of ARV treatment.

What should be assessed in the situation analysis?

- political, legal and social environments
- epidemiological data
- coverage of care, treatment and support services:
 - testing & counselling,
 - ARV treatment,
 - prevention of mother to child transmission (PMTCT),

- diagnosis and treatment of sexually transmitted infections (STIs),
- treatment and prophylaxis of opportunistic infections (OIs),
- tuberculosis (TB) services,
- post exposure prophylaxis (PEP),
- essential medicines and commodities,
- palliative care,
- counselling, social support
- ▶ health-seeking behaviour of the local population as well as attitudes and perceptions about HIV and ARV treatment
- ▶ utilization of current services (appropriateness, availability, accessibility and use of current services)
- ▶ administration and management systems
- ▶ involvement of stakeholders, including people with HIV
- ▶ financial obligations
- ▶ available human resources
- ▶ state of the current infrastructure, facilities, including procurement systems and storage facilities
- ▶ monitoring, evaluation and information management systems

In order to collect the most relevant information in a situation analysis, people from disciplines relevant to ARV treatment, including people with HIV and members of the community, should participate and contribute. A method of verifying the data and giving feedback to the data collectors should be put in place. Clear documentation of the data collected should be done in such a way as to facilitate future review and investigation.

- Reference No. 1.5: *Tool to Assess Site Programme Readiness for Initiating Antiretroviral Therapy (ART)*, May 2003.
- Reference No. 1.6: *HIV/AIDS NGO/CBO Support Toolkit: Strategic planning – Assessing the Situation*, 2002.

What to plan for

Planning can be divided into the following main categories, many of which will overlap. They need not be addressed in the order they are listed:

- ▶ setting goals of the treatment programme and targets—numbers to be treated;
- ▶ developing national treatment guidelines and protocols—choosing first-line and second-line treatments;
- ▶ deciding on the service-delivery approach;
- ▶ developing selection criteria for receiving ARV treatment;
- ▶ deciding on necessary levels, essential laboratory, clinical counselling and pharmaceutical services; and developing a plan for phased alleviation of shortages;
- ▶ developing a plan for patient registration and follow-up;
- ▶ developing a human-resources plan based on identifying personnel and training needs;
- ▶ estimating programme cost;
- ▶ developing a financing strategy;
- ▶ developing management systems;
- ▶ developing an information management system and a communication strategy; and
- ▶ developing monitoring and evaluation systems.

- Reference No. 1.7: *Guide to the strategic planning process for a national response to HIV/AIDS: situation analysis, 1998.*
- Reference No. 1.8: *Mobilising NGOs, CBOs and PLHA Groups for Improving Access to HIV/AIDS-Related Treatment. A Handbook of Information, Tools and other Resources: Chapter 4, May 2003.*
- Reference No. 1.9: *Introducing Antiretroviral Therapy (ART) on a Large Scale: Hope and Caution. Program Planing Guidance Based on Early Experience from Resource-Limited and Middle Income Countries, November 2002.*

Implementation plans

When the situation analysis has been completed and its findings have been analysed, implementation plans and guidelines should be drawn up to direct further action. The results of the situation analysis will help in planning the numbers of people to be treated and where treatment will be delivered (see Service delivery section).

Technical working groups should be formed to carry out detailed planning of activities, consisting of representatives from departments dealing with HIV/AIDS at clinical, laboratory, counselling and pharmacy levels. They should also include representation from people with HIV and communities. Planning will focus on policy, advocacy, logistics, resource mobilization, clinical and psychosocial care.

Coordination mechanisms and linkages should be established between all relevant levels, including the implementation level. These mechanisms should effectively link service delivery, supply management and distribution systems, laboratory services and community services and support. Specifically, links should be formed with programmes and organizations providing HIV prevention, care and support services (see Supply management of commodities and Service delivery sections).

- Reference No. 1.10: *Planning and implementing HIV/AIDS care programmes – A step-by-step approach, 1998.*
- Reference No. 1.11: *Organizational Plan, HIV/AIDS Clinic & Antiretroviral Treatment Programme, Thyolo District Hospital, Malawi, 2003.*
- Reference No. 1.12: *Implementation Guidelines for ART in Uganda, 2003.*
- Reference No. 1.13: *Guidelines for implementing collaborative TB and HIV/AIDS programme activities, 2003.*
- Reference No 1.14: *Toolkit for access to medicines and diagnostics for HIV/AIDS, TB and malaria, August 2002.*

Planning for documentation, monitoring and evaluation

The purpose of documentation is to record experiences, in order to learn from the efforts undertaken and to share the results and lessons learned within the organization and with others externally. Scaling up of ARV treatment is a new process, seeking to involve many different stakeholders, and it is being implemented under a wide variety of conditions. Detailed documentation from a range of programmes will be helpful to improve knowledge in the field. A well-documented evidence base will also make advocacy and policy work more credible.

- Reference No. 1.15: *Documenting and Communicating HIV/AIDS Work – A Toolkit to Support NGOs/CBOs, 2001.*

To assess how well objectives are being met, monitoring and evaluation should be included in the planning stage. At the planning stage, monitoring and evaluation means:

- ▶ selecting appropriate indicators;
- ▶ developing systems for data collection;
- ▶ conducting on-going review, analysis and feedback.

Conditions and needs may change during implementation. The use of indicators and regular evaluation will provide flexibility to adjust activities to accommodate these changes. Monitoring and evaluation should also be put in place from the start, responding to changes in what is required over time as the programme expands (see Monitoring and evaluation section).

- Reference No. 1.16: *Indicators for Monitoring & Evaluation of HIV Prevention, AIDS Care & STI Control Programmes – Easy Reference Guide for PHN Officers and Field Programme Staff, 2000.*
- Reference No. 1.17: *Quick Reference Guide Indicators & Instruments for Monitoring & Evaluation of USAID/UNAIDS/WHO HIV Prevention/AIDS Care/STI Control Programmes, 2002.*
- Reference No. 1.18: *Participatory Impact Monitoring (PIM) – Booklets 1-4, 1996.*
- Reference No. 1.19: *National AIDS programmes: a guide to monitoring and evaluation, 2000.*

2. ENABLING PUBLIC POLICY ENVIRONMENT

An enabling public policy environment is one that comprehensively addresses political, economic, social, legal and health issues. Such issues form the environment in which efforts to combat HIV/AIDS take place. The ways in which they are engaged can either enable or disable treatment programmes to a marked degree. It is therefore vital to address them when planning and implementing ARV treatment programmes. The issues discussed in this section include:

- ▶ Building and maintaining political commitment, including political commitment to mobilizing resources
- ▶ Involving a range of stakeholders
- ▶ Ensuring the greater involvement of people with HIV
- ▶ Promoting a rights-based approach to ARV treatment
- ▶ Regulatory environment affecting medicines and medical supplies including laboratory and prevention commodities
- ▶ Health sector policies

Policy for ARV treatment programmes must be addressed at operational (implementation), national and international levels. Policy is a tool that provides adequate framework and support at every level. While national and international policy frameworks and advocacy are an essential background to national ARV treatment programmes, it is also clear that policy has an equal and complementary role at local, implementation level. It can be used to engage stakeholders and resources, to challenge legal frameworks, to harmonize services within specific areas such as treatment access or testing & counselling. Policy is also necessary as a support for quality in service delivery, for example through accreditation or validation processes.

Building and maintaining political commitment

Why is building and maintaining political commitment necessary? Experience has shown that endorsement, active involvement and leadership by people in positions of authority is vital for implementing treatment, care and prevention programmes and for combating stigma and discrimination. This is 'political' in its broadest sense – it means involving those who have influence and decision-making capacity that impacts on the lives of those affected by HIV, not only in the areas of health and social welfare, but also in aspects of business, law, politics and economics. These people are most often the 'gatekeepers' who can allow or block, intentionally or not, many aspects of tackling the HIV epidemic. Once gatekeepers have been identified, strategic information can be shared with them and other partners can be mobilized (see Involving and mobilizing stakeholders section and Information management and communication section).

It is vital that there is a shared political commitment for working towards universal access to ARV treatment. Political commitment at all levels is a vital element in planning and implementing ARV programmes. This will have several important benefits:

- ▶ mobilizing opinion to support ARV treatment as a public health priority alongside HIV prevention and care for those affected by HIV/AIDS
- ▶ combating stigma and discrimination by confirming that HIV/AIDS is treatable and that treatment enables people to return to health and productive living
- ▶ mobilizing funding and other types of practical support for treatment, care and prevention

Political commitment to mobilizing resources is critical to the successful planning and implementation of an ARV treatment programme. Resource mobilization will mean identifying possible sources and opportunities, setting clear priorities, demonstrating success, sharing strategic information and building capacity for resource mobilization.

- Reference No. 2.1: *Scaling Up Antiretroviral Therapy: Experience in Uganda. Perspectives and Practice in ARV treatment. 2003*
- Reference No 2.2: *National ARV Treatment and Care Guidelines for Adults and Children (draft, April 2003).*
- Reference No 2.3: *Raising Funds and Mobilising Resources for HIV/AIDS Work, 2002.*

Involving and mobilizing stakeholders

Since HIV is not just a health problem but also a social, political, legal and economic one, the importance of involving and mobilizing a range of stakeholders in dealing with the epidemic cannot be over-emphasized. This is because they are affected and because they can play a number of different roles.

Different types of stakeholders include:

- ▶ People with HIV
- ▶ Healthcare workers
- ▶ Governments
- ▶ Non-governmental organizations (NGOs)
- ▶ Community based organizations (CBOs)
- ▶ Faith based organizations (FBOs)
- ▶ Medical associations
- ▶ Drug regulatory authorities
- ▶ Private sector
- ▶ Donors
- ▶ Academic institutions

Involving and mobilizing a range of stakeholders means making serious efforts to build and maintain relationships within and across different sectors of society – formal and informal, within government, community, business and civil society.

The benefits of involving a range of stakeholders include:

- ▶ access to an increased resource base
- ▶ more efficient use of resources
- ▶ improved impact and reach
- ▶ enhanced acceptability and ownership

Involving and mobilizing stakeholders should happen at all levels – i.e. central and implementation levels. While each stakeholder will have his or her own reasons for entering into partnership or collaboration over ARV treatment provision, it is important to keep differing interests balanced and focused on the primary purpose which is the support of people with HIV and promotion of public health. It is also important for the public policy environment to facilitate partnership between different stakeholders (see Involving and mobilizing stakeholders section).

- Reference No. 2.4: *Access to Antiretroviral Treatment and Care: Experience of the HIV Equity Initiative, Cange, Haiti. Perspectives and Practice in ARV Treatment. 2003*
- Reference No. 2.5: *Voices from the Community – Report of a Community Consultation on Antiretroviral Treatment in Zambia; Theme 9: The Role of People with HIV; Theme 10 Community involvement, November 2002.*
- Reference No. 2.6: *Mobilising NGOs, CBOs and PLHA Groups for Improving Access to HIV/AIDS-Related Treatment. A Handbook of Information, Tools and other Resources, December 2002.*

Ensuring the greater involvement of people with HIV

People with HIV are the most important stakeholders in an ARV treatment programme. Ensuring the greater involvement of people with HIV in all aspects of ARV treatment is a true reflection of political commitment. Too often this has remained a principle and has not been translated into action. The greater involvement of people with HIV in all aspects of ARV treatment is also consistent with a rights-based approach, which acknowledges that people have a part to play in decisions that affect their lives. This applies as much to medical treatment as to any other area of policy or action.

Benefits of ensuring greater involvement of people with HIV at all levels of ARV treatment:

- ▶ Active participation of patients in their own treatment encourages closer cooperation with healthcare workers and better feedback on the effects of treatment.
 - ▶ People with HIV who have successfully used ARV treatment are powerful advocates and educators for others accepting treatment: their ability to live a healthy life with HIV is believable testimony that the infection can be a chronic but treatable condition rather than a rapidly fatal one.
 - ▶ People with HIV who are newly diagnosed or starting treatment value counselling from other people with HIV who have had similar experiences.
 - ▶ People with HIV have first-hand experience of what makes a treatment service patient-friendly (or not), and should be involved in the design and running of ARV programmes
 - ▶ Experienced people with HIV can be involved in decisions about who is selected for treatment, alongside physicians and other community members, ensuring equity in selection when resources are limited.
 - ▶ As 'expert patients', selected people with HIV can be trained to assist in education of clinical and support staff to ensure that training and services are grounded in real-life experiences and offer realistic treatment and support.
 - ▶ Visibility of people with HIV who are using treatment successfully is a powerful tool for combating stigma and thus encouraging more people to come forward for HIV testing, counselling and treatment.
- Reference No. 2.7: *Antiretroviral Therapy in Primary Health Care. South African Experience. Perspectives and Practice in ARV Treatment, 2003.*
 - Reference No. 2.8: *Voices from the Community – Report of a Community Consultation on Antiretroviral Treatment in Zambia; Theme 9 The Role of People with HIV, November 2002.*

Promoting a rights-based approach to ARV treatment

The rights-based approach:

- ▶ is based on principles of equality, accountability, empowerment and participation;
- ▶ is based on international human rights standards;
- ▶ integrates the norms, standards and principles of international human rights into, plans, policies and practices.

Most countries are signatories to international legal instruments, declarations and guidelines that are critical components of the rights-based approach to ARV treatment programmes. Being a signatory to these instruments creates an obligation for signatory countries to adhere to the principles laid down in the instruments, under public international law. The instruments form a framework of rights that gives states a basis to formulate their local laws, policies and practices. International instruments provide standards that facilitate the creation of an enabling environment for HIV/AIDS treatment, care and prevention.

The most significant barriers to people's access to care and treatment are stigmatizing laws and practices. These discriminate against vulnerable populations such as sex workers, injecting drug users, men who have sex with men, and women and children. These include laws that discriminate against people with HIV on issues of employment and marriage, and deny access to healthcare and medicines. Such stigmatizing, discriminatory laws impede public health objectives and should be repealed or reformed. There must be careful attention to ensure that such vulnerable populations have access to ARV treatment programmes. Otherwise, the existing inequities will only be exacerbated.

In setting up an ARV treatment programme, countries should:

- ▶ identify the international instruments to which they are signatory;
- ▶ check how the principles embodied in the international instruments are reflected in their national laws and policies;
- ▶ ensure that the policies and implementation of the ARV treatment programme are within the principles included in national laws and policies and international instruments;
- ▶ identify which national laws and policies are barriers to universal access to ARV treatment, and
- ▶ formulate legal strategies to overcome these barriers, such as lobbying or litigation to repeal or reform existing laws and formulate new laws.

The **right to treatment** has now been officially recognized as a human right that flows from the right to health. In terms of ARV treatment programmes, international instruments and guidelines essentially set out a commitment for states to:

- ▶ establish an effective national framework that is transparent and participatory; and
- ▶ take measures to ensure for all people on a sustained and equal basis, the availability and accessibility of quality goods, services and information for HIV/AIDS prevention treatment, care and support, including ARVs and other medicines, diagnostic and related technologies.

- Reference No. 2.9: *Revised international guidelines on HIV/AIDS and human rights, 3rd International Consultation on HIV/AIDS and Human Rights, July 2002.*
- Reference No. 2.10: *Declaration of Commitment on HIV/AIDS, United Nations General Assembly Special Session on AIDS (UNGASS), June 2001.*
- Reference No. 2.11: *Draft Resolution on Access to Medication in the context of pandemics such as HIV/AIDS, Tuberculosis and Malaria, 2003.*
- Reference No. 2.12: *The Human Right to Health, National Courts and Access to HIV/AIDS Treatment. A Case Study from Venezuela. 2002.*

The regulatory environment affecting medicines and medical supplies, including laboratory and prevention commodities

A complex regulatory environment affects medicines and essential commodities, including laboratory and prevention supplies. It requires close attention to detail in order to ensure that the supply chain can deliver the materials necessary for providing safe and effective ARV treatment. It concerns regulation of the quality and safety of medical supplies, of who may prescribe or use them, the regulation of trade, the use of public money for treatments, and sanctions for misuse or misappropriation.

The regulatory environment for medicines and medical supplies will involve cooperation and collaboration between ministries of health, trade, finance and home affairs. It will cover transactions within particular countries but also extends to goods sourced from outside the country. The question of intellectual property rights is important in the use and availability of medicines and other technologies, but other trade considerations must also be taken into account, for example import licensing and taxation of imports and sales of medicines and other goods. Legislation and other measures to protect valuable medicines from theft, such as antiretrovirals, must also be considered, since they will be particularly vulnerable in conditions of scarcity, when they have high value for illegal trading.

