

Standards for quality HIV care: a tool for quality assessment, improvement, and accreditation



Report of a WHO Consultation
Meeting on the Accreditation
of Health Service Facilities
for HIV Care, 10–11 May 2004,
Geneva, Switzerland



World Health Organization



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Geneva 2004

Acknowledgements

WHO expresses gratitude to the participants of the WHO Consultation Meeting on the Accreditation of Health Service Facilities for HIV Care on 10–11 May 2004 in Geneva, Switzerland. Elizabeth Madraa and Karen Timmons chaired the meeting. Other participants were Esther Aceng, Michael Adelhardt, Mulamba Diese, Kathleen Fritsch, Chris Green, Pape Mandoumbé Gueye, Christoph Hamelmann, Andrei Issakov, Itziar Larizgoitia, Ulrich Laukamm-Josten, Jaouad Mahjour, Tom Mboya, David Miller, Virginia O'Dell, Jos Perriëns, Anuwat Supachutikul, Kenji Tamura, Anthony Tanoh, Paul vanOstenberg, Gundo Weiler, Stuart Whittaker and Tisna Veldhuyzen van Zanten.

WHO gratefully acknowledges comments and contributions by Bruce Agins, Rebecca Bailey, Huzeifa Bodal, Robert Colebunders, Adiego Dieudonne, Masami Fujita, Jantine Jacobi, Carrie Jeffries, Peggy Henderson, Ramachandran Murali, Ezekiel Nukuro, Soe Nyunt-U, Amolo Okero, Emanuele Pontali, Alasdair Reid, Reiyo Salmela, Gray Sattler, Pathom Sawanpanyalert, Diana Silimperi and Helena Walkowiak.

The Joint Commission International was a leading contributor in developing this publication. This meeting was financially supported by Gesellschaft für Technische Zusammenarbeit (GTZ) Backup Initiative (Germany).

Kenji Tamura and Jos Perriëns of WHO coordinated this work.

WHO Library Cataloguing-in-Publication Data

WHO Consultation Meeting on the Accreditation of Health Service Facilities for HIV Care (2004: Geneva, Switzerland) Standards for quality HIV care: a tool for quality assessment, improvement, and accreditation.

1. Anti-retroviral agents – supply and distribution 2. HIV infections – therapy 3. Acquired immunodeficiency syndrome – therapy 4. Health priorities – organization and administration 5. Strategic planning 6. Consumer participation 7. Developing countries I. Title.

ISBN 92 4 159255 9 (NLM classification: WC 503.2)

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Printed in France

Contents

Rationale	2
Quality systems for health care	3
Intended use of the publication and standards	4
Accreditation as a model for evaluating and improving quality	6
Key principles underpinning the accreditation framework	8
Major categories of standards for HIV care	9
Selecting model standards	10
Using the standards – getting started	11
Essentials for creating a national accreditation or certification programme	11
Essentials for implementing the standards in an HIV care site/organization	12
Minimum set of standards to initiate antiretroviral therapy	13
Proposed standards	14
1. Functions related to health care delivery	14
A. HIV testing, counselling and referral	14
B. Management of opportunistic infections, including TB	15
C. Provision of antiretroviral therapy	16
D. Support for adherence to treatment	17
E. Preventing mother-to-child transmission of HIV infection	17
F. Palliative care	17
G. The rights of people living with HIV/AIDS and reducing stigmatization	18
2. Functions related to links with communities	19
H. Community links	19
I. Promoting health and preventing and treating disease	19
3. Functions related to the service delivery	20
J. Leadership and human resource management	20
K. Management of drugs and supplies	21
L. Laboratory management	22
M. Information management	22
N. Financial management	23
Annex 1. Country experiences	24
Kenya	24
South Africa	25
Thailand	27
Uganda	29
Annex 2. Sample brief list of standards for community-based health service facility initiating and supervising antiretroviral therapy	32

Rationale

HIV/AIDS has had a shattering impact on many countries in the past decade, especially those in sub-Saharan Africa and South-East Asia. Prevalence and incidence statistics indicate that many developing countries are likely to be burdened beyond capacity with the significant care needs of increasing numbers of chronically or terminally ill people as a result of this devastating pandemic. This has enormous implications for all aspects of the economic, health and social fabric of the countries most significantly affected by HIV/AIDS. Significant numbers of health care workers are predicted to be at risk of becoming ill or of dying in the short to medium term. This situation is likely to profoundly affect not only the burden and management of the disease but also the economies of the countries that can least afford it.

In this urgent situation, WHO and its partners launched the Treat 3 million by 2005 (“3 by 5”) Initiative⁽ⁱ⁾. Given the proven feasibility of treating people living with HIV/AIDS in industrialized and developing countries, a global target of treating 3 million people with antiretroviral therapy by the end of 2005 is a necessary, achievable target on the way to the ultimate goal of universal access to antiretroviral therapy for everyone who requires such therapy. Although antiretroviral therapy cannot cure HIV infection, it has been proven to extend and improve life for large numbers of people living with HIV/AIDS. Antiretroviral therapy has thus transformed perceptions of HIV/AIDS from a fatal disease to a manageable, chronic illness in many countries.

Providing antiretroviral therapy in a primary health care system requires:

- ▶ taking into account the systemic links across primary, secondary, and tertiary health care facilities within a country as well as the links with home-based care programmes;
- ▶ considering the social support services available within the community or through home-based care;
- ▶ integrating antiretroviral therapy delivery with the delivery of other services such as HIV prevention programmes, counselling and testing, preventing mother-to-child transmission and health services essential to optimal antiretroviral treatment, control of tuberculosis (TB) and control of sexually transmitted infections; and
- ▶ strengthening and building the capacity for delivering antiretroviral therapy within multiple points in the health care system.

Capacity-building is necessary, not only for the sites where antiretroviral therapy is delivered but also for diverse delivery sites from community to national referral hospitals where key care and support services are delivered, such as antenatal care, counselling and testing and postnatal care. Specialized service programmes that serve as entry points to HIV care, such as TB programmes or sexually transmitted infection clinics, as well as untraditional non-specialized sites that may vary from country to country, must have the capacity to provide antiretroviral therapy. Support functions, especially laboratories and pharmacy services, must also be included. The specific tasks for each site must be clearly delineated and norms or expectations of performance defined.

Several countries that started providing antiretroviral therapy, such as Côte d’Ivoire, Kenya, South Africa, Thailand, Uganda and Zambia, have already introduced standards and external evaluation processes, commonly called accreditation, as a tool to ensure the quality of their clinical services (Annex 1 provides selected country experience). Many stakeholders in HIV care share this concern for quality. In 2002, the Fifty-fifth World Health Assembly (resolution WHA55.18) urged Member States to pay the closest possible attention to the problem of patient safety and to establish and strengthen science-based systems, necessary for improving patients’ safety and the quality of health care. Consequently, WHO has decided to synthesize the lessons learned in the accreditation of HIV care services and to offer these findings and strategies to its Member States and partners.

To achieve this, WHO collaborated with many partner organizations originally convened under the umbrella of the International HIV Treatment Access Coalition. The Coalition was established in late 2002 to improve access to antiretroviral therapy in developing countries, and a Quality of Care Working Group was established soon thereafter. This publication was developed in collaboration with the members of this Working Group, including the Joint Commission International (Oakbrook Terrace, IL, USA), the Council for Health Services Accreditation of Southern Africa (COHSASA, Pinelands, South Africa), the Institute for Hospital Quality Improvement and Accreditation (Bangkok, Thailand), the Quality Assurance Project/University Research Co. LLC (Bethesda, MD, USA), International Association for Physicians in AIDS Care (Chicago, IL, USA), the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH and the Division of Health, Department for International Development (United Kingdom), in consultation with experts from WHO Member States proposed by WHO’s regional offices.

Quality systems for health care

The concept of quality is one of the leading forces in improving health services. The perception of what quality entails differs between countries and sectors because of different value systems. Many definitions are in use, and all may be justified depending on the perspectives and objectives. A common aspect at the centre of the concept of quality is the needs of a client or community. The International Organization for Standardization (ISO) defines quality as “the totality of features and characteristics of an entity that bears on its ability to satisfy a stated or implied need”. In health care, the perception of the needs of a client or community varies with the different views and perspectives of the client, service provider and society and the social, political and economic environment.