Intellectual property rights (IPRs) include the following:

- ▶ patents – exclusive rights granted on a national basis (there are no international patents) to the inventor (innovator) of a product, such as a medicine, which prevents others from making and marketing the same product until the patent expires (for example, 20 years in the World Trade Organization (WTO) member countries);
 - ▶ trade marks – commercial names or symbols used to distinguish products from a specific trade source; for example, a trade or proprietary name for a medicine is the property of the manufacturer and is different from the ‘generic’ name, which can be used by anyone (the INN or international non-proprietary name); and
 - ▶ copyright – the rights of ownership of ‘expressive’ works such as articles, books and pictures; it may apply to the design of medicines packaging, for instance, but not to information about the medicine within it.
- Reference No. 2.13: *Technical Guide to the Contemporary Context and Procurement of HIV/AIDS Medicines and Related Supplies under Bank Funded Programs – Chapter on IPRs (in press).*
 - Reference No. 2.14: *Globalization and access to drugs: perspectives on the WTO/TRIPS Agreement. health economics and drugs, DAP Series No. 7, 1998.*

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement (1995) of the World Trade Organization (WTO) has become a major factor in determining whether marketing of generic products is permitted in individual countries and under what conditions they may be produced in one country and sold in another. The Doha Declaration, made at the WTO Ministerial Conference in 2001, made it clear that public health and

universal access to medicines should be a guiding principle for the application of IPRs. It also affirmed certain flexibilities within the TRIPS Agreement that can be used to protect public health interests in the trade in pharmaceuticals.

- Reference No. 2.15: *Implications of the Doha Declaration on the TRIPS Agreement and public health – health economics and drugs EDM Series No.12.*
- Reference No. 2.16: *Integrating Intellectual Property Rights and Development Policy; Commission on Intellectual Property Rights, September 2002.*
- Reference No. 2.17: *Implications of the Doha Declaration on the TRIPS Agreement and public health – health economics and drugs EDM Series No.12., July 2002.*

The **public health safeguards (flexibilities)** that can be used within the terms of TRIPS must be incorporated within national IPR legislation before they can be put into use. They include, among others:

- ▶ the right of a country to determine what its own public health interests or emergencies are;
- ▶ the right of a country to issue compulsory licenses to bring certain products onto the market and to determine the grounds on which this can be done; and
- ▶ the right of a country to determine when a company has 'exhausted' its patent rights, thus allowing parallel importing of the company's products when available at lower cost from another country

Many countries need legal assistance in understanding these issues and enshrining them within legislation. Some countries have unintentionally agreed to tighter IPR legislation than necessary, blocking the entry of generic medicines or parallel imports onto the market and thus blocking universal access to affordable and essential medicines and related commodities. If necessary, legislation should be changed or repealed in order to ensure that a country's citizens have full access to the medicines and other supplies that are essential for public health (see Supply management of commodities section).

- Reference No. 2.18: *Drug Patents Under the Spotlight – Sharing Practical Knowledge About Patents, May 2003.*
- Reference No. 2.19: *Cost-containment mechanisms for essential medicines, including antiretrovirals, in China – health economics and drugs EDM Series No.13.*

Other trade regulations may also affect the marketing or importation of medicines and medical supplies. There may be regulations that control what products may be imported into the country, by whom they may be imported, from which countries, and what (if any) importation taxes or tariffs are imposed. These may affect products ready for the market or raw materials or intermediate components of products. Sales taxes are also sometimes imposed on medicines, more often for non-prescription products. All of these can affect prices and the availability of essential medicines (see Supply management of commodities section).

Finally, regulatory measures to promote the security of medicines and supplies may be necessary or already be in place. ARVs, like other powerful anti-infective medicines, can find a ready market and high financial rewards for anyone who is able to divert supplies from the public health system to trade them through private and informal outlets. This provides incentives for corrupt practices but is also a danger to the public health goals of treatment. The public system will be deprived of essential supplies and diverted supplies are likely to be wrongly prescribed and used (see Supply Management of commodities section).

Health sector policies

The public policy environment of ARV treatment programmes also includes aspects that arise within the health sector or are specifically focused on HIV/AIDS. Health sector policies may be enshrined within national legislation on health or HIV/AIDS and regulations may be in place to enforce these policies. Once again, it is important to assess these aspects of health sector policies as part of the process of planning and implementing an ARV treatment programme (see Planning section).

They include:

- ▶ HIV treatment and prevention policies, which are likely to include provisions for prescribing ARVs and opportunistic infection (OI) treatments for adults and children with HIV; prophylaxis for mother-to-child HIV transmission (PMTCT), post-exposure prophylaxis (PEP) for health and emergency workers or for sexual assault victims; and universal precautions (UP) to prevent unintended transmission of HIV (see Human resources section).
 - ▶ Public health approaches to HIV/AIDS, including provision of ARV treatment. These should address questions such as who is eligible for treatment, who may provide treatment and how treatment may be supported to achieve the best public health benefit. Leveraging of human resources must be addressed, including financing, recruitment, training, and accreditation of facilities and healthcare workers, to deal with increasing numbers of people seeking ARV treatment (see Human resources and Service delivery sections).
 - ▶ Quality and safety of medicines for use in ARV programmes is the responsibility of the health ministry's Drug Regulatory Authority (DRA). DRA regulations will indicate the conditions under which new drugs may be registered, and who is allowed to prescribe, dispense or sell medicines (see Supply management of commodities section).
 - ▶ Regulations for the selection and use of medicines and medical supplies, including laboratory and prevention commodities, may exist at national level. They may also be developed for local use in accordance with any existing regulations, determining drug and patient selection criteria, treatment guidelines, and protocols for ARV delivery in different health-care settings (see Supply management of commodities section).
 - ▶ Funding mechanisms for medicines and medical supplies, including laboratory and prevention commodities—how ARV treatment programmes or other programmes will be funded, and how (or if) the public or programme users will be expected to contribute towards costs through cost-sharing mechanisms, subsidize service fees or other models (see Costing and financing section).
- Reference No. 2.20: *Access to Drugs for HIV/AIDS and Related Opportunistic Infections in Nigeria - a status report on the sociopolitical, economic, and policy climate on drug availability for People Living with HIV/AIDS (PLWHA) and recommendations for future access, September 2002.*
- Reference No. 2.21: *Rising to the Challenge: Zambia Nurses and Midwives Success Story. 2001.*

3. INVOLVING AND MOBILIZING STAKEHOLDERS

Because HIV affects the social, political and economic aspects of life as well as health, it is vital to involve communities and other stakeholders in all aspects of combating the epidemic, including treatment. By developing formal and informal linkages and partnerships, the success of an ARV treatment programme can be maximized. This section discusses the following:

- ▶ Reasons for involving and mobilizing stakeholders;
- ▶ Different types of partnerships, including community and public-private partnerships; and
- ▶ How stakeholders can be involved and mobilized within different types of partnerships.

Who are the stakeholders in an ARV treatment programme?

A stakeholder can be defined as any individual or group that is an 'interested party', participates in the planning, implementation, management or support of an ARV treatment programme and has particular interests in or expectations about its outcome. Certain stakeholders will have key roles as gatekeepers who can facilitate or block, intentionally or not, many aspects of setting up or successfully implementing an ARV treatment programme. When gatekeepers have been identified, strategic information can be shared with them and other partners can be mobilized.

The ARV programme manager and his or her colleagues in other departments are also stakeholders. It is vital that they understand their own strengths and resources from the beginning of the planning process, in order to better evaluate and decide how to use the resources brought by other stakeholders to the programme.

The 'community' represents those people closest to the patient who provide immediate support to or have influence on people with HIV. People with HIV, their families and communities are vitally important stakeholders in ARV treatment programmes. Patients and those close to them will, of course, be participants in treatment delivery and their cooperation and involvement is vital for treatment adherence. They are also very often the source of financial support—paying for transport, testing and even ARVs—and of informal counselling for the patient and for family members. In addition, they can contribute to programme design and management, community and health-worker education as well as advocacy. Finally, patients can also exert pressure on political bodies to strengthen their commitment.

Stakeholder involvement varies considerably, according to stakeholders' capacity or the needs of the programme and the general social, political and economic setting. Stakeholders in a resource-limited public health setting in Africa, for instance, will cover quite a different spectrum than those who have an interest in programmes in Eastern Europe, China or well-resourced countries.

Stakeholders may be representatives of people with HIV, the community or a range of civil society structures, government sectors and departments, the private sector, international agencies and organizations.

The programme manager or her/his colleagues will be able to identify some stakeholders; others will come forward with a request to be involved. The process of identifying and working effectively with the right range and type of stakeholders will ultimately have an impact on what outcomes the programme is able to achieve.

Each stakeholder will bring a variety of expertise or range of resources to the programme. Participation in an ARV treatment programme can occur at several levels, including policy-making, healthcare systems and delivery, and interactions with patients, families and communities. At each of these levels, programme managers can engage stakeholders in ways that will strengthen the programme and benefit the recipients of treatment, as well as possibly reciprocally benefiting the stakeholders.

Individual stakeholders will have their own reasons for entering into formal or informal participation in an ARV programme. It will therefore be important to keep differing interests balanced and focused on the primary purpose of the programme, which is to support people with HIV and promote public health.

A greater degree of service integration can be achieved if a multi-stakeholder process exists between various prevention, care and support, impact mitigation and treatment interventions, as well as across programmes. Successful stakeholder collaborations that begin in one setting can result in the extension of these initiatives to other parts of a country, or into new regions. Stakeholder participation can therefore be a catalyst for wider scaling up of access to ARV treatment.

What contribution can different stakeholders make to the programme?

Information about the range and capabilities of potential stakeholders will be an important aspect of planning an ARV programme. Different types of stakeholder need to be identified and assessments made of their capacities and willingness to be involved in the programme. If there is to be private participation in service delivery it is useful to establish quality standards and arrange for a system of accreditation to allow private providers to be in formal partnerships with public health services.

It will be helpful to map the range of stakeholders and their actual or potential relationships with the programme. This will provide a picture of the total resources available to the programme, the relationships of stakeholders to one another, and any gaps in resources that the programme manager will have to address in order to set up or implement the programme. The mapping should start with the programme's existing resources and personnel and then map other stakeholders around them. It should indicate the roles of both health and non-health stakeholders in providing services or resources that are supportive to the ARV treatment service. It should also indicate strengths and weaknesses of different players, which will allow planning for skills-building and enforcement of standards of practice.

While such a map will provide an overview at any given time, it is important to remember that ARV treatment programmes are likely to change in scope and size over time, especially during periods of scaling up. Stakeholders who are willing and able to be involved in the early stages might be compelled to modify their input when conditions change, either within the ARV programme or within their own work. Regular review of partnerships and involvement with stakeholders is recommended as part of monitoring and evaluation.

3. INVOLVING AND MOBILIZING STAKEHOLDERS

- Reference No. 3.1: *Mobilising NGOs, CBOs and PLHA Groups for Improving Access to HIV/AIDS-Related Treatment. A Handbook of Information, Tools and other Resources, May 2003.*
- Reference No. 3.2: *Pathways to Partnerships Toolkit, 1999.*

A further **stakeholder analysis** should be done with each key stakeholder in order to match its capacity and willingness to be involved with the needs of the ARV programme. This should ensure greater efficiency and clearer focus on the process of working with the key stakeholders. It will also provide a better estimation of their ability to remain involved when the programmes develop or change.

Questions that can be asked in a stakeholder analysis might include:

- ▶ Who is the stakeholder and, if it is an organization, who represents it?
- ▶ What are the stakeholder's probable interests in participating?
- ▶ What are the stakeholder's strengths and capacities and what specific benefits will be contributed to the programme?
- ▶ At what levels of the programme can the stakeholder become involved and what role would they play?
- ▶ What are each stakeholder's limitations and expectations?
- ▶ How will the stakeholder respond to changes and growth in the ARV programme?

- Reference No. 3.3: *Stakeholder Analysis: A Vital Tool for Strategic Managers.*

Engaging stakeholders in an ARV treatment programme

The process of engaging stakeholders requires that programme planners and managers should first take into account the existing situation, the chosen model of service delivery and the most central stakeholders—the patients and those responsible for treatment implementation, including the programme manager. This process can be complex and demands careful preparation, with allocation of sufficient time and resources for planning and management. Once it has been understood how these central players will relate to each other, it is then possible to start planning how to provide support from other stakeholders, fill any gaps and ensure that all stakeholders work together in a coordinated way.

Stakeholders will be able to contribute to the processes of planning, implementing, maintaining and supporting an ARV treatment programme if there is opportunity for shared decision-making and a clear understanding of expected outcomes. These must be managed in ways that primarily support the programme's objectives. Stakeholder agendas or objectives must not be allowed to overshadow the programme or to interfere with the overall process of stakeholder participation. It will be helpful to have a Memorandum of Understanding for each formal partnership between a stakeholder and the ARV programme so that it is clear how the relationship will work and who has responsibility for it.

The **forum for stakeholder participation** will depend on who is involved, at what level of the programme, and the objectives of the process. Some stakeholders will relate directly to the programme in a variety of ways and not necessarily in cooperation with other stakeholders. However, it is desirable to create ways of getting stakeholders together and working with them to coordinate their activities.

Multi-stakeholder forums and networks can have a number of functions, including:

- ▶ sharing information or experiences, problems and solutions;
- ▶ developing guidelines for good practice (e.g. for policy-making, care delivery activities, reporting);
- ▶ providing collaborative plans for implementing the ARV treatment programme;
- ▶ generating new proposals and ideas;
- ▶ doing advocacy and lobbying based on a shared understanding; and
- ▶ facilitating introductions and access to new contacts and potential sources of resources, etc.

■ Reference No. 3.4: *Networking for Policy Change: An Advocacy Model*.

■ Reference No. 3.5: *A Question of Scale? The Challenge of Expanding the Impact of Non-Governmental Organizations' HIV/AIDS Efforts in Developing Countries, 2002*.

Public-private interactions and ARV treatment programmes

Public-private collaborations and partnerships have become a common feature of health delivery and efforts to combat the HIV epidemic. For these to be effective, the public policy environment must support this type of partnership. They require particular attention as examples of stakeholder involvement because of the nature of the different partners and the differing priorities of public health provision and of private businesses and organizations.

Engaging the private sector can be a complex process for policy-makers and programme managers, but it might be a necessary strategy for achieving ARV service delivery goals. Working with private-sector providers to scale-up access to ARV treatment can be a helpful means of reaching the following five goals:

- ▶ expanding the coverage of ARV treatment;
- ▶ ensuring the quality and safety of ARV treatment;
- ▶ controlling and reducing the total costs of treatment;
- ▶ improving chronic care (HIV disease management) outcomes with ARV treatment; and
- ▶ achieving service integration with other prevention, care and support interventions, as well as public health programmes such as STI and TB control.

Private health providers, commodity suppliers and donors involve themselves in healthcare delivery in a number of ways and at varying levels of informal and formal arrangements. Some are very large-scale international interactions, such as the Global AIDS Vaccine Initiative (GAVI) and the Accelerating Access Initiative (AAI). Others may be bilateral, between a donor and a country or region. An example of this would be a drug producer that offers concessionary prices or donations. Still others may be on a much smaller scale, involving local businesses with specific health-delivery facilities or groups of people.

A possible classification of **private partners** in public-private arrangements that affect an ARV treatment programme could be according to four distinct types:

- ▶ **not-for-profit**, typically NGOs who have their own agenda and reasons for involvement but are not primarily concerned with deriving financial profits from their involvement;

- ▶ **for-profit**, typically businesses that may be involved for humanitarian reasons but have a duty to their shareholders or owners to derive financial returns from most of their activities;
- ▶ **private, facility-based** partners involved in aspects of health delivery, e.g. a private pharmacy or counselling service based at a public health facility; and
- ▶ **private, non-facility-based** partners involved in aspects of health delivery, such as a private doctor or testing laboratory running their own services but in collaboration with a public health facility.

Clearly, different types of public-private interactions will require different methods of management and coordination. They are likely to be more strongly supported and effective for the objectives of the ARV treatment programme when they meet the following criteria, whatever the type of private-sector partner (see Human Resources section).

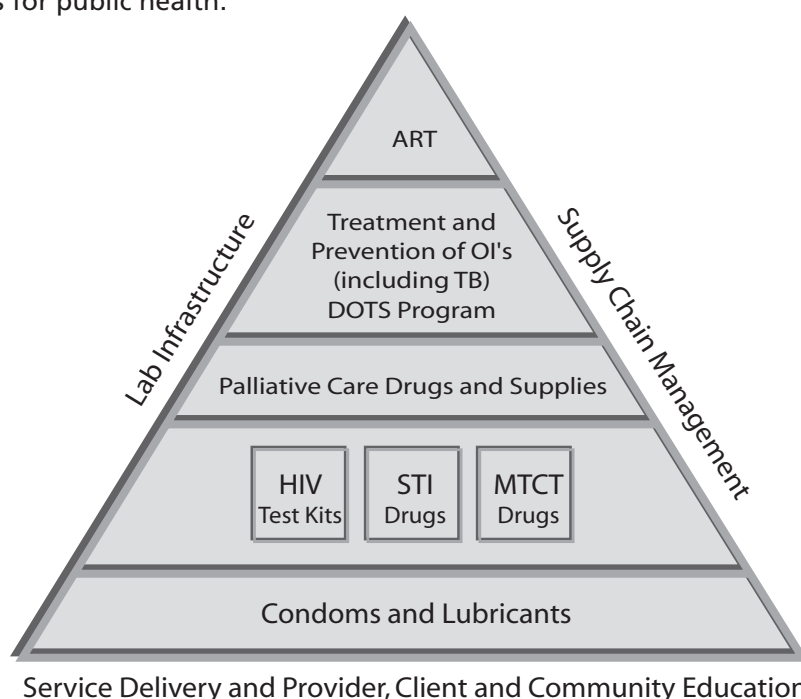
- ▶ They should contribute to the country's HIV/AIDS control programme strategic plan.
- ▶ They should be explicit in defining public health goals that are transparent, effective and have measurable impact.
- ▶ They should lead to non-exclusive collaboration between relevant partners from within public and private sectors.
- ▶ The private sector participant should be willing to make a long-term commitment following an initial pilot phase to assess the feasibility and likely success of the partnership.
- ▶ Management of the partnership should be competent, transparent and effective, respectful of its mandate, roles and responsibilities and willing to collaborate with other stakeholders and partners.
- ▶ They should have mechanisms to prevent conflicts of interest and guard against concerns about the motives for private-sector involvement. This can be achieved by having an appropriate buffer between the private participant and the operational aspects of the programme (such as a third-party manager or oversight by an independent expert steering committee).
- ▶ A formal partnership agreement should be established, with a legally binding Memorandum of Understanding that clearly defines the contribution, roles and responsibilities of each party.