Quality control determines to what extent a product (such as drugs, diagnostic equipment or condoms) or one of its components complies with a set standard. Usually applied at major steps of production, at the end of the production line or as part of procurement and trade processes, quality control provides information on the functionality and safety of the product or product component. A product that fails the quality control tests may need to be disassembled or disposed of. In the context of trade and procurement, quality control may be used to ensure that imported goods (such as antiretroviral drugs or test kits) are of an acceptable standard to benefit people. Quality control tests may provide detailed information about the defects of the product (such as drug content or condom burst volume); however, they offer little guidance on how to change the production process to avoid future production failures.

Quality assurance is a more comprehensive approach to quality. Based on a structure–process–outcome framework, quality assurance includes producer–provider and product–service aspects as well as the client perspective (needs, rights and preferences). Quality assurance is a process with the objective of improving the outcome of all health care in terms of health, functional ability and the well-being and satisfaction of health care users. It considers the structures and inputs required and assists in analysing and re-engineering service delivery processes and measuring outcome. The main purpose is to foster an environment in which everyone involved supports quality, is alert to problems of performance and opportunities for improvement and is prepared to take responsibility for setting in motion the needed changes to improve care. Thus, quality assurance is primarily rehabilitative rather than punitive, aiming to give the fullest possible play to the

capacities for self-expression and self-actualization innate to everyone⁽²⁾. The quality assurance approach is related to compliance with standards and can be applied to facilities, programmes, systems and sectors. It is rarely applied to whole institutions, firms and ministries.

An organization-wide approach to quality is known as total quality management. Aiming at continuously improving overall performance, total quality management allows the integration of other quality assurance approaches to quality such as quality control and accreditation. The comprehensiveness of total quality management draws on quality models that take all the functions and key elements of the entire organization into account. Total quality management is based on the whole system and on the participation of customers, clients and society. An important aspect is introducing quality models that aim to identify the key aspects of the organization or system such as leadership, staff, infrastructure, core processes of service delivery and key results inspired by the structure–process–outcome framework.

The best quality system may not function if there are no people to implement it, whereas simple systems can work very effectively if people are motivated and committed to improve the quality of care. Thus, the most suitable and sustainable environment for continuous quality improvement is the introduction of a quality culture based on common understanding, vision, purpose, values and principles.

Intended use of the publication and standards

This publication and the proposed standards are intended for WHO Member States and their authorizing bodies in developing their own framework of accreditation as a guiding principle to improve the quality of HIV care at all levels of health care facilities of the country, with a special focus on antiretroviral therapy. It also offers guidance for the managers and the quality improvement professionals within HIV health service facilities to improve their health services related to antiretroviral therapy. The proposed standards, indicators and methods for evaluating quality offer a model framework that may be used for:

- ▶ developing and/or strengthening national quality evaluation and accreditation programmes for health care facilities providing HIV care;
- ▶ developing public policy related to HIV care;
- ▶ improving the quality of current programmes or treatment facilities;
- ▶ creating new programmes or treatment facilities for HIV care; and
- ▶ building the capacity of communities and facilities to provide more effective and efficient HIV care.

Developing and/or strengthening national quality evaluation and accreditation programmes for health care facilities providing HIV care

Many countries have developed programmes for licensing and accrediting health facilities, especially hospitals. The accreditation standards used in national accreditation programmes are intended to evaluate the quality of all aspects of a health care facility and not specific treatment programmes. Thus, the standards for HIV care programmes are not intended to evaluate general infection control issues, fire safety, maintenance of biomedical equipment and other factors. The standards presented here can thus naturally extend existing accreditation programmes and will help create and sustain high-quality HIV care in high-quality health care facilities. Note that the standards are equally applicable to public and private facilities and treatment programmes.

Developing public policy related to HIV care

The standards proposed in this publication can be instructive to those responsible for developing national and local policy related to creating new treatment sites, reviewing existing facilities for potential designation as treatment sites, allocating new resources or reallocating existing scarce resources to HIV care and overseeing national treatment programmes. Accreditation of HIV care sites can provide important evidence on quality to the national and international agencies funding HIV care. The standards can also be helpful in developing policies that link public and private treatment efforts, link facilities with their community and link primary, secondary and tertiary treatment sites. The standards are also a useful framework for incorporating new knowledge as HIV care rapidly evolves.

Improving the quality of current programmes or treatment facilities

Standards are expectations of performance, and one of the most powerful tools that can move organizations towards better care, shape positive behaviour, remove unwanted variation in care processes and provide a framework for measuring results. The standards can help organizations understand how they can meet the treatment needs of a variety of populations such as drug users and prisoners and can help link prevention with the treatment of opportunistic infections. The person needing treatment is at the centre of the standards and thus helps focus a treatment programme on understanding and meeting the diverse needs of different treatment populations. Equally important is that the standards focus on improvement and not on sanctions and closing programmes.

Creating new programmes or treatment facilities for HIV care

Those planning new programmes frequently do not know where to focus their initial effort. The standards in this publication provide a starting-point upon which treatment programmes can grow and improve. Standards guide quality from the first person being treated and thus do not require later adjustments to processes of care to bring them into accordance with accepted

standards. The standards can also provide a vision of where programme need to mature and expand to improve effectiveness. Thus, the path ahead becomes more clear and understandable. In addition, even in the absence of national accreditation programmes, the standards permit self-assessment, including the identification of good practices and models of care found in case studies.

Building the capacity of communities and facilities to provide more effective and efficient HIV care

Many communities understand the importance of identifying care early in the local community, referral for testing and treatment and longitudinal community-wide support and follow-up. The problem often encountered is how to link all the resources in the community to ensure that people are not lost in the system, that scarce resources are shared and used wisely and that essential information related to treatment and education are shared in a way that respects the rights and dignity of all. The standards in this publication are valuable for assessing community capacity and eventual interventions to strengthen capacity from the training of new types of workers to coordinated public education, to the extension of programmes to forgotten vulnerable populations within the community and the dissemination of better practices.

Accreditation as a model for evaluating and improving quality

The term accreditation most commonly applies to the systematic assessment, against explicit standards, of an entire organization and not a particular clinical specialty area. Accreditation originated in the United States in 1917 as a method for the American College of Surgeons to assess the acceptability of hospitals as sites for surgery training. The model of accreditation spread first to other English-speaking countries and then to Europe, Latin America, Africa and the western Pacific during the 1990s, and at least 28 countries now have an operational accreditation programme ⁽³⁾.

In accreditation, a multidisciplinary team of health professionals usually evaluates the published standards in an organization by using standards for the specific environment in which the clinical care is delivered. The standards adopted nationally usually derive from an amalgamation of national statutes, government guidance, independent reports, the standards of other countries and biomedical and health services research.

A delegated ministerial authority or nongovernmental agency most commonly manages accreditation. Such agencies are responsible for developing, publishing and continually reviewing standards, conducting the on-site evaluation process and determining the level of compliance with standards an organization has achieved. Accreditation is designed to stimulate continuous improvement in quality rather than impose sanctions. A study WHO published in 2003 ⁽³⁾ describes the common and essential characteristics of accreditation programmes around the world. This study evaluated data from 78% of the 36 accreditation programmes known to operate at a national level. The survey findings are summarized below.

Legal framework

- ▶ One third of programmes are enabled by legislation.
- ▶ Only France and Italy legally mandate accreditation of all health services.
- ▶ Most legislation was passed in the late 1990s.
- ▶ Most programmes are not based on national legislation.

Relationship to government

- ▶ Government funds, wholly or in part, or directly manages half the programmes.
- ▶ Long-established programmes are independent of government.
- ▶ Most programmes established in the past five years are sponsored by government.
- ▶ Governments increasingly use accreditation as a means of regulation and public accountability rather than for voluntary self-development.

Development and revision of standards

- ▶ Accreditation traditionally developed in hospitals, and the standards later covered community services and networks of preventive and curative services.
- ▶ The long-established programmes generally began with standards and surveys related to management units and later developed standards that described expectations for all units of the organization.
- ▶ On average, standards are revised every 4.5 years; in programmes less than 15 years old, the average is about 2 years.

Transparency and public access to standards and reports

- ▶ One quarter of the programmes provide standards free to the public, and about half the programmes sell their standards.
- ▶ Two thirds of the programmes do not provide full reports to the public.
- ▶ Programmes that provides free reports also provide public access to their standards.

Site visits

- ▶ The most common survey duration is three days on site.
- ▶ The most common team size is three surveyors.
- ▶ The range reflects the complexity of the organization and thus the survey.