- Reference No. 3.6: *Public-Private Partnerships for Public Health*, 2002.
- Reference No. 3.7: *Antiretroviral Treatment in Developing Countries: The Peril of Neglecting Private Providers*, 2003. *British Medical Journal*, Jun 2003; 326: 1382 - 1384
- Reference No. 3.8: *Working with Private Sector Providers for Better Health Care: an Introductory Guide*.
- Reference No. 3.9: *Private Participation in Health Services*, 2003.
- Reference No. 3.10: *The WHO strategy for traditional medicine for 2002-2005*, 2002.
- Reference No. 3.11: *Promoting the Role of Traditional Medicine in Health Systems: a Strategy for the African Region 2001-2010*, 2000.

4. SUPPLY MANAGEMENT OF COMMODITIES

This section discusses the processes and stages required **for successful supply management of ARVs, other essential medicines, diagnostics and medical supplies** for an ARV treatment programme. The importance of continuity of supply is stressed as the primary goal of supply management. The stages and responsibilities involved in the supply cycle are discussed, including selection, procurement, distribution and supply, and use. Links are provided to practical advice and methods for successful performance of each stage.

The package of commodities that supports ARV treatment is complex, covering a wide range of medicines and other supplies. Most of these have special constraints concerning quality assurance, storage and use; they require special care and expertise to ensure that they are effective and safe to use. Some are already well-established components of essential drug, laboratory and HIV-prevention programmes. Others, such as ARVs and CD4 or viral load tests, are newer products that have only recently been included in lists of essential commodities for public health.



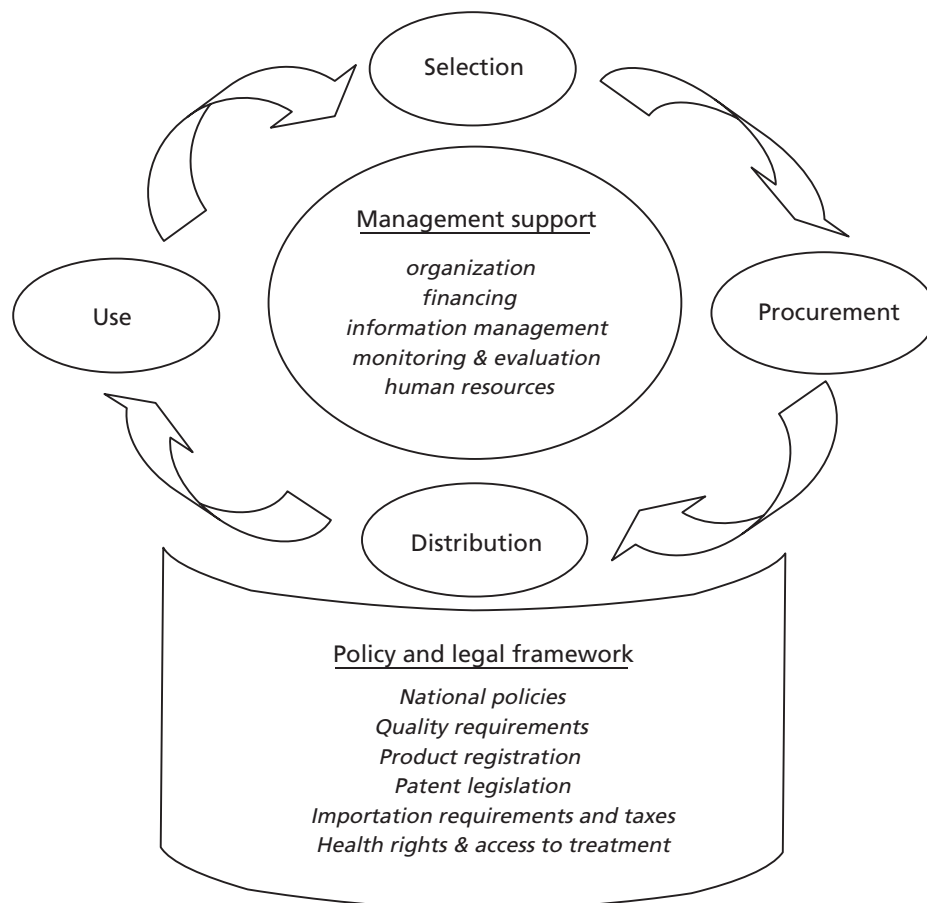
■ Reference No. 4.1: *Technical Guide to the Contemporary Context and Procurement of HIV-AIDS Medicines and Related Supplies under Bank Funded Programs (in press); Section 6 – Procurement.*

Supply and use of these commodities depends on support from functioning laboratory infrastructure, active supply chain management, and a planned and managed service delivery model. It also depends on appropriate education of providers, clients and community about the selection and use of medicines and other commodities within ARV treatment programmes.

The supply management cycle

The central aim of supply management for an ARV treatment programme is to achieve continuous availability and accessibility of all the necessary commodities. Effective treatment for people with HIV depends on avoidance of interruptions in the chosen drug regimen and availability of a second-line regimen in case of resistance or intolerance of the first-line regimen.

Supply management follows a well-recognized cycle, in which different players assume different responsibilities at each stage. Management support is at the centre of the cycle, enabling the whole system to work together. The entire cycle rests on a policy and legal framework that establishes the mechanisms for each stage and supports the commodity management system.



The supply management cycle

Stages of the supply cycle relating to an ARV treatment programme can be summarized as:

1. **Selection:** careful choice of medicines and other products according to national or WHO/UNAIDS guidelines;
2. **Procurement** of value-for-money goods of proven good quality and acceptable expiry dates, especially when some ARVs and HIV-related test materials have short shelf-lives and require cold storage;
3. **Distribution** systems that are effective and efficient for delivering goods to the point of use and ensuring no gaps in supply;
4. **Rational prescribing and use** of medicines and other supplies to support accurate diagnosis and high treatment adherence levels, preventing wastage, unwanted effects or development of drug resistance.

■ Reference No. 4.2: Adapted from *Managing drug supply 2nd ed., 2003 (book)*.

■ Reference No. 4.3: *Commodity Management in VCT Programmes: A Planning Guide, 2002*.

Coordination and cooperation for supply management

The supply cycle must ensure availability of the right products, at the right quantities, of the right quality and reasonable price, where they are needed and at the right times. Management of supply systems for ARV treatment programmes must therefore be agile and responsive in situations where there is uncertainty about many aspects of public health delivery and scaling up of ARV treatment.

Arranging for continuity of supply requires a high degree of coordination across the whole range of commodities that support ARV treatment delivery, including not only ARVs and other medicines but also laboratory supplies and commodities for prevention. Active communication and cooperation is required between all those responsible for the various stages of supply management.

Supply systems for ARV programmes may be centralized, offering some advantages for overall control, monitoring and cost-containment. Interventions and some support functions might instead be decentralized to implementation level, e.g. if commodity procurement is centralized to achieve better prices but delivery and payment are made locally. The degree of complexity will vary according to the setting, but systems should be designed and run in a transparent way so that there will be clarity about who is responsible for what, and how the various elements of the system are supposed to work together.

Who can help with supply management?

Existing structures should be used wherever possible to support the supply cycle for an ARV treatment programme and to carry out some of its tasks. This will provide the benefits of experience and prevent unnecessary duplication of effort, facilities or expenditure. A thorough assessment of needs and potential partnership resources should be done during planning of each stage of supply systems to ascertain possible partners, their capacities and willingness to work together.

For example, it will be necessary to look at existing drug procurement systems such as the National Drugs Programme, to estimate whether it is able to support ARV treatment programme supply management in this way. It will also be necessary to assess the levels of understanding among existing procurement staff about HIV, about the importance of incorporating requirements for 'new' essential drugs and supplies into the existing system. Some education may be needed to improve understanding about the importance of ARV treatment as a public health priority, in order to secure staff commitment to the stringent priorities of continuous supply for the programme.

- Reference No. 4.4: *Technical Guide to the Contemporary Context and Procurement of HIV-AIDS Medicines and Related Supplies under Bank Funded Programs (in press): Section 2 - Elements of the Supply Cycle.*
- Reference No.4.5: *Strategies for an Expanded and Comprehensive Response (ECR) to a National HIV/AIDS Epidemic, Module 7: Managing the Supply of Drugs and Commodities, 2001.*

Selection and quantification of commodities

Deciding what **(selection)** and how much **(quantification)** of each item to procure are the first steps in the supply chain. In order to carry this out successfully, a programme or service must:

- ▶ ensure that adequate systems exist for collecting the necessary data about patients, health needs, treatment facilities and commodities to support accurate quantification and monitoring of usage;
- ▶ accept and implement the use of standard treatment guidelines; and
- ▶ assess whether the chosen products can be made available, depending on the regulatory environment, potential sources of supply and available finances.

Selection of commodities

Who takes responsibility? Clinicians will take primary responsibility for selection, but must do this in conjunction with managers of the drug supply programme and those responsible for financing of the ARV treatment programme and the drug supply programme. Cooperation between clinical, procurement and finance professionals is needed to achieve a balance of rational, realistic and responsive selection of products.

How will it be done? Selection must be done on the basis of approved HIV treatment guidelines, balancing what is clinically desired with what is achievable in a given setting. The treatment guidelines or protocols must be adhered to in practice by all clinicians in the programme, so that the selected list of products reflects the actual use. The use of 'off-list' products must be banned or strictly controlled so that quantification can be based on usage estimates that are as accurate as possible.

Information to help with selection will be found in:

- ▶ national HIV/AIDS treatment guidelines/policies, which should indicate what HIV treatment regimens are approved and who is entitled to prescribe them;
- ▶ national drug policy, which will set out the basis for selection of essential drugs, provide guidance on requirements for registration of drugs and limitations on who may prescribe, dispense or sell them, and provide a National Essential Drugs List;
- ▶ policies and guidelines governing the procurement of other commodities such as laboratory supplies; and
- ▶ documents from WHO and other international agencies that provide guidance for programmes at national and implementation levels; for example, the WHO Guidelines on scaling up ARV therapy in resource-limited settings.

Some countries do not yet have well-developed policies for health commodities. Also, HIV-related commodities such as ARVs and CD4 tests may not yet have been included in existing HIV care policies, if they were drawn up before HIV treatment became a feasible public health option. The concept of scaling up ARV treatment is very new in most countries and has yet to be properly mainstreamed in health policy and HIV care documents. In these situations it will therefore also be necessary to consult global or regional policy statements and treatment guidelines provided by WHO and UNAIDS, in order to gain a full picture of what commodities are required and what is feasible within each country.

- Reference No.4.6: Scaling up antiretroviral therapy in resource-limited settings: guidelines for a public health approach, June 2002.

The regulatory environment

Who takes responsibility? Responsibilities for the regulatory environment affecting medicines and medical supplies are usually divided among different ministries:

- health (drug quality, safety, registration and prescribing, laboratory practice);
- trade (importation, sale of goods, consumer safety);
- finance (taxation, foreign exchange); and
- home affairs ministries (policing, prosecution of criminal breach of regulations).

How can ARV programme and supply managers affect this? Existing regulations will control what is possible within the short term for an ARV treatment programme. If there are regulations that conflict with the aims of a programme and promotion of public health, programme and supply managers should be able to negotiate with their colleagues in the relevant ministries to bring about necessary changes.

The regulatory environment will affect choices about commodities for use in particular countries and settings. When clinical managers have selected their favoured options for ARV treatment, laboratory and prevention commodities, it is vital at this early stage to check key facts about each commodity, for instance:

- Are they available on the market within the country?
- Can they be imported from outside the country if necessary?
- Are the costs (including delivery and other costs) acceptable within the programme's budget?
- Do patent regulations allow for competition between equivalent products within the country or prevent it, thus affecting what products are actually available and what prices can be negotiated?
- Do other trade regulations exist, such as those imposing import tariffs and taxes, which will add to costs and affect availability?
- Do other regulations exist that will affect the use of the products within the programme, such as prohibitions on prescribing or administration of certain drugs by nurses, or on specialist drugs by non-specialist doctors?

Where regulations conflict with an ARV treatment programme's aims or the overall HIV/AIDS plan for the country, it will be necessary to work for changes in regulations or laws that will remove obstacles to the programme's implementation. At the same time it will be necessary to continue to protect whatever public interest the original legislation was aimed at. While waiting for regulatory or other changes, alternative products will have to be chosen or higher prices paid, which will, in turn, affect the programme budget.

Narcotics-control regulations sometimes conflict with the clinical need for adequate pain relief, preventing the use even of weaker narcotics such as codeine. New structures will need to be provided to allow patients to receive the pain control they require while continuing to prevent widespread non-medical use.

Trade regulations might conflict with the need to support public health access to essential drugs. In some countries, taxes are imposed on import of essential drugs, or sales taxes are imposed at the point of supply. This means that the government is putting money into the health system and taking it out again through the taxation system, while also inflating the apparent costs of health delivery. Changes in regulations can correct this type of anomaly and increase transparency about the actual costs of treatment interventions.

Drug registration procedures for new drugs can be slow and expensive. When ARV treatment programmes require new drugs, the programme may be blocked while waiting for registration. However, some countries have set up 'fast-tracking' procedures that rely on external quality and safety verification, and have waived registration fees in order to ensure that ARV programmes start work. Advice and support for these modified procedures have been provided through WHO.

Financial constraints for supply management

Programme managers and those responsible for procurement will need to be fully aware of budgetary constraints on commodity procurement. When making selections, procurement managers and pharmacists should be able to provide information to their clinical colleagues about costs and cost-effectiveness of different options for ARV treatment or diagnostic commodities for treatment monitoring. Costs include the actual purchase prices of the commodities, but also delivery, storage and dispensing costs, plus any taxation or regulatory fees (for example, when registering new products).

The ongoing budget for a programme will also need to be checked against estimated requirements for commodities, especially where scaling up is in place or actual need is not exactly known during the start-up phase. This commodity supply aspect of financing an ARV treatment programme must be fully addressed during planning and closely monitored during implementation. Failure to do so will seriously increase the risk of causing treatment failures through interruption of supply.

Quantification

When the process of selection has been completed, including checks on the regulatory environment and budgetary constraints, the process of quantification can begin.

Quantification—deciding how much of each commodity to buy—is a technical process that is usually the responsibility of procurement staff as the first practical step towards procurement of goods. It can only be done successfully if users of commodities follow agreed policies and guidelines and have based their selection of commodities on them. If not, usage patterns are likely to be erratic and it will be difficult or impossible to decide how much of each commodity should be procured.

Accurate quantification is important for two key reasons:

- ▶ Making certain that enough of each product is purchased, with adequate expiry dates, which ensures that there are no stock-outs and that each patient receives continuous ARV treatment.
- ▶ Ensuring that products are not over-purchased, guards against wastage and over-expenditure that results from products expiring on the shelf before they can be used.

Quantification depends on three possible sets of data:

- ▶ Past usage (consumption) within the programme, generally provided from well-maintained stock records; this is useful for well-established programmes with predictable needs but not for new or rapidly changing situations;
- ▶ Usage in similar programmes or services, using records from those programmes or (sometimes) data from suppliers who are familiar with the programmes; this is useful in new programmes or with new treatments, if the programmes or services are sufficiently similar for the comparison to be valid.
- ▶ Patient morbidity data and standard treatment protocols, a combination of data that will reflect the actual context of a treatment programme if the figures are accurate. This method is more time-consuming, but is useful in promoting the employment of standard treatment and laboratory guidelines. However, careful judgement is necessary when morbidity figures are likely to be inaccurate or areas of unmet need have not yet been assessed.

At least two of these methods should be used for comparison each time, in order to prepare accurate estimates for procurement.

- Reference No.4.7: *Managing drug supply: Chapter 14 Quantifying Drug Requirements, Chapter 29 Investigating Drug Use. 1997.*

Procurement of commodities

Existing guidance for **good procurement practice** should be used in the design and management of procurement systems for ARV treatment-related commodities. These follow well-established principles based on experience gained with essential drug supplies for public health systems in developing countries, and founded on five strategic objectives:

- ▶ select reliable suppliers of high-quality products;
- ▶ procure the most cost-effective drugs in the right quantities;
- ▶ ensure timely delivery;
- ▶ ensure transparency in sourcing, pricing and management of supplies; and
- ▶ provide an early warning system for users about potential or actual problems within the supply chain that will affect short- or long-term availability of individual commodities.