Costs and benefits

- ▶ There is very little robust research evidence on the benefits of accreditation.
- ▶ The credibility of programmes is linked to their standards and the credentials of site visitors, both of which significantly contribute to cost.
- ▶ The rapid rise in voluntary accreditation is related to real or perceived direct financial incentives.
- ▶ There is little comparative cost information, as programmes vary in many ways that impact cost, such as whether site visitors are paid or volunteer.

Key principles underpinning the accreditation framework

Standards for quality HIV care are guided by a number of key principles related to health care services for people living with HIV/AIDS.

- ▶ People living with HIV/AIDS should be treated with respect with regard to their human rights, ethics, privacy and confidentiality, informed consent, autonomy and dignity.
- ▶ HIV/AIDS prevention should be part of a comprehensive HIV service delivery including the promotion of safe sex and condom use, interventions to reduce the mother-to-child transmission of HIV, harm reduction and universal precautions for health care workers.
- ▶ The health system and the community reach consensus about the level of services to be provided. The community, including people living with HIV/AIDS, participates in strategic planning, implementation and evaluation of services.
- ▶ Quality improvement principles are used to determine and improve the quality, effectiveness, efficiency and utilization of services and the satisfaction of service users.
- ▶ Services provided by the health system competent in antiretroviral therapy should include HIV testing and counselling, preventing and treating opportunistic infections including TB, delivering antiretroviral therapy, preventing mother-to-child transmission, adhering to treatment support and providing psychosocial support, with links to home- and community-based care.
- ▶ The health system should be coordinated and integrated to ensure continuity of service delivery among different providers and different levels of care.
- ▶ Human, logistic, and financial resources are considered in the design of HIV/AIDS programmes and services so that they are sustainable.

Major categories of standards for HIV care

Standards represent a generic statement of what is expected of the HIV therapy service site. Each standard has discrete elements that can be measured during the on-site evaluation process.

Many standards can also be measured by “indicators” that represent the rate of accomplishment of the standard or the expected threshold. For example, if the standard sets an expectation for HIV case-finding at a community level, the indicator would express a rate or number of new cases per 100 individuals or a similar rate. Thus, standards, measurable sub-elements of standards and indicators can all play an important role in understanding how the therapy site is progressing toward fully meeting all the requirements.

The key functions carried out in every health care delivery setting determine the level of quality of the services and the extent to which the desired outcomes are achieved. The standards included in each of these categories are identified. These categories identify the structures, processes or outcomes that are expected and that can be evaluated for their implementation and effectiveness.

The key categories proposed as the framework for the standards are functions related to health care delivery, functions related to the links with communities and functions related to the service resources and facility.

1. FUNCTIONS RELATED TO HEALTH CARE DELIVERY

- A. HIV testing, counselling and referral
- B. Management of opportunistic infections, including TB
- C. Provision of antiretroviral therapy
- D. Support for adherence to treatment
- E. Preventing mother-to-child transmission of HIV infection
- F. Palliative care
- G. The rights of people living with HIV/AIDS and reducing stigmatization

2. FUNCTIONS RELATED TO LINKS WITH COMMUNITIES

- H. Community links
- I. Promoting health and preventing and treating disease

3. FUNCTIONS RELATED TO SERVICE DELIVERY

- J. Leadership and human resource management
- K. Management of drugs and supplies
- L. Laboratory management
- M. Information management
- N. Financial management

Selecting model standards

Standards identified for each health service function are grouped into several major categories as presented above. The next section lists the draft standards. The standards were identified from by reviewing authoritative literature sources and relevant standards from standards-setting bodies and accreditation organizations around the world and by the working group members in each specific area.

The following criteria were considered in identifying standards that are valid, credible and able to be surveyed.

- ▶ The standard reflects contemporary and accepted knowledge and evidence.
- ▶ The standard clearly identifies the compliance expected.
- ▶ The standard is specific, measurable and time-bound – by self-assessment and by external assessment processes.
- ▶ The standard permits a valid measuring process.
- ▶ Organizations can identify what “evidence” they need to present to validate that they meet the expectation of the standard.
- ▶ The standard is associated with the quality and safety of the care provided to service users. In addition, other basic considerations for standards are as follows.
- ▶ They use simple language – no jargon.
- ▶ Each standard has one major principle to simplify the compliance expected.
- ▶ The standards-setting body writes the standard in the active voice (“The organization provides...” or “Caregivers support...”).
- ▶ The performance expected is resource neutral: both resource-rich and resource-constrained settings can mostly meet the indicator.
- ▶ The standard sets exact expectations and does not use “should” or “may” to reflect desirable but not required expectations.
- ▶ The standard identifies a person responsible for upholding the standards.

Using the standards – getting started

Essentials for creating a national accreditation or certification programme

1. Create a committee or national task force of key stakeholders to review the need for such programme, evaluate how this programme would interface with existing programmes and understand the resource implications for starting the programme (Box 1).

Box 1. Experience in Uganda

The National Advisory Board developed accreditation criteria and tools for health centres that would be authorized to prescribe antiretroviral therapy. The service delivery facilities were categorized into three groups. Accreditation tools were developed for each category. All health units that want to start an antiretroviral therapy programme have to be accredited by the Ministry of Health. A team of experts on antiretroviral therapy services selected by the Ministry of Health carries out the accreditation.

2. Develop and evaluate the standards and revise or add to them until the standard set is relevant to the HIV care sites and programmes in the country.
3. Have the standards approved by the appropriate authority within the government (Box 2).

Box 2. Experience in South Africa

The Council for Health Service Accreditation of Southern Africa, COHSASA, a not-for-profit organization, is pioneering the Accelerated HIV/AIDS Development Programme (AHDP) to provide a draft set of standards. The standards are to be endorsed by HIV and AIDS specialists and by the South African HIV/AIDS Clinicians Society. The accreditation tool developed and used by the National Department of Health was reviewed jointly and incorporated into COHSASA's AHDP standards. COHSASA is currently negotiating with the National Department of Health its offer to support the accreditation and the process of strengthening antiretroviral therapy service points.

4. Announce the programme and educate those whom the programme will impact (Box 3).

Box 3. Experience in Kenya

In Kenya, a nationwide sensitization and education campaign including all provinces was carried out to promote awareness of quality, ownership of the Kenyan Quality Model and commitment to leadership. These three-day workshops included sensitizing provincial and district leaders about their role in and possible contribution to improving health service delivery.

5. Create a public or private authority that will establish the implementation policies and procedures (such as what type of organizations can apply), and oversee a transparent process of evaluation, scoring (such as points or “not met”, “partly met” or “fully met”) and accreditation decisions (Box 4).

Box 4. Experience in Thailand

Thailand's Hospital Accreditation Programme mobilizes those who have experience in assessing quality and are working in the health care system to assist hospitals in implementing quality improvement. Regular hospital visits by these experienced consultants and sharing of knowledge and experience at the provincial level are used to encourage continuous improvement in 76 provinces.

6. Recruit and train those who will conduct the on-site evaluations (Box 5).

Box 5. Experience in Kenya

A new cadre of health workers has been introduced to support the Kenya Quality Model. Initially trained as health service inspectors, their role also includes promoting a culture of quality. Provincial and district health teams are being supported to exceed compliance with minimum standards and to apply principles and tools related to quality for continuously improving the quality of health service delivery.

Using the standards – getting started

7. Support organizations as they work to achieve standards and apply for accreditation.
8. Decide how organizations that achieve accreditation will be recognized (Box 6).

Box 6. Experience in South Africa

The surveyors in COHSASA's Facilitated Accreditation Programme evaluate the degree to which each hospital complies with the Programme's comprehensive standards and award an accreditation certificate in recognition of the excellence of services provided. Hospitals that do not meet standards are encouraged to continue efforts to improve quality by awarding different levels of achievement certificates, depending on the degree to which they comply with the standards.

Note that there is not one correct way to implement these steps. The experience of other accreditation bodies can be instructive and is available in publications from WHO and others.

6. Continue to collect data and perform self-evaluation to determine whether the gap has been closed.
7. If an accreditation or certification programme is in place, find out the requirements and apply for external evaluation to validate the organization's self-assessment.

Note that there is no best way to implement standards. The process and the speed will depend on leadership within the organization, the culture of the organization, the understanding of the principles of quality improvement and many other factors. Community-wide efforts to meet the standards will improve the synergy and momentum and provide the community and health care users with evidence of the focus on quality care.

In addition, books, journals and other sources can provide guidance on the process and useful tips and milestones. Annex 1 provides experience from Kenya, South Africa, Thailand and Uganda in establishing and implementing their own accreditation system and standards. These proposed model standards do not intend to exclude or suspend any health care facility that does not meet all of them, especially in the resource-limited settings, but should be used to improve the quality of the facility.

Essentials for implementing the standards in an HIV care site or organization

1. Gather the key leaders and staff of the organization and review the benefits of meeting standards and the work involved. Health care users and public representatives are helpful to this process and others.
2. Review the standards and decide which standards are relevant to the services and activities of the treatment site.
3. Educate staff on the standards. Dividing into smaller groups according to the domains of the standards is a strategy for starting.
4. Form a small team to conduct self-assessment to provide information on where the organization has the largest gap to fill in meeting the standards.
5. Form work groups to address these gaps, to develop the policies, procedures, staff training and forms and to identify better practices needed to implement the standards.

Minimum set of standards to initiate antiretroviral therapy*

The WHO/UNAIDS International Consensus Meeting on Technical and Operational Recommendations for Emergency Scaling-up of Antiretroviral Therapy in Resource-Limited Settings in November 2003⁽⁴⁾ identified four conditions as minimum requirements to initiate antiretroviral therapy in resource-constrained settings. They are 1) HIV testing and counselling, 2) personnel trained and certified to prescribe antiretroviral therapy and follow up recipients clinically, 3) an uninterrupted supply of antiretroviral drugs and 4) a secure and confidential patient record system. The categories and standards in Annex 2 are selected from the comprehensive list of categories and standards in this publication in accordance with these recommendations. This short list can be used as a model list and each country or authorizing body should appropriately adapt the standards to reflect the local conditions and requirements. This list, however, should not be used to exclude or suspend any existing health care facility that provides antiretroviral therapy and their activities; it should be used to improve the quality of these facilities.

* The WHO/UNAIDS International Consensus Meeting⁽⁴⁾ also recommended that 1) adherence support and 2) community mobilization and education on antiretroviral therapy be made available concurrently with (and following) the introduction of antiretroviral therapy. It also recommended developing a chronic HIV/AIDS care capacity in health facilities concurrent with, and not as a prerequisite for, the introduction of antiretroviral therapy.

Proposed standards*

1. Functions related to health care delivery

A. HIV testing, counselling and referral

A-1. The organization has established and followed a policy on HIV testing. ^(5–11)

- a. organization has a written testing policy.
- b. The policy reflects national laws and guidelines and WHO guidelines for rapid testing.
- c. The policy addresses the testing of vulnerable or at-risk populations such as intravenous drug users, prisoners, sex workers, refugees and health care providers.
- d. All staff are familiar with the policy.

A-2. The organization offers provider-initiated HIV testing to aid clinical diagnosis and management.

- a. The organization offers HIV testing and counselling to all pregnant women presenting for their first antenatal care appointment or at the time of delivery.
- b. The organization offers HIV testing and counselling to everyone with sexually transmitted infections.
- c. The organization offers HIV testing and counselling to everyone with a history of injecting drug use.
- d. The organization recommends HIV testing and counselling to everyone with TB as part of routine management.

A-3. HIV testing is only conducted with informed consent. ^(5–7)

- a. Test subjects and staff attest to the voluntary nature of HIV testing.
- b. The staff obtain informed consent from each person tested.
- c. The staff give each person the opportunity to decline testing.

A-4. The organization respects the confidentiality of test results. ^(4,6,7,9,11)

- a. The organization communicates test results to other people only with the consent of the person being tested.
- b. Only health-care professionals with a direct role in managing the person being tested have access to the results on a need-to-know basis.

A-5. The organization makes pre-test counselling available or it is available by referral. ^(6,7,9–11)

- a. Individuals specifically trained for the task perform counselling.
- b. Counselling takes place in an environment that ensures privacy.
- c. Counselling includes maintaining a positive health attitude.
- d. Counselling includes reducing the risk of HIV transmission.
- e. Counselling includes preventing mother-to-child transmission of HIV among reproductive-age women.
- f. Counselling includes verifying that the counselling is understood.

A-6. The organization makes post-test counselling available or refers for this.

- a. Individuals specifically trained for the task perform counselling.
- b. Counselling takes place in an environment that ensures privacy.
- c. Counselling includes preventing transmission.
- d. Counselling includes consideration of the need for support.
- e. Counselling includes information on antiretroviral therapy, including access, cost, benefits, adherence and possible adverse effects and drug resistance.
- f. Counselling includes encouraging people to promptly seek health care for opportunistic infections, including TB.
- g. Counselling includes maintaining adequate nutrition.

* These proposed model standards do not intend to exclude or suspend any health care facility that does not meet all of them, especially in the resource-limited settings, but should be used to improve the quality of the facility.

- h. Counselling includes verifying that the counselling is understood.

A-7. The organization refers to community-based services and other care settings, ensuring continuity of care and support.

- a. The organization refers to community-based post-test support services when appropriate.
- b. The organization considers the need for home-based services in referral.
- c. The organization refers to other treatment, care and service sites as needed to ensure access to these services and proximity to services.

B. Management of opportunistic infections, including TB

B-1. Caregivers routinely assess health care users for the presence of opportunistic infections and treat or refer them. ^(12–14)

- a. Guidelines specify that health care users are regularly assessed for opportunistic infections, including TB.
- b. Caregivers regularly assess all health care users for opportunistic infections including fungal, bacterial, viral, TB and other infections in accordance with the national or WHO guidelines.
- c. When caregivers suspect opportunistic infections, health care users are diagnosed and treated or are referred for diagnosis and treatment.
- d. When caregivers treat health care users for opportunistic infections, the organization makes medicine available according to the national or WHO treatment guidelines, protocols and/or national essential drug lists. ^(6,12,15,16)
- e. The organization takes measures to prevent opportunistic infections in accordance with the national and WHO guidelines. ⁽¹⁴⁾

B-2. Medicine is available for treating TB. ^(6,12,14,17,18)

- a. Medicine is available for treating people with TB.
- b. Medicine is available for treating people who develop drug toxicity on TB treatment.

B-3. The organization uses national or WHO guidelines for the scope and content of the assessment of everyone with active or suspected TB. ^(6,17,18)

- a. The staff take a health history and perform a physical examination at the first visit.
- b. The staff send sputum samples to an approved laboratory for smear microscopy for *Mycobacterium tuberculosis* for everyone with symptoms or signs suggesting TB.
- c. Chest X-ray services are available for investigating suspected smear-negative TB.

B-4. The organization uses national or WHO guidelines for delivering and supervising care to people with TB. ^(6,14,17,18)

- a. The organization treats active disease and latent TB, and monitors treatment, following national or WHO guidelines.
- b. TB treatment and supervision is in accordance with national or WHO guidelines.
- c. Concurrent provision of antiretroviral therapy for people on TB medicine follows national or WHO guidelines on antiretroviral therapy.

B-5. The organization consults people with TB in the care facility at regular intervals and evaluates them. ^(6,15,17,18)

- a. The organization plans the scheduling of appointments and tests to maximize access to health care consultation, laboratory tests and X-rays.
- b. The organization takes all precautions to minimize the risk of transmitting TB to staff and health care users in the health care setting ⁽¹⁵⁾.
- c. The staff weigh people with TB at every visit.
- d. The staff question people with TB about the possible side-effects of medicine at each visit.
- e. The staff record the number of TB medicine doses missed each month and takes appropriate action for suboptimal compliance.

B-6. The organization monitors the person with TB after TB treatment is completed. ^(6,17,18)

- a. The staff take sputum samples for smear microscopy at the end of treatment.
- b. The staff consult people with TB in accordance with accepted guidelines and policies.

Proposed standards

C. Provision of antiretroviral therapy

C-1. The organization has a transparent process for identifying the people who will receive antiretroviral therapy. ^(6-8,16)

- a. The organization has a written protocol to guide decisions on treatment eligibility.
- b. The protocol contains criteria to establish eligibility for antiretroviral therapy according to national guidelines.
- c. The organization treats everyone who meets the criteria for antiretroviral therapy.
- d. The organization only treats the people who meet the criteria.

C-2. The organization obtains a basic health inventory for each person suspected of having HIV infection. ^(6,11)

- a. The history includes when they were infected with HIV, if known.
- b. The history includes when HIV was diagnosed, if known.
- c. The history includes past and present HIV treatment, including prophylaxis taken for preventing mother-to-child transmission.
- d. The history includes TB, sexually transmitted infections and viral hepatitis.
- e. The history includes the presence or absence of fever, respiratory symptoms, enlarged lymph nodes, oral ulcers or infections, gastrointestinal symptoms or diarrhoeal diseases, weight loss and impaired functional ability.
- f. The history includes psychosocial factors.
- g. The history includes drug use (injecting and non-injecting), travel and sexual exposure.
- h. The history includes whether the spouse or partner and children have been tested for HIV.