The possibilities for achieving these strategic objectives will vary in different settings but will always depend on the successful application of these basic principles, no matter what combination of public, NGO or private services are used to manage procurement and delivery systems.

- Reference No. 4.8: *Operational principles for good pharmaceutical procurement (Interagency Guidelines), 1999.*
- Reference No. 4.9. *World Bank Technical Note: Procurement of Health Sector Goods, May 2000.*

Quality assurance—a primary consideration

Quality must be the primary consideration in choosing what medicines and tests to procure, and must not be compromised by pricing or other considerations. Quality assurance of medicines and health commodities is necessary to ensure that products are consistently produced and monitored, so that patient safety is protected and treatment interventions achieve the maximum benefit.

The quality of a product includes not only the actual drug or test but also the packaging, labelling and storage conditions, both during the production and distribution process but also on dispensing for the use of individual patients. The purchaser or consumer must be satisfied that production facilities and procedures, distribution and storage conditions are of sufficient and consistent quality to provide confidence in their effects when provided to patients.

WHO and a number of internationally recognized regulatory authorities provide well-established guidelines on good manufacturing practice and quality assurance. Individual countries may also have such guidelines in place. In addition, guidelines exist for good storage, distribution and dispensing practice. Application of these guidelines will assist in providing good quality medicines and supplies whose quality is maintained from the time of production until the commodities are put into use for the care of patients.

Monitoring of these aspects throughout the procurement system requires considerable technical expertise and ample facilities. These will be available in some countries, often administered by the Drug Regulatory Authority. Regulatory systems are at different stages of development in different countries but are one of the chief means for a country to regulate what medicines are supplied to the public and to prevent substandard or ineffective medicines from being used. External assistance is available through WHO and other bodies when in-country capacity is lacking.

- Reference No.4.10 Quality assurance of pharmaceuticals, a compendium of guidelines and related materials, Vol 1 , Geneva, World Health Organization, 1997 and Vol. 2 GMP and inspection (update in print), 1999.
- Reference No. 4.11 WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-sixth Report, 2002.
- Reference No. 4.12: Effective drug regulation. What can countries do? 1999.

Sourcing and pricing

The process of sourcing and pricing of commodities involves:

- ▶ identifying who produces the required commodities and who will act as suppliers (the producer or an intermediary such as a trader or wholesaler);
- ▶ checking the quality of the producer and supplier as well as the products they offer, including the quality of service, continuity of production and ability to deliver on time;
- ▶ determining who can offer the best price when confidence has been established about the quality and equivalence of comparable versions of a particular product; and
- ▶ negotiating to obtain further price advantages on the basis of quantity and competition.

It is important to establish good linkages with businesses involved in commodity supply, and to develop relationships that enable ARV treatment programmes to reach their goals. Good business relationships will provide motivation for suppliers to perform well, to avoid exploitation and to respond flexibly and helpfully to public health needs, especially during times of uncertainty.

Sourcing of commodities

Sourcing requires market intelligence, meaning active research of the global and local pharmaceutical markets and of possibilities for procurement within and from outside a

particular country. Many developing and least-developed countries have very limited capacity for local production, although some basic essential drugs might be produced, usually from imported raw materials. Importation of newer medicines and tests will therefore be the norm for ARVs and many other HIV-related commodities for some time to come.

Commodities identified for procurement through the selection process may be:

- ▶ multiple-source (generic and innovator), especially if a product is no longer controlled by patent regulations and competition exists between equivalent versions, for example drugs, dressings and condoms;
- ▶ single-source (innovator) if the patent holder has a monopoly on the market for the product in a particular country; this applies to proprietary HIV tests and (usually) to new medicines;
- ▶ single-source (generic or innovator) if the product is off patent but not commercially profitable and only available from one producer.

Procurement officers might require external assistance in gathering information about sources, both within the country and from the international market. Information can be obtained for HIV-related single-source (innovator) medicines, or about both generic and innovator products through United Nations agencies and a number of international NGOs.

WHO and NGOs such as Médecins sans frontières (MSF) and Health Action International (HAI) have produced a number of helpful documents on various aspects of sources, prices and patents, which are regularly updated and can be accessed via the Internet.

- Reference No. 4.13: Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS, 2002.
- Reference No. 4.14: Global Drug Facility: An Initiative of the Global Partnership to stop TB, Global Drug Facility.
- Reference No. 4.15: UNICEF procurement services.
- Reference No. 4.16: WHO Fact Sheet on drug price information services. What is WHO doing to improve drug price information? 2003.
- Reference No. 4.17: Medicine Prices, a new approach to measurement (working draft for field testing and revision)
- Reference No. 4.18: Essential Drugs and Medicines Policy: TRIPS, Globalization and Access to Medicines.
- Reference No. 4.19: Campaign for Access to Essential Medicines: Resources, Reports and Publications.

In some circumstances, donations might be considered as a source of medicines. However, experience with donations has shown over the course of many years that there are severe constraints to their usefulness for ongoing public health treatment programmes. Specifically, donors are often unable to supply drugs that conform exactly to those selected for standardized treatments and continuity of supply usually cannot be guaranteed over a prolonged period. Since these two factors—conformity to standard treatment guidelines and continuity of supply—are core elements of ARV treatment, use of donations for public health ARV treatment programmes in high-prevalence settings may be problematic. However, there has been some success with carefully planned and controlled, single-source donation schemes for specific disease programmes, such as ivermectin for river blindness and, more recently nevirapine for PMTCT. The WHO Guidelines for drug donations should be followed on this subject and WHO/EDM should be consulted for advice on the ways in which donation programmes can be implemented and made successful.

- Reference No. 4.20: Guidelines for drug donations, revised 1999.

Other important considerations in deciding on sources and acceptable prices include the delivery periods that suppliers can offer and their reliability in practice. Unreliable deliveries can be seriously harmful for treatment of individuals, programme success and credibility, so ability to achieve timely delivery must be considered along with quality and price.

Requirements for storage space must also be heeded during the process of supplier selection and price negotiation, both for individual products and for bulk supplies. Individual products may have special temperature requirements for storage, which will affect provision of facilities during procurement and after dispensing to the patient, especially in hot or extremely cold countries. The bulk volume of supplies depends on the packaging as well as on the product, and different suppliers may provide equivalent products in vastly different volumes; assessment must therefore be made of dimensions and storage requirements before placing a firm order for a product.

- Reference No. 4.21: *Managing drug supply, the selection, procurement, distribution and use of pharmaceuticals, Chapter 13.4, 1997.*

What prices can be achieved?

Pricing is usually done at the same time as sourcing and is the responsibility of procurement staff. Several lists of indicative prices exist for HIV-related products and essential drugs that can be used for this process. These provide price guides, which can be helpful during selection and at the beginning of price negotiations. A supplier might offer individual products from a standard price list, but there are often possibilities for downward negotiation of prices, particularly if large amounts or regular supplies are required.

Individual programmes or facilities may not be able to achieve sufficient order volume to obtain the best prices, but experience with procurement of essential drugs has shown that joint procurement arrangements between programmes or through a national clearing-house can allow for downward negotiation of prices. Examples include the Organization of Eastern Caribbean States (OECS) Drug Procurement Service and church-related services such as MEDS in Kenya and Joint Medical Stores in Uganda.

Some individual innovator companies have agreed to sell their products at significantly lower cost under price agreements ('differential' or 'tiered' pricing) for resource-limited countries experiencing serious public-health problems; well-resourced countries will pay higher prices for the same products. Suppliers of differentially priced products generally seek safeguards to ensure that there is no 'leakage' of low-price products into countries that are not part of the price agreement. In other countries, the government sets maximum price levels or 'reference' prices that indicate the maximum that the public health system will pay for each product.

- Reference No. 4.22: *Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS, 2002.*
- Reference No. 4.23: *Guidelines for price discounts of single-source pharmaceuticals. 2003*

Pre-qualification of products and suppliers

When preparing to make a selection of the drugs to be used, independent information on the drugs' patent situation should be sought. There are ongoing efforts by WHO, MSF and others to enable easier access to this information and quicker purchase of good-quality drugs.

Steps must also be taken to ensure acceptable quality, one of these being pre-qualification of suppliers and products. This is a process of verifying the manufacturer's claims about quality assurance, Good Manufacturing Practice and other standards, and checking the quality and safety of commodities such as medicines and tests. Many countries and programmes lack adequate testing laboratories and the process of verifying supplier claims about quality is time-consuming and requires special expertise.

A number of schemes exist to share verified information about the quality of pharmaceuticals and of HIV tests. These schemes have focused on evaluating products and manufacturers of the new 'essential' commodities for treatment of HIV. The WHO schemes aim particularly at providing assistance for countries without local capacity for quality assurance or testing. The drugs pre-qualification list includes both generic and originator drugs.

Reliance on the WHO lists of pre-qualified products is recommended. It saves time and effort, and provides independent verification of claims about quality. However, the fact that a product or producer is not listed does not necessarily mean that they are of bad quality—simply that they have not yet satisfied requirements for inclusion in the scheme. The pre-qualification list is constantly being revised and extended, so an up-to-date version must always be consulted. In-country procurement managers can also set up their own pre-qualification schemes where facilities and human resources are adequate for this.

- Reference No. 4.24: *HIV/AIDS drugs pre-qualification, pilot procurement, quality and sourcing project: access to HIV/AIDS drugs of acceptable quality, 2003.*
- Reference No. 4.25: *WHO HIV diagnostics: HIV test kit evaluation.*
- Reference No 4.26: *Patent situation of HIV/AIDS-related drugs in 80 countries 2002.*
- Reference No 4.27: *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa? AIDS, 2001.*
- Reference No 4.28: *TRIPS: Drug Patents, Technical note: Pharmaceutical patents and the TRIPS agreement, July 2000.*

Other schemes exist, such as the Pharmaceutical Inspection Cooperation Scheme (PIC/S) the International Conference on Harmonization (ICH). Few (if any) limited-resource countries are signatories to these schemes at present, although some countries may choose to rely on the data that are made available under them.

- Reference No. 4.29: *Pharmaceutical Inspection Cooperation Scheme*
- Reference No.4.30: *The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use*

Methods of procurement for ARVs and related commodities

Procurement methods vary according to product availability, quantity required and price. Procurement may be done at a centralized national procurement facility to take advantage of a concentration of skill, experience and bulk handling. This is likely to be preferred in the early phases of scaling up when careful monitoring of supply and demand will be required. It may alternatively be decentralized to service provision level to allow greater control and responsiveness to change at local level.

Methods employed for procurement include competitive bidding or tendering (either open or limited), 'shopping' (comparison of quotations) for off-the-shelf small quantities of products, contracting with specific suppliers for a period of repeat supply, and procurement from United Nations or not-for-profit supply agencies. Different methods will be required

for different commodities and quantities. Some donors also impose their own guidelines for procurement that must be followed when using their funds—for example, the World Bank. Procurement staff must be conversant with the range of options and their advantages or disadvantages. In some instances, existing donor guidelines may introduce long delays before orders can be placed with suppliers, and it may be necessary to negotiate with donors to streamline procedures so that ARV treatment programmes are not held back from treating patients.

- Reference No. 4.31: *Managing drug supply: The selection, procurement, distribution and use of pharmaceuticals, Chapters 16 & 17. 1997.*
- Reference No. 4.32: *Technical Guide to the Contemporary Context and Procurement of HIV-AIDS Medicines and Related Supplies under Bank Funded Programs (in press).*

Distribution & supply

Careful management of distribution, including storage and transport, is essential for the smooth-running of the supply cycle and ensuring continuity of supply. This has four aims:

- ▶ ensuring maintenance of product quality;
- ▶ reducing wastage;
- ▶ preventing theft, pilfering or diversion to outlets other than the one intended; and
- ▶ controlling use and gathering information for ongoing procurement needs.

Good storage and distribution practice

The processes of storage and distribution occur at several stages in the supply chain. They require adequate premises and transport facilities that are secure, of sufficient capacity for the volume of goods to be handled and maintained in a state designed to maintain the quality of the goods. This means that they must be clean and dry, with goods stored off the floor, with adequate temperature control, and sufficient space between goods to facilitate handling and stock control. Different commodities will require different storage and distribution conditions, particularly if they are temperature sensitive. These requirements must be included when assessing storage and distribution needs.

- Reference No. 4.33: *Managing drug supply: the selection, procurement, distribution and use of pharmaceuticals, Chapter 21, 1997.*
- Reference No. 4.34 *WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty-seventh Report. Geneva, World Health Organization, 2003 (WHO Technical Report Series, No. 908).*

Inventory control

Inventory or stock control refers to the amount, location and value of each commodity that is located within a supply system. Management of inventory depends on information systems that provide methods and feedback for:

- ▶ tracking storage and movement of goods at every level within the supply system, from central storage through to stocks ready for use at the health facility;
- ▶ enabling managers to know the total amounts of a commodity that are within the supply system, and where they are;
- ▶ recording acquisition and issue of stocks; and
- ▶ providing data for monitoring and further procurement.

Simple systems of paper or computer-based inventory control can provide adequate data for most programmes. Access to supplies must be restricted to those commodities that are permitted for use within the programme. Inventory records must be regularly monitored, to provide assurance that items are being issued correctly and not diverted or misused. Good quality of inventory records is also essential to provide data for review and decisions about future procurement

In changeable conditions, such as the scaling up of ARV programmes, it is essential to review inventory levels frequently, such as every month, rather than the six-month or annual review usually employed for inventory control. It is also important to remember to include within the inventory sufficient stock for occasional unforeseen problems or emergencies.

- Reference No. 4.35: *Managing drug supply: the selection, procurement, distribution and use of pharmaceuticals, Chapter 15, 1997.*

Use of commodities

Use of commodities completes the supply management cycle, but is also the starting point of a new cycle of selection, procurement, distribution and use. Supply aspects that are important at the point where commodities are put into use include:

- adhering to guidelines for treatment, diagnosis or prevention;
- recording which commodities are used for which patients and why;
- providing feedback into the supply system of data required for planning continuity and further procurement, including prescribing, dispensing and laboratory records;
- providing feedback on how acceptable products are to patients; and
- communicating requirements for new products or changes in guidelines that will result in variations in usage and changes in procurement.

Prescribing and patient support are primarily clinical responsibilities for doctors, nurses and pharmacists, but it is also essential that there are mechanisms for two-way exchange of information between clinical staff and procurement staff. Since treatment continuity is so important in ARV and TB programmes, long-term support of patients depends to a high degree on the continued efficiency and reliability of supply.

Monitoring and evaluation systems for the supply management cycle must therefore include methods of matching data about performance of supply cycle tasks with the experience at clinical level. Methods exist for monitoring usage of essential drugs, which can be applied to ARV treatment programmes. Methods also exist for monitoring effectiveness within procurement systems. However, as yet there is little published information about methods that would match ARV treatment usage data against procurement performance, which would help to indicate their effects on treatment continuity and effectiveness within the ARV treatment programme context.

- Reference No. 4.36: *Managing drug supply: the selection, procurement, distribution and use of pharmaceuticals, Chapters 31 & 32, 1997.*
- Reference No 4.37: *Rapid Pharmaceutical Management Assessment: an Indicator-Based Approach.*
- Reference No. 4.38: *WHO HIV test kit bulk procurement scheme, 2003.*
- Reference No. 4.39: *UNICEF List of MTCT plus drug prices, 2003.*
- Reference No. 4.40: *Untangling the Web of Price Reductions, 2003.*
- Reference No.4.41: *International Drug Price Indicator Guide 2002.*
- Reference No. 4.42: *WTO OMC Fact Sheet - TRIPS and pharmaceutical patents (web site)*
- Reference No. 4.43: *Toolkit for Access to Medicines and Diagnostics for HIV/AIDS, TB and Malaria: Selected Resource Materials*

5. SERVICE DELIVERY

This section discusses the service delivery aspects of an ARV treatment programme.

These relate directly to the safe and effective delivery and use of ARV treatment within the continuum of comprehensive care and prevention. Issues discussed in this section include:

- ▶ service delivery planning;
- ▶ approaches for service delivery; and
- ▶ components of service delivery that must be addressed to provide quality ARV treatment and improve coverage of services, including:
 - employing standardized protocols for testing, counselling, treatment and patient selection;
 - providing linkages to other services and involving stakeholders, including people with HIV;
 - strengthening service components related to ARV treatment;
 - raising awareness of the benefits and availability of ARV treatment;
 - using and developing strategies to promote adherence and prevention;
 - employing strategies to address stigma and discrimination; and
 - developing operations research.

ARV Treatment—an integrated approach to chronic care

ARV treatment is life long and requires a chronic disease approach. This is a different approach from typical models of acute and episodic care. Health providers and decision-makers should familiarize themselves with WHO's strategy for comprehensive chronic disease care in resource-limited settings and use it to guide the planning and implementation of ARV treatment programmes.