C-3. The organization follows standard diagnostic protocols for every person suspected of being infected with HIV. ^(6,11)

- a. The protocol includes HIV antibody testing.
- b. The protocol includes the presence or absence of opportunistic infections or tumors.
- c. The protocol includes TB diagnosis in accordance with national guidelines.

- d. The protocol includes appraisal of any nervous system or mental complications.
- e. The protocol includes identifying drug dependence and the need for substitution treatment.
- f. The protocol includes assessing nutritional risk and the nutritional support of those at risk.

C-4. The organization follows management protocols based on national or WHO guidelines for all people living with HIV/AIDS. ^(6-8,10,11,16,19)

- a. The organization follows national or WHO protocols for all people living with HIV/AIDS.
- b. The organization includes antiretroviral therapy as part of the protocol followed.

C-5. The organization treats children using special guidelines published for use among infants and children. ^(16,20)

- a. The organization uses national or WHO guidelines for treating children.

C-6. The caregivers and health professionals monitor people receiving care for adverse or toxic drug reactions. ^(6,16)

- a. The organization gives all caregivers education and verifies them to ensure that they understand the antiretroviral therapy regimens they are initiating or supervising for recognizing adverse or toxic drug reactions.
- b. Caregivers identify people presenting with treatment-related adverse or toxic drug reactions.
- c. For people who develop adverse or toxic drug reactions, the event is recorded in their clinical record and reported to national pharmacovigilance systems.
- d. People who develop adverse or toxic drug reactions continue the drug when possible, receive an alternate course of treatment or may be referred to another treatment programme.
- e. The organization gives alternative care to people who are no longer treated or who suffer adverse or toxic drug reactions.

D. Support for adherence to treatment

D-1. The organization supports people being treated to facilitate their adherence to the prescribed treatment. ^(6,19,21)

- a. The organization enlists community-based volunteers and family members to assist in supporting the people being treated.
- b. The organization assigns a support person to each person being treated.
- c. The organization trains and verifies support people to ensure that they understand how to assist the person receiving antiretroviral therapy with his or her drug regimen.
- d. Whenever possible, the support person accompanies the person being treated to the appointment with the caregiver and reports on progress and on barriers encountered.

D-2. The organization refers people being treated to other organizations or individuals who can help to address their social needs. ^(6,8,19,21)

- a. The organization has a policy that supports the social needs of the people being treated.
- b. The organization has a mechanism and operating procedure to assist the people being treated in meeting their social needs.
- c. The organization has an effective referral mechanism to other organizations or individuals in place to support the social needs of the people being treated.

E. Preventing mother-to-child transmission of HIV infection

E-1. The organization follows guidelines for preventing mother-to-child transmission. ^(6,11,16,22,23)

- a. The management protocol includes national or WHO guidelines for preventing mother-to-child transmission.
- b. The organization trains health care workers in accordance with the national or WHO guidelines for mother-to-child transmission.

E-2. The organization gives all women of reproductive age living with HIV/AIDS appropriate counselling and antiretroviral prophylaxis. ^(6,7,11,16,22–24)

- a. The organization offers counselling on contraceptive methods and the risks to mother and child of unwanted pregnancy to women of childbearing age living with HIV/AIDS.
- b. The organization gives pregnant women antiretroviral prophylaxis to prevent HIV transmission from mother to child in accordance with national or WHO guidelines.

E-3. The organization appropriately treats infants born to mothers living with HIV/AIDS. ^(11,16,20,23,24)

- a. The organization treats all infants born to women living with HIV/AIDS in accordance with national or WHO protocols.
- b. The organization gives appropriate prophylaxis against opportunistic infections to all infants born to women living with HIV/AIDS in accordance with national or WHO protocols.

E-4. The organization gives mothers living with HIV/AIDS additional counselling specifically on infant feeding. ^(11,23,25–29)

- a. The organization gives all mothers living with HIV/AIDS counselling on the risks and benefits of breastfeeding and of various locally appropriate feeding options.
- b. The organization gives all mothers living with HIV/AIDS specific guidance and support for breastfeeding or replacement feeding for at least the first two years of the child's life.
- c. If breast-milk substitutes are provided, the organization ensures that this is done in accordance with the International Code of Marketing of Breast-milk Substitutes ⁽²⁶⁾.

F. Palliative care

F-1. The organization supports the right of people living with HIV/AIDS to respectful and compassionate care at the end of life. ^(6,30)

- a. The organization makes staff aware of the unique needs of people at the end of life.
- b. The organization assesses people being treated for acute and chronic symptoms related to the disease process or treatment.
- c. The organization intervenes to prevent pain and manage pain and manage primary or secondary symptoms.

Proposed standards

- d. The organization reassesses people being treated for their response to acute and chronic symptom management.
- e. The organization's intervention addresses the psychosocial, emotional and spiritual needs of the person living with HIV/AIDS and his or her family regarding dying and grieving.
- f. The organization involves the person living with HIV/AIDS and his or her family in decisions on care.

F-2. The organization supports the right of people living with HIV/AIDS to the appropriate assessment and management of pain. ^(6,30)

- a. The organization makes staff aware of the needs of people suffering from pain.
- b. The staff queries people living with HIV/AIDS about pain on a routine basis.
- c. The staff appropriately assess people with pain or refer them for such assessment.
- d. The staff give people with pain the available treatment for pain.
- e. The staff reassess people being treated for their response to pain management.

G. The rights of people living with HIV/AIDS and reducing stigmatization

G-1. The organization is responsible for providing processes that support the rights of people living with HIV/AIDS and their families during care. ^(6,7,30)

- a. The organization provides people living with HIV/AIDS information on the care and services the organization provides.
- b. The organization provides information on alternative sources of care and services when the organization cannot provide the care or services.
- c. Staff provide care that respects the values and beliefs of the people living with HIV/AIDS.
- d. The staff respect the need of the people living with HIV/AIDS for privacy for all examinations, procedures and treatments.
- e. The organization respects each person's health information as being confidential.

- f. The organization implements safeguards to prevent the loss or misuse of information about people living with HIV/AIDS.
- g. The organization safeguards the possessions of people living with HIV/AIDS when the organization assumes responsibility or when people living with HIV/AIDS are unable to assume responsibility.
- h. People living with HIV/AIDS and their families participate in care decisions to the extent they wish.
- i. The organization informs people living with HIV/AIDS and their families about their rights to refuse or discontinue treatment and about the consequences of their decisions.
- j. The organization informs people living with HIV/AIDS about available care and treatment alternatives.
- k. Staff members can explain their responsibilities in safeguarding the rights of people living with HIV/AIDS.
- l. People living with HIV/AIDS are able to discuss their concerns with an independent advocate or ombudsperson.
- m. The process of handling the deceased person is respectful and dignified.

G-2. The organization obtains informed consent from people living with HIV/AIDS through a process the organization defines and trained staff carry out. ^(6,30)

- a. The organization informs people living with HIV/AIDS of their diagnosis and condition.
- b. The organization informs people living with HIV/AIDS about the proposed treatment.
- c. The organization informs people living with HIV/AIDS about the potential benefits and drawbacks of the proposed treatment.
- d. The organization informs people living with HIV/AIDS about possible alternatives to the proposed treatment.
- e. The organization has listed the procedures and treatments that require separate consent.
- f. The organization documents consent in the clinical record by signature or a record of verbal consent.

2. Functions related to links with communities

H. Community links

H-1. Organization leaders plan with community leaders and the leaders of other organizations to meet the community's needs related to preventing and treating HIV/AIDS. ^(6–8,30)

- a. The organization's leaders plan with recognized community leaders and with the leaders of other health care and service organizations in its community.
- b. People living with HIV/AIDS and members of other affected communities participate in the governance of the organization.
- c. The organization has appropriate referral mechanisms in place to ensure ongoing community support after discharge.
- d. People living with HIV/AIDS and members of other affected communities contribute to and participate in staff development and training.
- e. People living with HIV/AIDS and members of other affected communities participate in monitoring and evaluating services and in quality assurance.

I. Promoting health and preventing and treating disease

I-1. The organization has a planned approach to collaborating with other community organizations and agencies to provide and support information and education related to promoting health and preventing disease to people living with HIV/AIDS.