The **chronic disease approach** is based on the following principles:

- ▶ Provides interface between an informed, supported patient and informed, supported care providers;
- ▶ Focuses on long-term care with regular follow up;
- ▶ Is planned as part of a comprehensive care, support and prevention strategy
- ▶ Offers delivery of services across a range of levels to ensure broadest possible access;
- ▶ Provides effective communication and referral systems across different levels where services are provided;
- ▶ Offers patient-centred care and education to encourage active participation in care and promote adherence to long-term treatment and protective behaviour;
- ▶ Provides care linked to family and community;
- ▶ Emphasizes prevention;
- ▶ Monitors and evaluates quality of services and long-term patient outcomes.

- Reference No. 5.1: *Innovative care for chronic conditions: building blocks for action, 2002.*
- Reference No. 5.2: *Extending essential care. Integrated management of adolescent & adult illness (IMAI), 2003.*
- Reference No. 5.3: *Integrated management of adolescent & adult illness (IMAI). General principles of good chronic care module, 2003.*
- Reference No. 5.4: *Continuum of care for people living with HIV/AIDS Operational Framework.*

Planning service delivery

Planning for the following elements of service delivery will help to determine the approach in terms of where ARV treatment will be provided, how it will be provided and who will be involved (see Planning ARV treatment programmes section):

- ▶ **Epidemiology:** The number of individuals in the population who are infected with HIV
- ▶ **Testing and counselling uptake:** How many of those people choose to find out their sero-status? The rate of testing and counselling uptake will influence the rate of entry into ARV treatment services; it is thought that individuals will be encouraged to find out their HIV status through testing and counselling if better treatment options become accessible to them.
- ▶ **Enrolment criteria:** The proportion of people who need treatment is known (10% for an early epidemic, 15% for a mature epidemic and 20% for an advanced epidemic). Given these data, what is the total number of people who need ARV treatment, based on the number of people with HIV and the stage of the epidemic?
- ▶ **Numbers of people to be treated:** Based on current resources, how many people can be provided with safe and effective treatment?
- ▶ **Coverage of existing services:** Determined by what services are accessible to what parts of the population. How many are currently covered, where and in what way?
- ▶ **Health-seeking behaviour:** whether individuals understand their needs for care, treatment and prevention, and where they choose to access these.
- ▶ **Ensuring access:** covers a broad category that includes: addressing barriers such as lack of information or understanding, affordability, marginalization and stigma.
- ▶ **Durability of therapy:** the period of time that individuals on treatment continue to be adherent and derive benefit from treatment.

Approaches to service delivery

A range of viable and valid approaches is necessary for scaling up ARV treatment, particularly in resource-limited settings. As suggested by the chronic disease management process, ARV treatment is best supported through approaches that are based on integrated HIV/AIDS care, treatment, support and prevention.

Implementing an ARV treatment programme within existing health systems and linking it with existing healthcare services will provide an opportunity to improve overall health service delivery. It will also provide better support for long-term patient care and achieve better health outcomes. This will also simultaneously contribute to the goals of health system strengthening and health sector reform. These approaches will require a concerted, coordinated effort by a range of stakeholders if the healthcare system is to be strengthened beyond the narrowly defined needs of an ARV treatment programme (see Guiding principles section).

- Reference No. 5.5: *Antiretroviral Therapy in Primary Health Care: Experience of the Khayelitsha Programme in South Africa. Perspectives and Practice in Antiretroviral Treatment, 2003.*
- Reference No. 5.6: *Scaling Up Antiretroviral Therapy: Experience in Uganda. Perspectives and Practice in ARV treatment, 2003.*
- Reference No. 5.7: *Integrated management of adolescent & adult illness (IMAI) HIV care module, 2003.*

Approaches to delivering ARV treatment successfully, within any specific setting, will be determined by:

- local circumstances;
- availability of resources and existing infrastructure;
- relationships between various providers at different levels of care; and
- health-seeking behaviour of the population.

Although there may be different approaches to service delivery within countries and between countries, the principles of the recommended public health approach for scaling up ARV treatment should be common to the varying approaches.

The number of people seeking care, treatment and prevention is rapidly increasing and there is urgent need to provide decentralized services to cope with the growing demand and to make care, treatment and prevention more accessible. Services should therefore be implemented in ways that will help to address this need for decentralization, which favours embracing a range of approaches for delivering treatment, including community or district-based delivery approaches. This will require clearly defined functions, roles and responsibilities at each level.

- Reference No. 5.8: *A Public Health Approach to Antiretroviral Treatment: Overcoming Constraints. Perspectives and Practice in Antiretroviral Treatment, May 2003.*
- Reference No. 5.9: *Access to Antiretroviral Treatment and Care: Experience of the HIV Equity Initiative, Cange, Haiti. Perspectives and Practice in ARV Treatment, 2003*
- Reference No. 5.10: *Access to Treatment for HIV/AIDS: Report of a Meeting of International Experts, 2003.*
- Reference No. 5.11: *Introducing Antiretroviral Therapy (ART) on a Large Scale: Hope and Caution - Programme Planning Guidance Based on Early Experience from Resource-Limited and Middle-Income Countries.*

The approach to ARV treatment delivery should ensure access to care across a continuum—from health facility to community to home. This will require a strengthening of the relationship between the health services and the community. The approach should also ensure that ARV treatment services are accessible close to the populations served. Health planners should aim for a balance between approaches that call for new systems to provide treatment services and an approach that improves and builds on existing programmes and services.

ARV treatment delivery can be situated within the existing health system across a range of entry points. A range of different health services can serve as entry points for ARV treatment, including TB, counselling and testing, PMTCT, STI, primary healthcare and community support (see box below). TB programmes, in particular, offer a useful framework for the delivery of ARV treatment. This would require close collaboration in the planning phase, plus harmonization of services at the implementation level (see Planning section).

Possible entry points to HIV/AIDS care and ARV treatment:

- ▶ Testing and counselling;
- ▶ TB treatment and contact tracing;
- ▶ STI/reproductive health care, including follow-up and partner notification;
- ▶ Antenatal care/PMTCT;
- ▶ Inpatient/specialist care;
- ▶ Primary health care; and
- ▶ Community support.

The delivery approach for ARV treatment should be defined in terms of the following:

- ▶ Site;
- ▶ Level;
- ▶ Entry points in other services;
- ▶ Population to be treated and numbers to be treated;
- ▶ Referral systems; and
- ▶ Partnerships and links with other service components and stakeholders.

Depending on the approach to service delivery, it should be decided which healthcare workers will perform which tasks in terms of:

- ▶ who can prescribe;
- ▶ who will provide clinical care;
- ▶ who will provide follow-up patient care;
- ▶ who will conduct treatment-preparedness activities, including patient education and support for adherence; and
- ▶ who will conduct HIV prevention activities.

Training and implementation guidelines can be developed accordingly (see Human resources section). It will be important to ensure teamwork and sharing of tasks between different healthcare workers to achieve scale in ARV treatment. The active involvement of people with HIV, families and members of the broader community will be crucial. Involving healthcare workers, people with HIV, families and members of the community will also be essential for ensuring effective referral, follow-up and ongoing support. Experience from TB prevention and control efforts in resource-limited settings has shown that this service delivery strategy can be successful both in terms of positive treatment outcomes and achieving scale in treatment.

- Reference No. 5.12: *Scaling Up Antiretroviral Therapy: Experience in Uganda. Perspectives and Practice in ARV treatment, 2003.*
- Reference No. 5.13: *Antiretroviral Therapy in Primary Health Care. Experience of the Khayelitsha Programme in South Africa. Perspectives and Practice in ARV Treatment, 2003*
- Reference No. 5.14: *Access to Antiretroviral Treatment and Care: Experience of the HIV Equity Initiative, Cange, Haiti. Perspectives and Practice in ARV Treatment, 2003*
- Reference No. 5.15: *Voices from the Community – Report of a Community Consultation on Antiretroviral Treatment in Zambia, November 2002.*
- Reference No. 5.16: *Integrated management of adolescent & adult illness (IMAI) HIV care module, 2003.*
- Reference No. 5.17: *Guidelines for Implementing Collaborative TB and HIV Programme Activities, 2003.*
- Reference No. 5.18: *Integrating HIV and TB at Service Delivery Level, Draft, September 2003.*
- Reference No. 5.19: *Partnership work: the health service – community interface for HIV/AIDS prevention, care and treatment. Report of a WHO Consultation (in press).*
- Reference No. 5.20: *Avaliação da Qualidade da Assistência Ambulatorial nos Serviços Públicos de Atenção no Brasil. Departamento de Medicina Preventiva-FMUS. Setembro de 2001.*

The components of ARV treatment services include:

- ▶ **Counselling and testing services** that are:
 - easily accessible,
 - integrated with follow-up and ongoing counselling services, including education for treatment literacy, adherence and HIV prevention; and
 - provide referral and linkages to other care, support and prevention services, such as community and clinic referral networks for other psychosocial needs, such as welfare support, legal support, etc.;
- ▶ **Trained counsellors and community supporters** who are able to identify the psychosocial needs of individuals, and assist them with treatment adherence and with accessing care, support and prevention;
- ▶ **Trained personnel** who have sufficient knowledge about HIV care, prevention and ARV treatment, are familiar with treatment guidelines, able to prescribe ARVs and have access to specialist clinical decision support;
- ▶ **Basic medical services** that are capable of identifying and treating common HIV-related illnesses and opportunistic infections, providing OI prophylaxis, initiating and monitoring ARV care and referring individuals to higher levels of care or into community and home-based care services.
- ▶ **Reliable laboratory services** capable of routine laboratory investigations such as full blood count and chemistry. Access to a referral laboratory is desirable, for CD4+T-lymphocyte counts and viral load estimations to monitor therapy;
- ▶ **Reliable, affordable and continuous supplies of quality ARV medicines and other essential commodities** such as medicines to treat OIs and other related illnesses;

Elements of service delivery

Addressing the following elements in the delivery of ARV treatment services will help to ensure quality of ARV treatment and improve coverage of services:

- ▶ Standardized protocols for testing, counselling, treatment and selecting patients
- ▶ Linkages with other services and involving a range of stakeholders including people with HIV
- ▶ Strengthening of components related to ARV treatment service delivery
- ▶ Awareness-raising of the benefits and availability of ARV treatment
- ▶ Use and development of strategies to promote adherence and prevention
- ▶ Employment of strategies to address stigma and discrimination
- ▶ Development of operations research

Standardized protocols for testing, counselling, treatment and selecting patients:

These will greatly simplify patient care and follow-up, if used along with simplified laboratory and patient information. All of these should be reviewed regularly, updated and used for training of healthcare workers (see Human resources section and Testing and counselling toolkit section).

- Reference No. 5.21: *Scaling up anti-retroviral therapy in resource-limited settings: guidelines for a public health approach*, June 2002.
- Reference No. 5.22: *Affordable Antiretrovirals in South Africa – Treatment Protocol*, February 2002.
- Reference No. 5.23: *Guidelines for clinical management of HIV infection and HIV-related illnesses (AFRO)*, March 2003.

- Reference No 5.24: *WHO HIV/AIDS Treatment and care protocols for Ukraine and countries of the Commonwealth of Independent States, August 2003.*
- Reference No. 5.25: *The MTCT-Plus Clinical Manual. January 2003.*
- Reference No. 5.26: *Revised Guidelines for HIV Counselling, Testing and Referral, 2001.*
- Reference No. 5.27: *The use of antiretroviral therapy: a simplified approach for resource-constrained countries. 2002*

Linkages with other services and involving a range of stakeholders, including people with HIV: Comprehensive care and prevention for individuals receiving ARV treatment cannot be provided by a single institution or organization alone. Treatment services should be delivered as part of a package of prevention, care and support interventions, with close linkages to community structures, especially NGOs, CBOs, private providers and traditional healers and with the participation of people with HIV. Effective referral networks are necessary between the range of stakeholders and services at health-facility level and community level to achieve continuity of care, treatment and prevention and to meet the range of needs of people with HIV. Community participation in HIV interventions often begins through involvement in prevention activities, which provide a good starting point for mobilizing support for treatment services. Individuals on treatment often become strong advocates for HIV prevention and are more likely to participate in community prevention activities, as well as in promoting the benefits of care and support.

- Reference No. 5.28: *Integrated management of adolescent & adult illness (IMAI) HIV care module, 2003.*
- Reference No. 5.29: *Integrated management of adolescent & adult illness (IMAI) general principles of good chronic care module, 2003.*
- Reference No. 5.30: *Integrated management of adolescent & adult illness (IMAI) acute care module, 2003.*
- Reference No. 5.31: *Integrated management of adolescent & adult illness (IMAI) palliative care module and caregiver booklet 2003.*
- Reference No.5.32: *Improving Access to HIV/AIDS-Related Treatment: A Report Sharing Experiences and Lessons Learned on Improving Access to HIV/AIDS-Related Treatment, 2002.*
- Reference No. 5.33: *Mobilising NGOs, CBOs and PLHA Groups for Improving Access to HIV/AIDS-Related Treatment - A Handbook of Information, Tools and other Resources. May 2003.*
- Reference No 5.34: *Partnership work: the health service – community interface for HIV/AIDS prevention, care and treatment. Report of a WHO Consultation (in press).*

Strengthening of components related to ARV treatment service delivery: Evidence has shown that testing and counselling are important entry points for accessing HIV care, treatment, support, and prevention. Too few people know their sero-status, even in high sero-prevalence settings, and this means that more individuals seek care later in the course of their HIV infection when symptoms can no longer be ignored. It is important to strengthen testing and counselling and other service components related to ARV treatment, such as supply management to prevent stock outs, nutrition, psychosocial support, PMTCT, prevention and treatment of TB, OIs and STIs. This also means that referral systems must be strengthened between the different service delivery components of an ARV treatment programme (see Supply management of commodities section and the section Testing and counselling toolkit).

- Reference No. 5.35: *Antiretroviral Therapy in Primary Health Care. Experience of the Khayelitsha Programme in South Africa. Perspectives and Practice in ARV Treatment, 2003.*
- Reference No. 5.36: *Access to Antiretroviral Treatment and Care: Experience of the HIV Equity Initiative, Cange, Haiti. Experience of the Khayelitsha Programme in South Africa. Perspectives and Practice in Antiretroviral Treatment, 2003.*
- Reference No. 5.37: *Technical consultation on voluntary HIV counselling and testing: models for implementation and strategies for scaling of VCT services, Harare, Zimbabwe, 3-6 July 2001.*

Raising awareness of the benefits and availability of ARV treatment: Health-seeking behaviour is a complex issue that is influenced not only by the availability of treatment or services, but also by the perceived benefit that these provide and by their accessibility and affordability. Knowledge about ARV treatment in the general population and even among people with HIV tends to be poor. Myths and misinformation about ARVs contribute to inappropriate beliefs about treatment—some expect that it is a cure for HIV while others are convinced that it is toxic. An effective information and education strategy that is focused on ARV treatment will reinforce the introduction of treatment and could also promote the uptake of testing and counselling, contribute to behavioural change and help to reduce stigma and discrimination.

- Reference No. 5.38: *Voices from the Community - Report of a Community Consultation on Antiretroviral Treatment in Zambia, November 2002.*

Strategies to promote adherence and prevention: Maintaining adherence to ARV treatment is the greatest challenge to achieving success in an ARV treatment programme. A very high level (>95%) of adherence is required to avoid treatment failure. Interventions to improve adherence and prevention should be a high priority within ARV treatment programmes. Individuals who are on treatment also need to maintain a healthy lifestyle and safer sexual practices to avoid the risks of acquiring new complications of HIV, contracting infectious diseases such as STIs, and spreading HIV or resistant virus to others. Therefore, prevention for people with HIV is critical for long-term adherence.

Experience from TB prevention and control has shown that early community involvement is essential for good treatment outcomes. Service delivery models for chronic HIV disease management should be designed to provide a strong emphasis on adherence and prevention through a multidisciplinary approach. A number of service delivery strategies are being used for improving adherence to ARV treatment and protective behaviour. These include the DOT-HAART strategy based on the TB directly observed therapy model. A similar model, based on directly administered ARV treatment (DAART) is being used in institutional settings such as prisons or where there is regular access to individuals (such as in the workplace). Overall, there is a need to develop more strategies and tools to support adherence and prevention.

There are many interventions that have been used for improving adherence and prevention and have proven to be effective for various disease conditions. Examples include:

- education in self-management;
- pharmaceutical care programmes;
- nurse, pharmacist and other health professional intervention protocols;
- counselling;
- behavioural interventions;
- follow-up and reminders; and
- community and social support (i.e. informal or formal support received by patients from other members of their community).

- Reference No. 5.39: *Adherence to long-term therapies: evidence for action, Chapter 12, 2003.*
- Reference No. 5.40: *Promoting Adherence to HIV Antiretroviral Therapy, 2002.*
- Reference No. 5.41: *Voices from the Community – Report of a Community Consultation on Antiretroviral Treatment in Zambia, November 2002.*

- Reference No. 5.42: *Positive Prevention. Prevention Strategies for People Living with HIV/AIDS (draft background paper).*
- Reference No. 5.43: *Community contribution to TB care, a Latin American perspective, 2002.*
- Reference No. 5.44: *Community contribution to TB care, an Asian perspective, 2002.*
- Reference No. 5.45: *Community TB Care in Africa, 2001.*
- Reference No. 5.46: *Integrated management of adolescent & adult illness (IMAI) HIV care module 2003.*

Strategies to address stigma and discrimination: Evidence shows that stigma and discrimination prevent people from accessing treatment, care and prevention. Involvement of a range of stakeholders, including healthcare workers, communities and people with HIV, can contribute significantly to reducing stigma and to providing a supportive environment for all people with HIV. This plays an important role in supporting adherence and prevention. NGOs, CBOs and people with HIV/AIDS also play an important role in providing information and education and in working with service providers to increase the coverage and use of services. Community education efforts also help create a more supportive environment for treatment, care and prevention programmes (see section on Involving and mobilizing stakeholders).

Providing ARV treatment for vulnerable populations, such as women, children, sex workers, MSM, or IDU, will be an important consideration for service delivery. Since these populations are typically stigmatized and discriminated against, they risk exclusion from ARV treatment programmes. ARV treatment programmes must be developed in a way that responds to the needs of the specific individuals who they are meant to support. They should also address the barriers to access often experienced by vulnerable populations.

- Reference No. 5.47: *Sex Workers: Part of the Solution, 2002.*

Operations research: The goal of operations research (OR) is to increase the efficiency, effectiveness and quality of services delivered by providers, and the availability, accessibility, acceptability to and use of services by users. An important objective of OR is to provide managers and decision-makers with the information to improve or scale up service delivery. ARV treatment programmes should consider developing OR as part of planning process.

- Reference No. 5.48: *Designing HIV/AIDS Intervention Studies. An Operations Research Handbook, 2002.*

6. HUMAN RESOURCES

In many of the communities where ARV treatment is urgently needed, there is already a shortage of skilled human resources to provide routine health care. In areas of the world where there have been high rates of HIV infection, there are growing numbers of people with HIV who are in need of the full range of care, treatment and prevention services. Human resources numbers and skills required should be determined against the background of needs of the community, the existing facilities and the resources that might be available. This section discusses:

- ▶ Human resource needs of an ARV treatment programme
- ▶ Better use of existing skills (reducing dependence on highly skilled human resources)
- ▶ Training needs
- ▶ Knowledge, attitude and practices of health care workers
- ▶ Addressing the impact of HIV/AIDS on health care workers

Human resources are the most critical component of health systems and delivery. There must be political commitment at all levels to develop and support human resources, such as training, motivation and ensuring a safe working environment. Many different types of human resources are needed for the safe and effective delivery of ARV treatment. These include people with skills in management, administration, supply management, clinical care and community-based care.

Human resource needs

To determine human resource needs for an ARV treatment programme, an analysis of skills and tasks should be done. This analysis should involve a range of stakeholders (see Planning section). Human resource requirements will be further defined on the basis of the service delivery approach. Depending on the approach chosen for service delivery, roles and responsibilities should be clearly defined. A range of skills and teamwork is needed, shared between clinical and other skill types (e.g. administrative, management, procurement and financial), as are awareness and sensitivity to one another's roles and responsibilities.

New partnerships are required between healthcare workers, community members, people with HIV, traditional healers, patients and their families. Evidence shows that involvement of communities and people with HIV helps in supporting adherence and improving treatment outcomes. Participation of communities, peers and family members has been shown to be essential for large-scale rollout of ARV treatment. Again, for these new partnerships to function effectively, roles and responsibilities within these new partnerships must be clearly defined.

In order to manage human resources efficiently, there is a need for an updated human resource information management system. Such a system could provide ready information on the different skill sets available and the numbers of healthcare workers (see Information management and communication section).

- Reference No.6.1: *Human Resource Management Rapid Assessment Tool for HIV/AIDS Environments. A Guide for strengthening HRM Systems. February 2002.*
- Reference No. 6.2: *The National Strategic Framework for Expansion of HIV/AIDS Care & Support in Uganda, 2001/2 – 2005/6, February 2002.*

Making better use of existing skills

Some successful pilot projects for delivering ARV treatment have relied on strategies to reduce dependence on highly skilled physicians. In these pilot projects, aspects of patient care and follow-up have been shared among different cadres of healthcare workers, the community and family members. To address the lack of highly skilled human resources, existing skills should be upgraded and leveraged to cope with the demands of delivering ARV treatment services. Strategies that reduce dependence on highly skilled personnel will enable a larger number of people to access ARV treatment. For example, clinical officers could be trained to prescribe and monitor treatment of people with HIV. Sharing the different aspects of patient care and follow-up between different cadres of healthcare workers will depend on health sector policies and the chosen service delivery approach (see Enabling public-policy environment section and Service delivery section).

- Reference No.6.3: *A Strategy for the Implementation of Antiretroviral (ARV) Therapy in Kenya. A strategic document developed by the Ministry of Health, with technical support. November 2002 to February 2003. Phase 1; refer pp. 52-55.*
- Reference 6.4: *Rising to the Challenge: Zambia Nurses and Midwives Success Story. 2002.*
- Reference 6.5: *Involving private practitioners in tuberculosis control. Issue, interventions and emerging policy framework. 2001.*

Training

Training of human resources in providing ARV treatment is essential for the safe and effective delivery and use of ARV treatment. Training should be integrated within the pre-service training of healthcare workers as well as within the ongoing service training. Even though ARV treatment may not be widely available, healthcare workers should be equipped with up-to-date and accurate information about ARV treatment. This type of training should be ongoing.

Different cadres of healthcare workers will have different training needs and these will have to be met on an ongoing basis. Training will have to be developed and conducted for different cadres of healthcare providers, including people with HIV and community members; the different levels of training will interact with each other. The content, appropriateness and delivery of training for different cadres of healthcare workers will depend on their allocated roles and responsibilities, again based on the service delivery approach that is chosen. The content of the training should be based on standard treatment protocols and clinical management guidelines. Standardization of training and developing guidelines for accreditation of training is a way of ensuring quality of treatment and follow-up of training.

Training standards should be the same for public and private sector service providers. Building skills and competencies through training should be linked to opportunities to use these skills in practice. It will be important to have provision for evaluation of training and continuing education.

- Reference 6.6: *International treatment access coalition training and programme matrix 2003.*

Training of healthcare workers should begin in a phased manner in conjunction with the expected subsequent increase in resources and expertise. A medium-term human resources plan should be developed, because setting up training and filling the necessary positions will take time to accomplish. The impact of the private sector's recruitment needs should also be recognized. Skills that are lost due to staff migrating out of the country and general

staff turnover must be addressed as part of a proactive human resource strategy and ongoing training.

Health care workers' knowledge, attitudes and behaviour influence the way in which HIV care, treatment and prevention services are delivered and used. This is most apparent at the level of patient interaction. Improving health worker knowledge, attitudes and behaviour requires training, supervision, leadership, guidance and professional support. Training for all cadres of health workers should enable them to develop and maintain appropriate knowledge, attitude and behaviours.

- Reference No.6.7: *National Guidelines for Training on ART in Uganda, Draft, April 2003.*
- Reference No.6.8: *Global health-sector strategy for HIV/AIDS, 2003-2007: providing a framework for action, 2003.*
- Reference No. 6.9: *WHO Fact Sheets on HIV/AIDS for nurses and midwives, 2000.*

Addressing the impact of HIV/AIDS on healthcare workers

Healthcare workers are also among those affected by HIV/AIDS. The impact of HIV/AIDS on healthcare workers can increase staff turnover and adversely affect staff morale as well as their ability to perform in their jobs. Providing a safe working environment includes workplace programmes for HIV prevention, treatment, psychosocial support, PEP and UP. These are important measures for addressing the impact of HIV/AIDS on healthcare workers. Healthcare workers should benefit from the available treatment services so that their ability to perform in their job is not adversely affected. Issues of staff motivation, confidentiality, non-discrimination and stigma reduction for healthcare workers should also be addressed within the context of workplace initiatives for healthcare workers.

The following strategies can be used to address inadequate skills and numbers of health care workers:

- provide pre-service and in-service training;
 - share tasks related to patient-care and follow-up among different cadres of health care workers;
 - address attrition;
 - address issues of motivation; and
 - ensure a safe working environment for health care workers.
- Reference No.6.10: *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post-exposure Prophylaxis, 2001.*
 - Reference No.6.11: *Developing HIV/Workplace and Medical Benefits policies (Draft Summary), 2003.*
 - Reference No.6.12: *Workplace HIV/AIDS programmes – an Action Guide for Managers, 2002.*
 - Reference No. 6.13: *Implementing the ILO Code of Practice on HIV/AIDS, International Labour Organization, 2002.*
 - Reference No. 6.14: *Implementing the ILO Code of Practice on HIV/AIDS and the world of work: an education and training manual,. International Labour Organization, 2002.*
 - Reference No. 6.15: *AIDS and HIV infection:.. information for United Nations employees and their families, 2001.*

7. INFRASTRUCTURE

Infrastructure is defined as the material support that is needed for treatment programmes, including outlets such as health facilities, physical facilities, commodities (medicines, clinical supplies, laboratory supplies) and the equipment, skills and logistics that enable them to work together to support health service delivery. Essentially, it is everything that you would physically find upon entering a facility, as well as transport and communication facilities. The issues discussed in this section include:

- ▶ the basic infrastructure requirements for ARV treatment;
- ▶ the ability to monitor effectiveness ;
- ▶ the development and strengthening of a network of facilities;
- ▶ patient follow-up mechanisms; and
- ▶ information management.

Infrastructure of health systems in many resource-limited countries has suffered from lack of regular maintenance and long periods of disrepair. In spite of this, a number of pilot projects have shown that the safe and effective provision of ARV treatment in resource-limited settings is entirely possible. In agreement with the concept of a phased approach to scaling up, ARV treatment set-up should build on whatever infrastructure already exists. To begin with, it should be clearly understood what the minimal infrastructure needs are for ARV treatment to commence.

Infrastructure requirements of an ARV treatment programme

Evidence indicates that ARV treatment can commence even where the existing basic health infrastructure requires strengthening. Epidemiological data and patient volume should guide the choice of health facilities to be invested in. The approach chosen to deliver ARV treatment should direct the investment needs. The delivery approach will influence the choice of the site and the extent of service provided.

In conjunction with relevant stakeholders an assessment should be done of the current state of infrastructure to gauge what investments need to be made. Since strengthening of infrastructure will be done in a step-wise manner, clear guidelines should be followed on what health facilities should be upgraded and when. Resource limitation will also oblige a phased approach. Infrastructure will need to be strengthened and upgraded further as the programme expands and accommodates greater demand. There should be regular review of infrastructure to address gaps and/or reallocate financing (see Planning ARV treatment programmes section and Service delivery section).

The basic infrastructure requirements for ARV treatment include:

- ▶ a room for confidential counselling;
- ▶ a room for clinical consultation;
- ▶ laboratory facilities for at least a rapid HIV test and diagnosis of OIs;
- ▶ secure storage and dispensing facilities for ARV medicines;
- ▶ set-up of a confidential patient registry;
- ▶ information-management systems and effective communications within and between facilities and other service providers.

These are the minimum requirements for providing safe and effective ARV treatment. Some health facilities may be set up to provide more comprehensive services. Others may serve as points from which referrals for more complex diagnosis are made, but might still provide basic clinical monitoring of diagnosed patients.

- Reference No.7.1: *Scaling Up Antiretroviral Therapy: Experience in Uganda. Perspectives and Practice in ARV treatment. (in press)*
- Reference No. 7.2: *A Strategy for the Implementation of Antiretroviral (ARV) Therapy in Kenya. A strategic document developed by the Ministry of Health, with technical support. Phase 1, November 2002 to February 2003.*

Clinical facilities

Clinics and healthcare facilities in many resource-limited settings have suffered from long periods of neglect. The need for upgrading healthcare facilities has to be accommodated in scaling up ARV treatment. This will mean that resources must be allocated specifically for this.

Laboratory infrastructure

Diagnosis: WHO recommends a minimum of a confirmed rapid HIV antibody test and haemoglobin or haematocrit determination, in order that ARV treatment can be started safely. There must be proof of infection before starting ARV treatment, and screening for anaemia is essential before starting zidovudine-containing regimens. In the absence of facilities to conduct the recommended tests, ARV treatment can start when the patient meets certain clinical criteria described in WHO stage IV. Diagnosis by laboratory tests is considered important for identifying patients at optimal stages for ARV treatment.

ARV treatment monitoring: The ability to monitor treatment is an important element of ARV treatment. Apart from clinical observation, periodic CD4 cell counts and viral load tests are recommended, to assess the progress of treatment. Competitively priced laboratory technologies to determine CD4 cell counts and viral load are increasingly available. Furthermore, a number of pilot projects are successfully managing patients on ARV treatment while conducting CD4 counts just twice a year. In resource-limited settings, the phased approach for scaling up ARV treatment recommends upgrading of laboratory facilities to provide the full range of ARV treatment monitoring, to be done at large central health facilities. Samples can be transported from smaller peripheral centres to the reference laboratories, provided transport and logistics infrastructure is upgraded at the same time. This would enable an optimal use of laboratory and human resources trained in the relevant diagnostic skills.

OI diagnosis: Laboratories should also have the necessary equipment to diagnose OIs. Here too there should be clear criteria to define what is required for a laboratory, from machinery and reagents to safety procedures and apparatus. In preparation for strengthening laboratories, the following should be assessed:

- What equipment is in place?
- What tests can the lab perform with existing levels of staff?
- What minimum tests can be done that could give adequate assessment of the patients' condition? How often do these tests have to be done?
- Has all staff received the same basic training?
- Is equipment regularly maintained? How long do repairs take? What is the main obstacle to repair? Are spare parts available and accessible?

- ▶ What safety measures (gloves, masks, hoods against TB exposure, re-sheathing needles, sharps disposal, incinerator, waste management) are enforced in the lab?
- ▶ How long is the turnaround time for results to get to the clinician?
- ▶ What is the availability of lab reagents and their storage requirements?
- ▶ What is the process for sending samples to higher-level facilities and getting back results?

WHO has issued guidelines for minimum laboratory tests needed to assess the progress of a patient on ARV therapy.

- Reference No.7.3: *Guidance modules on antiretroviral treatments. Module 5 - Laboratory requirements for the safe and effective use of antiretrovirals, Module 5 - Laboratory requirements for the safe and effective use of antiretrovirals, 1998.*
- Reference No.7.4: *Scaling up antiretroviral therapy in resource limited settings: guidelines for a public health approach, 2002.*
- Reference No.7.5: *Technical Working Group for the Development of an HIV/AIDS Diagnostic Support Toolkit. Meeting Report, 2002.*

Support facilities

Other aspects of infrastructure that must also be reviewed and strengthened are facilities for secure storage of medicines and other supplies, such as maintenance and office supplies. Communications within and between facilities is also an important feature of infrastructure. These would include regular meetings and briefings between departments, in person, or by radio, telephone or e-mail, or both. Ideally, referral mechanisms, links between service-providers, regular updates on new and relevant information relating to treatment access and scaling up should be conducted without impediment. Transport should also be considered, including transport of samples for analysis to the referral centre, and collection of medicines and other supplies needed for service delivery. There might also have to be arrangements to transport patients or staff, in the event that public transport is not affordable or efficient.

Patient follow-up

There needs to be an efficient and confidential method of recording and following up patients enrolled in ARV treatment. The infrastructure should facilitate follow-up if patients migrate between treatment centres, for example because of employment-related mobility. At the same time, the system must prevent fraud or the issuing of multiple prescriptions. A confidential patient registry of all individuals who are on treatment at a site is important for providing chronic care follow-up, assessing adherence and determining treatment outcomes. The ideal would be to have a centralized information system that links patients and drug flows and can allow for patient tracing. Infrastructure must reflect the need to protect confidentiality in the areas of counselling, dispensing and treatment.

Although computerized information systems offer many advantages in managing clinical information, record-keeping can be performed manually and paper-based information systems at the clinic level can be supplemented with centralized computer databases. The applicability of computer-based information systems in various settings requires further investigation and specific strategies for technology transfer, technical support, data integrity and security, deployment and integration with existing technology.

- Reference No. 7.6: *A Strategy for the Implementation of Antiretroviral (ARV) Therapy in Kenya. A strategic document developed by the Ministry of Health with technical support. November 2002 to February 2003, Phase 1*

Information management

Information management is a key issue ranging from management of patient data and follow-up, to synchronization of management and data for procurement, distribution, dispensation and storage (see Information management and communication section).

Networking of facilities

A ready network of facilities will hasten the scaling up of ARV treatment. Efficient and effective communication between referral centres and facilities will be very useful in strengthening partnerships. Infrastructure should be set up to facilitate efficient and regular communication between relevant departments and stakeholders in the service process. It is important to have functional operational relationships between different departments within the health system, such as coordination and information-sharing between clinical care, lab services and pharmaceutical services. The possibility of accessing ARV treatment may mean that many more clients come forward to be tested and treated through other entry points including ANC clinics, STI clinics and TB clinics. There will have to be a link between the patient and pharmacy records so that authorized personnel can quickly follow, for example, what regimen the patient has been on, and for how long.