- a. The organization participates in education programmes within the community.
- b. The education is designed to transmit key messages on general health promotion and disease prevention via the popular mass media within the community, and where antiretroviral therapy is available, the benefits of learning HIV status.
- c. The education is provided in schools, workplaces and other settings within the community.

- d. The education targets individuals at risk because of age, social conditions, diagnosed disease or cultural factors.
- e. People living with HIV/AIDS and members of other affected communities are closely involved in information and education related to health promotion and disease prevention.

I-2. The organization participates in community and regional policy and programmes on disease surveillance.

I-3. Prevention programmes include and emphasize the early diagnosis and treatment of sexually transmitted infections and opportunistic infections (including TB) and the prevention of HIV transmission. ^(6,7)

- a. Prevention programmes are community based.
- b. Prevention programmes emphasize early diagnosis of sexually transmitted infections, opportunistic infections (including TB) and HIV.
- c. Prevention programmes emphasize the link between TB and HIV.
- d. Prevention programmes include notification of sex partners.
- e. Programme targets include high-risk populations such as sex workers, injecting drug users and men who have sex with men.
- f. Prevention programmes include the distribution of condoms, needle exchange and other programmes relevant to the population served by the site.
- g. Prevention programmes include education on blood safety, universal precautions and other education targeting health care workers and other staff.

I-4. Medicine is available for treating sexually transmitted infections. ^(6,30)

- a. Medicine is available for treating sexually transmitted infections caused by *Chlamydia* spp., *Neisseria* spp. and *Treponema* spp.
- b. Medicine is available for treating sexually transmitted infections caused by herpes simplex virus and other pathogenic agents.

Proposed standards

I-5. The organization refers people with suspected sexually transmitted infections for treatment.⁽⁷⁾

- a. The organization refers people with suspected sexually transmitted infections for treatment and counselling.
- b. Staff giving treatment consider the appropriateness of a syndromic approach.

I-6. The organization and community assess and measure the outcomes and effectiveness of education programmes.

- a. The organization assesses the effectiveness of its education programme at least annually.
- b. People living with HIV/AIDS and members of other affected communities participate in monitoring services, education and quality assurance.

3. Functions related to service delivery

J. Leadership and human resource management

J-1. The governance and leadership of the organization is clearly identified.^(6,11,30)

- a. The organization describes its governance structure in written documents.
- b. The documents describe governance responsibilities and accountability.
- c. The organization has an organization chart or document.
- d. Those responsible for governance appoint the organization's senior manager or director.
- e. The senior manager or director manages the organization's day-to-day operations.
- f. People living with HIV/AIDS participate in the governance of the organization.
- g. Members of other affected communities participate in the governance of the organization.

J-2. The leaders match the human and other resources of the organization with the needs of the community.⁽¹¹⁾

- a. Leaders decide whether the organization has the capacity to provide testing and counselling, to treat people living with HIV/AIDS, to manage opportunistic infections including TB and sexually transmitted infections and to provide laboratory and other diagnostic services.
- b. The leaders use national guidelines and laws or WHO guidelines for staffing and competence to establish the services to be provided.
- c. The leaders decide what services will be provided on site and what services will be provided through referral to other sites in the community.
- d. The leaders decide what services will be provided under contract arrangements and how the quality of those services will be monitored.

J-3. Managing quality and safety⁽¹¹⁾

- a. Those responsible for governance support and promote efforts to improve quality and safety.
- b. The process of monitoring quality includes collecting data, analysing them and reporting the results.
- c. Quality monitoring includes both clinical and managerial processes and outcomes.
- d. The safety programme is organization-wide and includes safety, risk management and quality control activities for both attending people and staff.
- e. The organization has defined and implemented an ongoing programme for identifying and reducing unanticipated events and safety risks to attending people and staff.
- f. The organization has a reporting system for unintended, adverse events that jeopardize the safety of people living with HIV/AIDS, their families and staff.

J-4. Organization leaders ensure the presence of a programme or programmes for recruiting, retaining, developing and ensuring the continuing education of all staff. ^(6,7,11,16,30)

- a. The organization has a transparent process in place to recruit staff.
- b. The organization has a process in place to ensure that all new staff have the appropriate qualifications and competence for their assigned tasks.
- c. The organization evaluates staff at least once, as defined by the organization.
- d. The organization orients new staff members to the organization, job responsibilities and their specific assignments.
- e. The organization gives staff in-service education and training to permit them to assume new duties and new roles.
- f. The organization provides adequate time for all staff to participate in relevant education and training opportunities.
- g. The organization makes efforts to recruit people living with HIV/AIDS and/or members of other affected communities.
- h. The organization supports the use of teams to deliver services and manage people living with HIV/AIDS over time.

J-5. Organization leaders support the recruitment, retention, development and continuing education of the community. ^(6,7,19,30)

- a. The organization orients community workers to the organization and to their responsibilities and specific assignments.
- b. The organization supports the training of community members and health care workers to meet local, regional and national needs for competent, trained workers at all levels.
- c. The organization participates in programmes that provide respite and other support services to caregivers.

K. Management of drugs and supplies

K-1. The organization stocks an appropriate selection of medicine, reagents and supplies for prescribing or ordering or has them readily available. ^(6,19,30)

- a. The organization makes lists of medicines, reagents and supplies available at the facility.
- b. The organization has a system in place to regularly review and update the lists.
- c. The medicines list includes drugs for antiretroviral therapy, opportunistic infections and managing pain and symptoms in accordance with the national or WHO antiretroviral therapy guidelines.
- d. The medicines list includes other drugs, such as methadone for substitution therapy, appropriate for the services offered by the programme.

K-2. Procurement of high-quality medicine for anti-retroviral therapy and opportunistic infection

- a. The organization procures drugs that have been registered in the country or provided with authorizing waivers.
- b. The organization maintains and uses a list of recognized and trusted suppliers that are known to provide high-quality products and services.

K-3. Availability of medicines for antiretroviral therapy, opportunistic infections and managing pain and symptoms

- a. The organization establishes monitoring systems that ensure the continuous availability of medicines for antiretroviral therapy, opportunistic infections and palliative care.
- b. The organization has a process in place to track the movement and use of drugs and to prevent misuse and losses from theft or expiring stock.
- c. The organization restricts the access of unauthorized people to drug receiving, storage and dispensing areas.
- d. The organization stores drugs securely with protection from excessive heat, sunlight, rain and humidity and a system ensuring that the drugs expiring first are used first.

Proposed standards

K-4. The organization ensures that the person receiving therapy gets appropriately labelled drugs and drug information

- a. The organization dispenses drugs in a container and clearly labels them with the name of the drug and dosage instructions.
- b. The organization provides information to people receiving therapy on the drugs they use, including dosage, adverse reactions and possible drug interactions.
- c. Medicine counselling includes verification that the person receiving counselling has understood the counselling.

L. Laboratory management

L-1. Laboratory testing, as required by the needs of people living with HIV/AIDS, is available on site or off site. ^(8,16,30)

- a. Laboratory tests available include rapid HIV antibody test, haemoglobin test and pregnancy test.
- b. Laboratory tests available include confirmatory HIV antibody tests, CD4 count, full blood count, alanine aminotransferase assay and sputum smear microscopy.
- c. Laboratory tests available include full serum chemistry, mycobacterial culture, CD4 count and viral load count.
- d. Laboratories meet national requirements and testing norms or WHO guidelines.
- e. Laboratories maintain the security and confidentiality of test results.

L-2. Laboratory equipment is regularly inspected, maintained and calibrated. ⁽³⁰⁾

- a. The organization has a programme for managing laboratory equipment.
- b. The organization has an inventory of the equipment available and that in use.
- c. The organization has a written record of inspection, testing, calibration and maintenance that would be carried out according to defined procedures by the manufacturers.
- d. The organization has a plan for inventorying, handling, storing and using hazardous materials

and for controlling and disposing of hazardous materials and waste.

M. Information management

M-1. The organization follows national or international recommendations on monitoring and evaluation. ^(6,25)

- a. The organization maintains the confidentiality, security and integrity of data and information.
- b. Clinical records contain sufficient and updated information to identify the person receiving treatment, support the diagnosis, justify the treatment, document the course and results and promote continuity of care among health care providers.
- c. The clinical record contains an updated summary list of all significant diagnoses, procedures, drug allergies, medicines, clinical history, physical examination findings, HIV status and contact information.
- d. The organization has an efficient system for storing and retrieving clinical records.
- e. Designated qualified personnel accept the verbal orders of authorized individuals and are available to enter these orders into the clinical records.
- f. The organization monitors key performance indicators and uses them to improve the process.

M-2. The organization has links to national or international monitoring and evaluation systems appropriate for the scope of its activities. ^(6,25)

- a. Leaders are familiar with the policy and guidelines for the national or international monitoring and evaluation system.
- b. Leaders are actively involved in coordinating the monitoring and evaluation needs.
- c. Staff with designated monitoring and evaluation functions are trained for and familiar with the national or international monitoring and evaluation system.
- d. The organization has a monitoring system with proper recording and reporting, consistent with the needs of national or international monitoring and evaluation systems.
- e. The monitoring system supports financial

monitoring as required by funding sources and other national and international agencies.

- f. The monitoring system supports the delivery of health care services.

N. Financial management

N-1. Designated accounting staff are competent to take on financial tasks

- a. The staff responsible for financial accounting and financial management have appropriate qualifications and skills.
- b. The organization has made designated financial staff familiar with internal and external accounting requirements that specifically apply to various sources of funding for the HIV/AIDS response (national resource allocation and multilateral and bilateral financing mechanisms).
- c. The organization identifies and addresses the training needs of staff with designated accounting and financial management functions.

N-2. The organization has a financial accounting system to manage the allocation of resources.

- a. The system includes defining the processes and ensuring the availability of information on disbursement.
- b. The organization maintains appropriate records of project assets, liabilities, receipts and expenditures.
- c. Internal and external audits ensure the integrity of internal systems, controls and financial reports.
- d. The organization feeds back financial information to facilitate management and to continuously improve performance.

N-3. The financial management system addresses the efficient and effective use of funds

- a. The organization uses funds in accordance with stated objectives of the HIV/AIDS response at the policy and implementation levels.
- b. The organization defines, collects and processes minimum data for financial monitoring and budgeting in accordance with financial requirements.

- c. The organization manages fund flows to ensure timely project implementation in accordance with operational plans.

- d. The organization manages the budget within agreed financial estimates and targets.

N-4. The organization's financial reports and updates support the implementation and continuation of the HIV/AIDS response.

- a. Managers of the HIV/AIDS response are informed on time about spending exceeding or falling short of the current budget.
- b. The organization makes a timely financial report available according to the stated reporting requirements and planning cycles.
- c. The organization distributes a timely financial report to budget holders and involved funding sources.

Annex 1. Country experiences in accreditation of health service facilities for HIV care

Kenya

The Government of Kenya is committed to providing access to quality health care services for all Kenyans. Accreditation of service providers forms an integral part of the existing quality system, the Kenyan Quality Model (KQM).

Context

In January 2001, the Government of Kenya established the Department of Standards and Regulatory Services (DSRS). The DSRS faced constraints of limited resources, uncontrolled expansion of private-sector outlets (of unknown standards), challenged motivation and health-sector performance and fragmented quality improvement efforts. Thus, the DSRS was assigned to conceptualize a comprehensive approach to improving quality that builds on existing experience and provides the necessary guidance for standardizing, regulating and improving the quality of Kenya's health system. The DSRS developed a comprehensive quality framework – the KQM – to promote the safety and effectiveness of health services and to increase the efficiency of the health system by strengthening performance and reducing waste. The DSRS developed a set of Kenyan health standards⁽⁹⁾ and a corresponding quality assessment tool – the master checklist⁽⁹⁾ – which form the core tool for self-assessment and external quality assessment.

A nationwide sensitization and education campaign including all provinces was carried out to promote awareness of quality, ownership of the KQM and commitment to leadership. A new cadre of health workers to support the KQM has been introduced. They were initially trained as health service inspectors, but their role also includes promoting a culture of quality.

In conjunction with this, a national database including a computer-based data entry tool (KQM Data Entry Tool) and server software was developed. The database is used to compile and analyse information on quality assessment for strengthening the health care system, in particular through additional guidance on priority-setting and resource allocation.

To date, the application of KQM has identified several priority areas for improvement, in particular on financial management, use of clinical and public health standards and guidelines as well as human resource issues (such as staff satisfaction).

The application of KQM is currently being scaled up under DSRS guidance and will be linked to the process of contracting health care facilities within the new National Social Health Insurance Scheme.

KQM – AIDS sub-module

Kenya is currently developing an HIV/AIDS sub-module of KQM. The overarching framework of KQM has allowed for the development and programming of specific sub-modules (in this case HIV/AIDS), which address not only the health sector but also take into account the multisectoral nature of the national HIV/AIDS response. This characteristic of the sub-module brings clarity to the roles and responsibilities of various actors, creating the necessary synergy required for the response and, finally, forms the basis for coordination and dialogue.

For alignment with internationally recognized good practice, Kenya has embarked on integrating and harmonizing the WHO HIV/AIDS accreditation standards with the KQM framework. The standards used under the KQM HIV/AIDS sub-module apply to the entire national HIV/AIDS response that can be applied at various levels across the continuum of service provision (prevention, mitigation, care and treatment).

Definitions in the context of the HIV/AIDS response

The KQM HIV/AIDS sub-module defines quality as: the totality of features and characteristics of the Kenyan AIDS response that enables the needs of potential or actual HIV/AIDS patients/clients to be met.

Quality improvement of services related to HIV/AIDS is defined as a process:

- ▮ of improving adherence to standards and guidelines;
- ▮ of improving the structure, process and outcome of the HIV/AIDS response by applying quality management principles and tools; and
- ▮ of meeting the needs of patients/clients in a culturally appropriate way.

In the context of Kenya's response to HIV/AIDS, KQM recognizes two groups of clients with different needs and service requirements:

- ▮ HIV-negative: prevention and mitigation; and
- ▮ HIV-positive: care and treatment, mitigation and prevention.

Improving access to and the quality of counselling and testing services therefore play a pivotal role in the KQM HIV/AIDS sub-module.

Approaches

The KQM HIV/AIDS sub-module supports two main approaches: standards and quality management.

Standards. The DSRS, in collaboration with the Centre for Quality in Health Care, provides leadership in standardization and regulation. The KQM HIV/AIDS standards in combination with clinical and public health standards and guidelines state the expected performance levels within Kenya's health system, including the public and private sector. Standards and guidelines must be developed and revised based on evidence and consider the perspective of communities, especially people living with HIV/AIDS, orphans, widows and widowers and respecting the rights of patients/clients.

Compliance with standards serves as an entry point to improving quality. The HIV/AIDS Checklist based on the KQM HIV/AIDS standards represents the main tool for assessing whether expectations are being met. Compliance with standards must be monitored through self-assessment by providers and verified by quality improvement facilitators and surveyors.

Quality management. Complementary to the standards approach, the DSRS and Centre for Quality in Health Care provide guidance and motivation to surpass basic standards on the way to excellence in health care through regular quality assessment (self- and external assessments) and continuous quality improvement (see the previous discussion of the quality management component of KQM).

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South Africa

Accreditation of antiretroviral therapy service points in South Africa

On 19 November 2003, South Africa's cabinet approved the outline of a plan to provide antiretroviral drugs for people with advanced HIV disease and immunosuppression. The Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa⁽³²⁾ called for the accreditation of antiretroviral therapy service points that would offer comprehensive HIV and AIDS services. The accreditation process is conducted under the leadership and responsibility of the National Department of Health.

The accreditation process started in January 2004. The first-round assessment of 113 facilities nominated by the nine provinces was conducted by a team of provincial and national experts of the Department of Health itself. Each site visit lasted a whole day. It included group discussions with all relevant service providers, site managers and representatives of the district health management team as well as physical inspections of the laboratory, pharmacy, consultation and counselling and support areas. Referral networks, pharmaceutical ordering, distribution and control systems as well as laboratory support systems were also assessed.

A standardized accreditation tool was used that the National Department of Health developed. The accreditation tool has a well-defined set of minimum criteria

Annex 1. Country experiences in accreditation of health service facilities for HIV care

that need to be fulfilled to become an accredited antiretroviral therapy service point. They are based on nationally defined standards for infrastructure (input), processes and service deliveries (output and outcomes). The standards cover all service components of the continuum of HIV/AIDS prevention, treatment, care and support. Minimum criteria in this context refer to minimum requirements for quality standards and initial output targets (workload and the number of people served). Only accredited antiretroviral therapy service points will be authorized to prescribe and dispense antiretroviral drugs under the public sector antiretroviral therapy programme, which has no user charges at the point of service for eligible people. In addition to the assessment of minimum criteria, the accreditation tool is designed to identify areas that need to be strengthened further according to a total quality management approach and in order to meet annual capacity targets (number of people receiving antiretroviral therapy) derived from national and provincial strategic and implementation plans. The one-day assessment includes the agreement on a strengthening plan with detailed description of activities to be performed, of verifiable output, budget needs, responsibilities and time lines.