In many parts of the world, borders are increasingly fluid. The movement of people and goods related to health will have an impact on monitoring and regulation, while also presenting an opportunity for networking facilities and resources across regions. Service providers should take these possibilities into account when conducting assessment and planning.

- Reference No.7.7: *Guidelines for organizing national external quality assessment schemes for HIV serological testing*, January 1996.

As far as is possible, ARV treatment should be delivered within whatever infrastructure is already present. One of the lessons learned about infrastructure for successful delivery of ARV treatment is that well-planned site preparation is critical. Responsibility for this among the stakeholders should be clearly delineated. Attempts should be made to select sites made up of a network of facilities rather than single, isolated facilities. There should be a well-communicating referral network. Once the infrastructure criteria for providing ARV treatment have been defined, an accreditation scheme should be put in place. These requirements should be officially endorsed to ensure quality of ARV treatment in both public and private facilities.

8. COSTING AND FINANCING

Inadequate financing and the poor capacity of health systems have been major reasons for the lack of ARV treatment programmes in resource-limited settings. This section discusses issues related to costing and financing of an ARV treatment programme including the following:

- ▶ defining targets—programme's strategic target (i.e. people who need ARV treatment);
- ▶ defining programme components and the unit cost of each component;
- ▶ determining unit cost per patient;
- ▶ defining the actual numbers of people who receive ARV treatment;
- ▶ adopting a phased approach;
- ▶ identifying cost-reduction strategies; and
- ▶ evaluating existing financial options.

Estimating costs

Estimating costs for an ARV treatment programme requires detailed data about the numbers of people requiring treatment, the planned components of the programme and knowledge of actual costs for these components. Several tools exist to estimate the costs of HIV/AIDS programmes, although none of them has been specifically designed for ARV programmes.

Estimating programme costs entails:

- ▶ defining programmatic targets in terms of the vision for the numbers to be treated;
- ▶ defining programmatic components and determining unit costs for each of the components;
- ▶ defining unit cost per patient; and
- ▶ determining the actual number to be treated.

- Reference No. 8.1: *AIDS Treat Cost software. 2003*
- Reference No. 8.2: *Resource Needs for HIV/AIDS: Model for Estimating Resource Needs for Prevention, Care, and Mitigation. 2002*
- Reference No. 8.3: *Costs of Scaling HIV Programme Activities to a National Level in Sub-Saharan Africa: Methods and Estimates, 2001.*
- Reference No. 8.4: *Design and Application of a Costing Framework to Improve Planning and Management of HIV/AIDS Programmes, 2000.*
- Reference No. 8.5: *Goals Model For Estimating the Effects of Resource Allocation Decisions on the Achievement of the Goals of the HIV/AIDS Strategic Plan Version 3.0. March 2003.*
- Reference No. 8.6: *A Step-by-Step Methodological Guide for Costing HIV/AIDS Activities, 2000.*

Defining the programme's strategic targets

Defining the programme's strategic targets is the first step in estimating an ARV treatment programme's financial needs. In order to define the programme's strategic target in terms of how many people will be provided with ARV treatment, one must consider the following (see Service delivery section):

- ▶ HIV/AIDS prevalence
- ▶ population type to be treated
- ▶ uptake of counselling and testing (related to health-seeking behaviour)
- ▶ numbers of symptomatic people known in health facilities (related to health-seeking behaviour)
- ▶ clinical eligibility for ARV treatment
- ▶ proportion of patients that must switch to second- and third-line treatments to be taken into account, since these regimens are usually more expensive than first-line treatments

Defining components and determining unit costs per component

When the programmatic target has been established, the next step is to define the ARV treatment programme components and unit cost of each component. Identifying the programmatic components should be based on the national HIV/AIDS strategic plan and the service delivery approach.

Cost components include both recurrent costs (e.g. labour, materials and supplies, operating costs) and capital costs (e.g. vehicles, buildings, equipment), which may be specified for each activity of the programme (e.g. clinical treatment and care, lab monitoring, training, monitoring & evaluation). In addition to activities that are strictly ARV-related, basic HIV care and support (e.g. testing and counselling, prevention and management of opportunistic infections, psychosocial support, palliative care, home-based care) should be strengthened or developed at the same time.

Unit costs of programme components can be derived from different sources:

- **published listings**, in particular for materials and supplies. For instance, price information of ARVs and other essential medicines and diagnostics used for HIV/AIDS are published by WHO and MSF.

- Reference No.8.7: *Untangling the Web of Price Reductions: a Pricing Guide for the Purchase of ARVs for Developing Countries*, 2002.
- Reference No. 8.8: *Sources and Prices of Selected Drugs and Diagnostics for People Living with HIV/AIDS*, May 2003.

- **ongoing small-scale projects** in the country; costs can be extracted from them using existing costing tools.

- Reference No. 8.9: *Design and Application of a Costing Framework to Improve Planning and Management of HIV/AIDS Programmes*, 2000.
- Reference No. 8.10: *A Step-by-step Methodological Guide for Costing HIV/AIDS Activities*, 2001.

- **existing costing studies**. Several costing studies exist, for instance on the cost of the ARV programmes in Brazil and Mexico, the estimated costs of a national treatment programme in South Africa and the costs of HIV/AIDS hospital care in Zimbabwe. However, such external data should be used with caution, since certain costs, in particular the cost of labour, may be country-specific, and figures can quickly become outdated.

- Reference No. 8.11: *Direct Costs of AIDS Treatment in Brazil*, 2001.
- Reference No. 8.12: *Costing of HIV/AIDS Treatment in Mexico*, 2003.
- Reference No. 8.13: *HIV/AIDS Care in Mexico in the Era of HAART: a Multi-Centre Study of Costs and Utilization in the Mexican Public Sector*, 2002
- Reference No. 8.14: *Providing Antiretroviral Treatment for All Who Need it in South Africa. CSSR Working Paper No. 42*, 2003.

Care must be taken when extrapolating unit costs from small-scale programmes to the national level. Fixed start-up costs make up a relatively large proportion of the total costs in pilot programmes, and cost per patient may therefore be overestimated, resulting in overestimation of the true costs of a national programme.

- Reference No. 8.15: *Costs of scaling HIV programme activities to a national level in sub-Saharan Africa: methods and estimates*, 2001.
- Reference No.8.16: *Methods for Estimating the Costs of a Nation-Wide HAART Programme in Botswana*, 2002.

Calculating the unit cost per patient and setting the actual target for the number of people to receive ARV treatment

Based on the programme's strategic target (i.e. the number of people who need ARV treatment) and the costs of programmatic components, the unit cost per patient can be calculated.

From an assessment of the unit cost per patient and the actual funding available for the ARV treatment programme, the target for the actual number to be treated can be established.

A phased approach for financing an ARV treatment programme should be adopted. This would mean that as more funds are mobilized on an ongoing basis, services can be improved and expanded and the target number of people receiving treatment can be revised upwards to meet the programme's strategic target.

Cost reduction strategies

Despite the price reductions that have occurred in recent years, ARVs are still a major cost component of treatment programmes. Overall, costs of commodities will continue to be the major component of treatment programme costs. They can, however, be reduced through a number of measures to negotiate lower prices and allow local competition in the market for ARVs, other expensive medicines and diagnostics (see Supply management of commodities section).

In addition to attempting to reduce costs of medicines and other commodities, other costs of the ARV treatment programme can be reduced by:

- ▶ employing low-cost laboratory techniques to monitor ARV treatment. WHO identifies several scenarios for lab monitoring that are of increasing quality but also of increasing cost. Programmes must balance cost with quality in terms of types and frequency of tests performed, based on available resources;
- ▶ avoiding unnecessary laboratory tests such as the viral load test, and wherever possible reducing the frequency of required laboratory tests;
- Reference No. 8.17: *Scaling up anti-retroviral therapy in resource-limited settings: guidelines for a public health approach 2002.*
- ▶ centralizing laboratory services, to provide important cost savings through volumes of samples. The appropriate balance between centralized and decentralized lab tests is determined by the cost of transportation of samples and their stability;
- ▶ involving other organizations in providing ARVs. For instance, NGOs that are already active in HIV prevention and care could also be involved in ARV treatment. Furthermore, private companies, having a clear interest in reducing HIV-related morbidity and mortality in their workforce, could be involved in ARV programmes or assisted in setting up their own.
- Reference No. 8.18: *Mobilising NGOs, CBOs and PLHA Groups for Improving Access to HIV/AIDS-Related Treatment. A Handbook of Information, Tools and other Resources, May 2003.*

Some cost recovery is likely to occur, from a societal perspective, because of a reduction in lost productivity of patients. A formal cost-effectiveness study will be necessary to show to what extent costs of a treatment programme are offset by its benefits. Guidelines for this are available.

- Reference No. 8.19: *Evaluating Programmes for HIV/AIDS Prevention and Care in Developing Countries, 2002.*

Key cost reduction strategies include:

- ▮ careful selection of medicines and supplies;
- ▮ bulk purchasing – national, regional;
- ▮ increasing competition;
- ▮ ARV price observatory;
- ▮ parallel importing of branded ARVs;
- ▮ compulsory licensing on patented ARVs;
- ▮ drug donations;
- ▮ review of possible re-allocation of services;
- ▮ harmonization and enforcement national standards in treatment;
- ▮ low-cost laboratory monitoring;
- ▮ standardized monitoring tests and schedule;
- ▮ centralized laboratory services; and
- ▮ cost sharing among partners.

Existing options for financing

Many of the financing options for ARV programmes have limitations. Any one, or any combination of, the following mechanisms would help to address the limitations:

- ▮ a public sector that can afford to provide a substantial portion of the funding;
- ▮ widespread social insurance;
- ▮ substantial donor-financing or development loans, or both.

One of the main sources for assisting countries to improve access to ARV treatment is the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). GFATM has been in existence since 2001 and, to date, has awarded US\$1.5 thousand million to 153 programmes in 92 countries, 65% of which was for HIV/AIDS treatment, prevention and care programmes.

Main options for financing ARV treatment programmes include:

- ▮ public funding;
- ▮ national insurance/social security schemes;
- ▮ private insurance;
- ▮ community financing;
- ▮ patient pays (out of pocket);
- ▮ external assistance from donor agencies; and
- ▮ local development activities.

- Reference No. 8.20: *The Global Funds to Fight AIDS, Tuberculosis and Malaria, 2003.*
- Reference No. 8.21: *Nine guidance modules on antiretroviral treatments, Module 2, 1998.*
- Reference No. 8.22: *Mobilizing resources for accelerating access to HIV/AIDS Care, 3rd Meeting of Contact Group on Accelerating Access to HIV/AIDS-Related Care, 2001.*
- Reference No. 8.23: *Health reform and drug financing, selected topics, health economics and drugs DAP Series No. 6*

- Reference No. 8.24: *Paying for HIV/AIDS services: lessons from national health accounts and community-based health insurance in Rwanda 1998-99, case study, September 2001.*
- Reference No. 8.25: *Guidelines for studies of the social and economic impact of HIV/AIDS, September 2000.*
- Reference No. 8.26: *Fact Sheet: meeting the need, 2002, UNAIDS , 2002*
- Reference No. 8.27: *Financing Care: the Country Perspectives, 2003.*

9. MANAGEMENT SYSTEMS

An ARV treatment programme is an integral part of health systems of a country, operating within the national strategic HIV/AIDS plan and its comprehensive HIV care plan. An effective management system is therefore necessary to manage and coordinate the resources—financial, human and material—within the programme and to ensure the programme's coordination with the national HIV/AIDS and comprehensive HIV care plans. (See Involving and mobilizing stakeholders section, Human resources section, and Supply management of commodities).

This section discusses the following issues:

- ▶ four essential functions of a management system, including advising; management of day-to-day activities, monitoring & evaluation and coordination;
- ▶ the need for efficient management and coordination in decentralization; and
- ▶ aspects of coordination in an effective management system.

- Reference No. 9.1: *Preparing and Implementing MAP Support to HIV/AIDS Country Programmes in Africa, 2002*
- Reference No. 9.2: *Establishing an HIV/AIDS Programme in Developing Countries: the Ethiopian Experience, 2002,*
- Reference No. 9.3: *Fighting Against AIDS: the Brazilian Experience, 2002,*
- Reference No. 9.4: *Nine guidance modules on antiretroviral treatments, Module 3, Section I – Organization of ARV treatments into HIV care and general health service, 1998.*

Management system

The management system should be defined during the planning of the programme, ensuring that it has the capacity and resources for coordination and making connections between policy, decision-making and implementation. Management functions can be carried out at different levels and may be centralized or decentralized. There will be a spread of functions between different levels, which depends on the degree of delegation possible within different countries and settings.

Four **functions** of the **management system** for an ARV treatment programme:

- ▶ An **advisory function**, responsible for policy issues on the implementation of the treatment programme
- ▶ **Day-to-day management** for implementation of the programme
- ▶ **Monitoring and evaluation**
- ▶ **Coordination** within the programme and with other stakeholders

- Reference No. 9.5: Report of the Meeting on the Evaluation of the UNAIDS HIV Drug Access Initiative, 2000.
- Reference No. 9.6: *Fighting Against AIDS: the Brazilian Experience, 2002.*
- Reference No. 9.7: *Nine guidance modules on antiretroviral treatments, Module 3, Section I – Organization of ARV treatments into HIV care and general health service 1998.*

A formal advisory body should carry out the advisory function. Its tasks are to support the management system and to advise on policy issues. Membership of the advisory body should include health professionals (public health and clinicians) directly involved in the programme, and representatives of private practitioners, professional bodies, social security and other providers of ARV services such as insurance companies and employers.

Issues that an advisory body would address include (see Enabling public policy environment section):

- ▶ national policy formulation on ARV treatment, including financing, pricing mechanisms and phased approach;
- ▶ development of country-specific practical guidelines;
- ▶ estimation or assessment of realistic drug needs;
- ▶ selection of clinics/sites suitable for the provision of ARV treatment;
- ▶ capacity-building for clinicians, counsellors and drug administrators at identified sites;
- ▶ establishment of a distribution system for ARV drugs;
- ▶ development of process indicators and evaluation tools; and
- ▶ dissemination of information on the impact of ARV treatment.

■ Reference No. 9.8: *Fighting Against AIDS: the Brazilian Experience, 2002.*

Day-to-day project management of an ARV treatment programme should include overseeing different programmatic and administrative aspects of the programme, such as capacity-building (i.e. infrastructure and training), procurement & distribution, monitoring & evaluation and finance.

Financial management

A financial management system is necessary to manage cash flow and allocation of resources. This requires that:

- ▶ records of project assets, liabilities, receipts and expenditures are maintained appropriately; and
- ▶ financial information is provided to facilitate management and to improve performance continuously.

Financial management comprises several basic elements:

- ▶ planning and budgeting;
- ▶ disbursement;
- ▶ recording and reporting of financial transactions; and
- ▶ ensuring the integrity of internal systems, controls and financial reports through internal and external audits.

The financial management system should address all levels involved in an ARV treatment programme, including policy and implementation levels. Only the financial data that are minimally required should be collected. To enable financial monitoring, reports need to be prepared. These should establish that:

- ▶ funds are being used appropriately,
- ▶ fund flows are enabling project implementation to stay on track, and
- ▶ budgeted costs will not be exceeded.

■ Reference No. 9.9: *Preparing and Implementing MAP Support to HIV/AIDS Country Programmes in Africa, 2002.*

Contracting out

To reduce the burden of ARV treatment programmes on already over-stretched health ministry resources, certain management services may be contracted out. For example, contracting out project management and administrative functions can be very cost-effective and can strengthen the coordinating and policy role of the management system. Contracting for services can have several additional advantages, such as:

- ▶ it can free staff for tasks that they alone can fulfil, such as setting policy and providing care;
- ▶ it can reduce costs, through competition in tendering;
- ▶ it can increase the project management team's control since contractors are more likely to comply if there are sanctions against poor performance; and
- ▶ it can engage the private sector more closely in addressing HIV/AIDS.

Centralized and decentralized management

It has been argued that the scaling-up process within HIV/AIDS programmes requires a shift from a centralized approach to decentralized mechanisms of planning and implementation. These mechanisms include a much broader range of actors for the different components of an HIV/AIDS programme, such as prevention, reduction of mother-to-child transmission and orphan care.

Although ARV treatment programmes generally involve only one sector (the health sector), certain aspects of scaling up through a more decentralized approach can also apply here. The need for strong central coordination remains, but the focus of the central management function in a decentralized approach is more on the setting of policies and programme parameters, financing of projects, facilitation & training, and monitoring & evaluation, rather than on implementation, which takes place at decentralized levels.

- Reference No. 9.10: *Preparing and Implementing MAP Support to HIV/AIDS Country Programmes in Africa, 2002.*
- Reference No. 9.11: *Scaling Up HIV/AIDS programmes to National Coverage. 2000.*

Coordination

Coordination of an ARV treatment programme comprises the following:

- ▶ **Coordination of different ARV treatment efforts.** Along with the use of standard treatment guidelines, ensuring common standards for treatment will help to support adherence and ensure that treatment efforts are complementary. This is especially important if ARV treatment programmes are to build on existing experience, pilot projects, and other small-scale experiences.
- ▶ **Coordination of the treatment programmes with other AIDS activities and other health sector undertakings** such as the Global Fund Country Coordinating mechanism, and the national strategic plan (see Involving and mobilizing stakeholders section). This would also help to ensure integration within the health system.
- ▶ **Coordination of activities at each of the central and implementation levels and between the central and implementation levels** is also critical for effective management and to ensure safe and effective treatment. This is because different but inextricably linked activities will take place at different levels, e.g. procurement of essential commodities at the central level while provision of treatment is at the implementation level.

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- ▶ **Coordination of a range of stakeholders** is also important for the effective management of an ARV treatment programme.
 - Reference No. 9.12: *Scaling Up Antiretroviral Therapy: Experience in Uganda. Perspectives and Practice in ARV treatment. (in press)*

10. INFORMATION MANAGEMENT AND COMMUNICATION

Management of information and communication is essential for every aspect of planning and implementation of an ARV treatment programme. It is necessary to make information available that is complete, accurate and timely for a variety of decision-makers. This will allow them to make well-informed plans and choices for the implementation, monitoring & evaluation and further planning and support of the programme. Effective information management systems are particularly important for monitoring and evaluation (see Monitoring and evaluation section).

At the programme planning stage it is therefore necessary to develop a communications strategy that will:

- ▶ enable day-to-day implementation and management of the programme;
- ▶ create a formal mechanism to collate and disseminate relevant information within the programme and to communities and other stake holders;
- ▶ be used to create awareness about ARV treatment and the roles of various stakeholders in the development and implementation of the ART programme;
- ▶ support advocacy for resource mobilization and programme support among stakeholders.
- ▶ enable necessary information to be shared that will guide scaling up in quality and scope of the programme throughout the country and various population groups as needed.

Information management systems are often neglected within the context of healthcare delivery. However, in the context of an ARV treatment programme an information and communication management system is a vital necessity that must be given special attention both in the initial stages of planning and throughout the implementation and development of the programme. This goes beyond the usual parameters of traditional health management information systems, because of the special nature and context of ARV treatment programmes, especially regarding the following issues:

- ▶ new and often expensive medicines and technologies, requiring specific human resources, skills, facilities and finances;
- ▶ a paramount need to ensure no interruptions in treatment for each patient and active monitoring throughout treatment;
- ▶ the need for rapid introduction and scaling up of treatment delivery;
- ▶ uncertainties and lack of detailed experience of planning and implementing ARV treatment programmes within public health contexts in limited-resource settings; and
- ▶ the need for sharing information among different players so that responses to changing needs within or outside the programme can be rapid and effective.

Existing health information systems may need to be modified in order to allow for the special needs of ARV treatment programmes, for example modifying clinical forms or setting up multidisciplinary working groups to share information on a regular basis. Where systems do not already exist, they will have to be set up before the ARV treatment programme starts.

Some important questions must be considered when modifying existing systems or setting up new ones, such as:

- ▶ What information is needed?
- ▶ Who needs to have the information?
- ▶ What information and communication systems already exist?

- ▶ What is the capacity to adequately manage the information for use in the ARV treatment programme?
- ▶ Who will collate and package the information for the ARV treatment programme?
- ▶ Who are the target audiences at community, service and policy levels and among other stakeholders?
- ▶ What are the key lessons learned and what are the policy and programme implications of these?
- ▶ What are the linkages with the monitoring and evaluation component of the ARV treatment programme?

- Reference No. 10.1: *Management Sciences for Health: The Electronic Resource Centre.*
- Reference No. 10.2: *MTCT-Plus Patient Data Manual January 2003.*

What types of information could be useful?

Clinical monitoring

- ▶ Patient demographics
- ▶ Laboratory data
- ▶ Disease profiles
- ▶ Drug use
- ▶ Adherence to treatment regimens
- ▶ Drug-resistance monitoring
- ▶ User satisfaction with treatment & services

Human resources

- ▶ Capacity
- ▶ Numbers of staff
- ▶ Performance appraisal
- ▶ Skills mix
- ▶ Training needs
- ▶ Gaps in staffing
- ▶ Staff turnover and sick leave

Supplies and commodities

- ▶ Tracking storage, expiry dates and movement of ARVs and lab supplies
- ▶ Tracking availability and usage of office supplies and clinical forms, etc.
- ▶ Tracking usage and maintenance of utilities (electricity, water, etc.)
- ▶ Tracking performance of distribution systems (delivery schedules, storage conditions, etc.)

Regulatory issues

- ▶ Sharing information about the evolution of regulatory environment, e.g. changes in drug registration, patent regulations or controls on prescribing and use of drugs
- ▶ Inclusion of essential ARV treatment supplies within national essential drugs lists, etc.

Policies and procedures

- ▶ Availability for the range of activities of the programme
- ▶ Appropriateness for the context of the programme
- ▶ Implementation

Finances and costs

- ▶ Tracking flows of finance to implementation—is the money where it is needed?
- ▶ Tracking continuity of financing—do financial flows promote or hinder continuity of treatment?

Tracking partners and other players active in ARV treatment

- ▶ Degree of participation in national ARV treatment programme
- ▶ Separate or independent activities and their effects on the national programme
- ▶ Adherence to government standards and norms for ARV treatment and health delivery

Communication within and outside the ARV treatment programme

Sharing of information is vital within the ARV programme, of course, and it is essential to realize that a multidisciplinary approach is a key to good use of the information. For example, many aspects such as planning and management of infrastructure, human resources and commodity supply will depend on knowing what type of treatment delivery has been chosen, what groups are to be served and what changes and developments are expected when scaling up.

However, it is also important to remember that there are many other players outside the public health system providing ARV treatment and HIV-related care in most countries. They include individuals and organizations such as private industry, private practitioners, NGOs and traditional healers. In order to support a national ARV treatment programme and coordinate the treatment activities of all players, a planned system should be developed to disseminate standardized treatment protocols, procedures and guidelines as widely as possible among such providers and to share documentation of their activities.

It is also critical that information management systems of an ARV treatment programme are able to track the work going on beyond health systems, in other areas such as education, business and specific population groups (e.g. military, marginalized groups and children). These are important elements of the context of any ARV treatment programme, beyond the formal health sector. Communication of information will be necessary in both directions, both to shape the responses of the programme to people's needs and to share information with the wider population about ARV treatment, its relationship with HIV prevention and care and with the wider socioeconomic impact of the epidemic.

11. MONITORING AND EVALUATION

The public health approach to scaling up ARV treatment relies strongly on monitoring and evaluation (M&E). These have the aim of determining:

- ▶ what activities are efficient and effective and should be expanded further; and
- ▶ what activities are not and should be improved or terminated.

This section discusses the following:

- ▶ Defining monitoring and evaluation and the aims of each
- ▶ M & E as a part of the planning process
- ▶ M & E as a function of management
- ▶ Framework for monitoring and evaluating an ARV treatment programme
- ▶ Suggested indicators
- ▶ Defining roles and responsibilities
- ▶ Allocation of resources
- ▶ Strategic use of data collected during M & E

Defining monitoring and evaluation

There is a clear distinction between monitoring and evaluation. Monitoring focuses on tracking programme inputs and outputs (i.e. process), but evaluation aims to assess the outcomes and impact of the programme (i.e. effectiveness). However, the two are closely linked and have to be considered together to provide an overall picture of the programme. For instance, evaluation of inputs and outputs can help to explain how and why an intervention has achieved its effects. The focus of monitoring and evaluation may shift during the lifetime of a programme, from assessing inputs, processes and outputs in the early stages of a programme, to assessing outcomes and impact when it has been functioning for some time.

The aims of monitoring and evaluation are to:

- ▶ collect evidence of activities and results;
- ▶ determine programme effectiveness in reaching predefined objectives and targets; and
- ▶ identify and address problems.

- Reference No. 11.1: *National AIDS programmes: a guide to monitoring and evaluating HIV/AIDS care and support, 2000.*
- Reference No. 11.2: *Evaluating Programmes for HIV/AIDS Prevention and Care in Developing Countries, 2001.*

Monitoring and evaluation as part of planning and managing an ARV treatment programme

Monitoring and evaluation are clearly defined and important aspects of planning and managing an ARV programme. To ensure that monitoring and evaluation activities will produce useful results, they should be incorporated into the ARV treatment programme at the planning stage, through a comprehensive monitoring and evaluation plan. Such a plan should describe the overall purpose, the specific questions to be addressed, the design and methods to be used, what data are to be collected and how, what resources will be necessary, and who will implement the plan. (See Planning ARV treatment programmes section and Management systems section).

Responsibility for monitoring and evaluation may be held at central level, but may also be decentralized to implementation levels; careful coordination and sharing of data must be organized and managed.

Roles and responsibilities

Those who are responsible for monitoring and evaluation have the task of:

- ▶ planning and developing systems for monitoring and evaluation;
- ▶ collecting and generating data from different sources;
- ▶ verifying data;
- ▶ analysing and interpreting data; and
- ▶ reporting and dissemination.

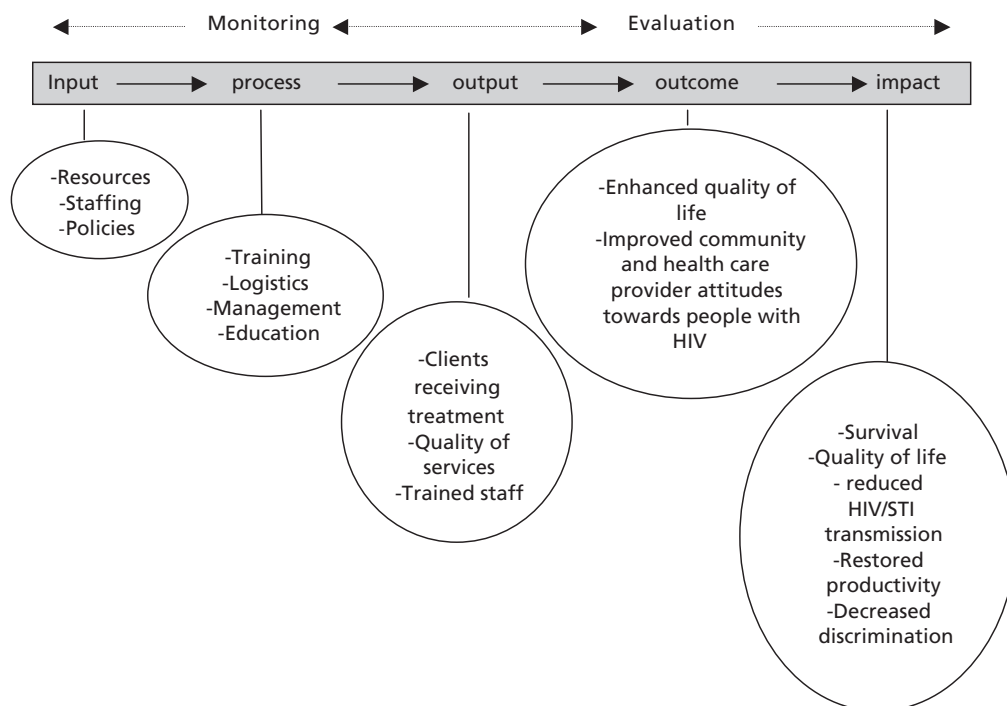
Human resources are limited in many countries, so monitoring and evaluation for the ARV treatment programme is probably best integrated wherever possible into existing monitoring and evaluation activities. Some examples are the activities of other AIDS programmes (e.g. surveillance, prevention, monitoring of UNGASS goals) or the ministry of health, or NGOs or the faith-based sector. For indicators measuring the impact of the programme, quantification may require specific expertise, accessed through collaboration with specialized organizations such as national or international academic research groups.

- Reference No. 11.3: *Assessment of a Pilot Antiretroviral Drug Therapy in Uganda: Patients' Response, Survival, and Drug Resistance, 2002.*

Framework for monitoring and evaluating an ARV treatment programme

A coherent monitoring and evaluation system is based on a clear idea or framework of how a programme is expected to produce a given set of results. A commonly used framework comprises the following:

- ▶ **Input** – financial, material and human resources invested in the programme
- ▶ **Process** – types of activities, including education, training, logistics and management
- ▶ **Output** – deliverables of the programme including trained staff, numbers of people treated
- ▶ **Outcome** – intermediate effect of the programme, including facilities with comprehensive care and prevention services
- ▶ **Impact** – reduced morbidity and mortality in people with HIV, improved community productivity, reduced stigma and discrimination



National policies and guidelines, equipment, staffing and finance are essential inputs for an ARV treatment programme, which lead to programme outputs through processes such as training, logistics and management. Programme outputs are defined here as ARV treatment services, including access, utilization and quality. Utilization of services by the people who need ARV treatment is one such programme output. The impact of the ARV treatment programme refers to improved quality and increased length of life for people with HIV.

Indicators

One of the critical steps in designing and carrying out monitoring and evaluation is the selection of appropriate indicators to measure the progress of a programme. With limited budgets and competing needs for resources, the amount of data that can be collected for monitoring and evaluation purposes is limited and should be critically selected. Only data that can be linked to the objectives of a programme should be collected. Data that are collected without a clearly defined purpose are unlikely to be used and should be avoided. Efforts should be made to keep the number of indicators to a critical few.

■ Reference No. 11.4: *National AIDS Programmes, a Guide to Monitoring and Evaluation, 2003.*

UNGASS has identified several core indicators to measure the progress of national HIV/AIDS programmes. For ARV treatment, this includes the percentage of people with advanced HIV infection that receive ARV treatment. A further indicator is the percentage of facilities with the capacity to deliver appropriate care to people with HIV. These two indicators represent the minimum amount of data that should be collected in any ARV treatment programme. When their baseline values have been established (i.e. prior to the start of the ARV programme), they can be monitored over time to see how well targets are being reached.

■ Reference No. 11.5: *Monitoring the declaration of commitment on HIV/AIDS: guidelines on construction of core indicators, 2002.*

In addition to these UNGASS indicators, countries may wish to collect additional data to monitor specific aspects of their ARV treatment programme in more detail. These sources also provide tools for data collection and analysis (see Supply management of commodities section):

- Reference No. 11.6: *Strategic information for ARV therapy programmes 2003.*
- Reference No. 11.7: *National AIDS Programmes, a Guide to Monitoring and Evaluation. 2000.*
- Reference No. 11.8: *National AIDS Councils Monitoring and Evaluation Operations Manual, 2002.*
- Reference No. 11.9: *Expanded Response Guide to Core Indicators for Monitoring and Reporting on HIV/AIDS Programmes, 2003.*
- Reference No. 11.10: *Handbook of Indicators for HIV/AIDS/STI Programmes, 2000.*
- Reference No. 11.11: *National AIDS Programmes, a Guide to Monitoring and Evaluation, 2000.*
- Reference No. 11.12: *Rapid Pharmaceutical Management Assessment: An Indicator Based Approach. 1995.*

Financing of monitoring and evaluation

Monitoring and evaluation activities can be funded either from national funds or through donor organizations. Since donor organizations want to see if the money they contribute is well spent, they are often willing to contribute substantially to the funding of monitoring and evaluation activities. However, as donor funding is often only guaranteed for a limited period, over-dependence on this source for financing might compromise the continuity and sustainability of monitoring and evaluation activities. To avoid this, countries should either ensure that sustainability is built into donor-funded projects from the start, or fund the majority of monitoring and evaluation activities through national funds.

Strategic use and dissemination of data

When the data have been collected, analysed and interpreted, they should be properly disseminated and used. The results of monitoring and evaluation activities should be communicated to all relevant stakeholders, including the project management team and advisory committee of the ARV treatment programme, the national AIDS body, the ministry of health, and those that fund the programme such as donors, NGOs and taxpayers. Results should also be shared with those who collect the data so that they may provide feedback on their results. This can be done for instance through annual reports, annual planning and evaluation meetings and scientific publications.

- Reference No. 11.13: *Assessment of a Pilot Antiretroviral Drug Therapy in Uganda: Patients' Response, Survival, and Drug Resistance. 2002.*

In general, the data generated by monitoring and evaluation systems are used in three major ways:

- **Planning, revising and improving the programme;** for example by identifying bottlenecks and weaknesses. The ultimate goal is to determine what activities are efficient and effective and can be expanded further and replicated (e.g. in other areas), and what are not and should be improved or terminated.
- **Attributing change in the epidemic to interventions undertaken;** for instance with regard to reduction of morbidity and mortality among HIV-infected patients or reduction of the numbers of new orphans.
- **Advocating for action;** for instance by showing that providing ARV treatment in resource-limited settings is feasible and has a measurable impact on the target population.

- Reference No. 11.14: National AIDS Programmes, a Guide to Monitoring and Evaluation, 2000.

Dissemination and use of monitoring and evaluation results should reach all stakeholders who have an interest in the ARV programme and in the overall HIV/AIDS programming for the country or region. This will help to ensure proper use of the results of monitoring and evaluation for support and improvement of the programme and its goals.

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