After the first round of accreditation visits to 113 facilities in all 53 districts, 27 fulfilled the minimum criteria. The National Department of Health designated them as the first antiretroviral therapy service points in the public sector. Treatment started shortly afterwards in April 2004. The process of follow-up visits and strengthening facilities is ongoing. Meanwhile, provinces are nominating further facilities for the accreditation process according to the five-year implementation plan. Although the National Department of Health has overall responsibility for the functioning and the quality of health services, the Department requires immense capacity to conduct the accreditation and promote the processes of strengthening site capacity and quality. This challenge will further increase during the first five-year implementation plan and needs to be considered in strategic and operational plans.

The accreditation process has provided numerous useful key lessons.

- ▶ Accreditation of service points for comprehensive HIV/AIDS prevention, treatment, care and support in developing countries primarily ensures and certifies that minimum qualitative and quantitative criteria are met that allow the accredited facility (and its referral network) to provide all components of a comprehensive package of HIV/AIDS prevention, treatment, care and support for at least a few people per month initially without interrupting other essential services.
- ▶ Accreditation of antiretroviral therapy service points in developing countries is a regulatory tool and control instrument governments can use to ensure that public sector resources are used responsibly, to improve the equity of services and to align implementation targets with the progress in building capacity. It also has the potential of increasing public accountability if the targets, processes and findings are transparent.
- ▶ Accreditation in this context is therefore a point of entry to service provision rather than an end-point (certificate of excellence for a targeted workload level). This is important, since it determines how rapidly services will be available and accessible to an increasing proportion of the people in need in resource-constrained settings.
- ▶ Standards should be developed based on existing national guidelines, regulations and best evidence from comparable populations and health systems. Existing data elements, indicators, and their targets as defined in the various components of the national health information system should be used to determine standards. This is in accordance with “the three ones” (one agreed HIV/AIDS action framework that provides the basis for coordinating the work of all partners, one national AIDS coordinating authority with a broad-based multisectoral mandate and one agreed country-level monitoring and evaluation system) as proposed by UNAIDS.⁽³³⁾

- ▶ The key constraints identified are deficits of skilled human resources at the service and management levels and a service gap between low-income and high-income areas as well as rural and urban areas.
- ▶ Under such conditions, the accredited sites will generally have low capacity to treat people. There are two options for meeting treatment targets during the first two years: rapidly expanding the capacity for treatment among the few sites accredited initially (usually mostly higher-level hospitals) or rapidly expanding more accredited sites (usually more lower-level hospitals and the first layer of primary health care facilities). Evidence is increasing that only the second option will provide a realistic chance that programme implementation will strengthen the district health system, whereas the first option will reverse past gains.
- ▶ Strengthening the plans of accredited sites requires integrating them into one-year and mid-term work plans and financial plans at the service point, district and higher levels. Initially, a quarterly review process with on-site visits should be institutionalized. To ensure this process, capacity constraints within the National Department of Health need to be addressed, and collaboration with organizations specializing in assessing quality and developing services may be worth considering.
- ▶ Regular surveys of user satisfaction should form a key component of the strengthening process.
- ▶ District health service assessment tools should complement the relatively facility-based accreditation tool as soon as possible.

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COHSASA

In 1994, the Pilot Accreditation Programme for South African Health Services was launched as a research and development programme in the Faculty of Medicine at

the University of Stellenbosch. The Programme grew rapidly, and in 1995 the University of Stellenbosch transferred the accreditation copyright and obligations to COHSASA, which was subsequently registered as a not-for-profit organization and started operating in 1996.

COHSASA is pioneering the Accelerated HIV/AIDS Development Programme (AHDP) to provide a draft set of standards. The standards for AHDP are currently in a pilot stage and due to be endorsed by HIV and AIDS specialists and by the South African HIV/AIDS Clinicians Society. The accreditation tool developed and used by the National Department of Health was reviewed jointly and incorporated into COHSASA's AHDP standards. These developments are recent, and COHSASA is currently negotiating with the National Department of Health about its offer to support the accreditation and strengthening process of antiretroviral therapy service points. Many of these service points are already in the COHSASA Facilitated Accreditation Programme.

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Thailand

The Thai Hospital Accreditation Programme began as a research and development project under the Health Systems Research Institute, an independent government organization, in 1997 and became institutionalized under the Institute as the Hospital Quality Improvement and Accreditation Institute in 1999.

The Programme covers all hospital services, both acute care and psychiatric services. It has gradually been constructed with widely accepted principles and concepts of quality systems including organizational limitations and cultural diversity. The Programme promotes the voluntary use of the self-assessment mechanism along with a positive approach towards the survey process. The Programme considers the accreditation process as an educational process rather than an inspection or auditing process. It is financed through a contractual agreement with the National Health Security Office, the Health Promotion Foundation and the Ministry of Public Health and from service-generated income.

Annex 1. Country experiences in accreditation of health service facilities for HIV care

With the power of being recognized by the Thai Hospital Accreditation Programme, the hospitals are encouraged to make a foundation for quality culture based on such critical principles as focusing on health care users, multidisciplinary teamwork, continuous performance review and improvement and professional responsibilities in standards and ethic.

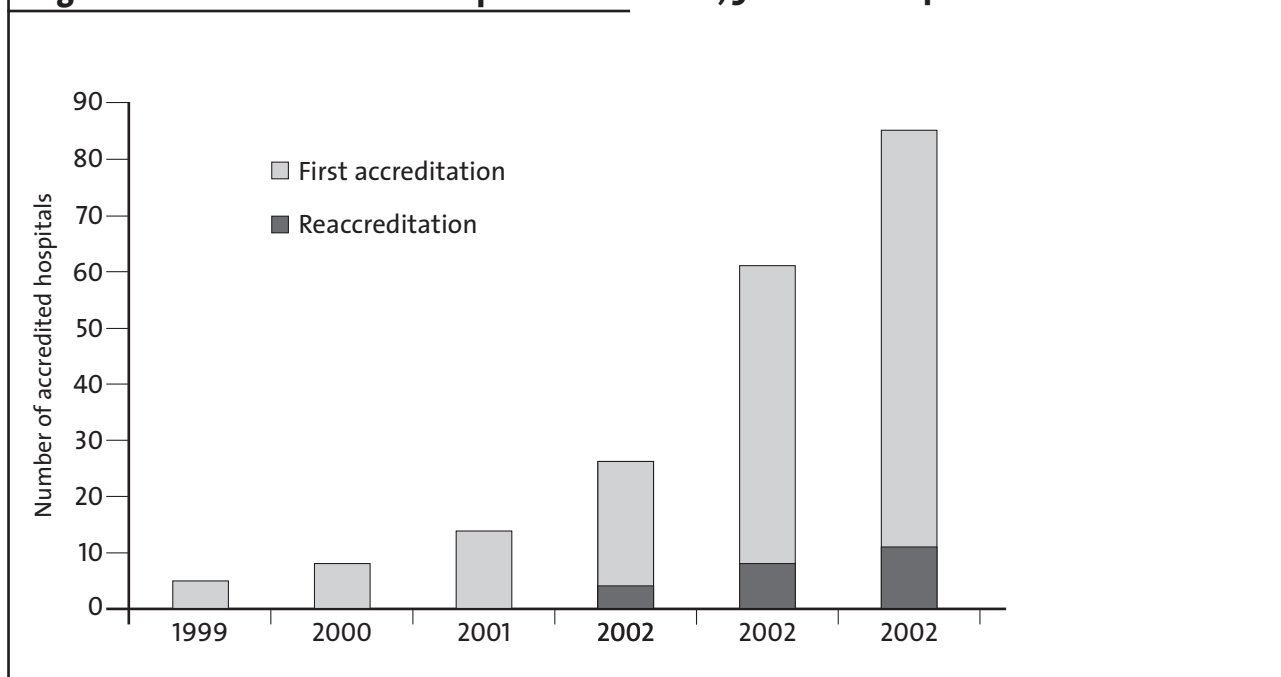
The stepwise quality improvement and recognition was initiated as a response to the government policy on universal coverage of health care, with the reality that many hospitals still lack adequate resources to cope with the workload they face. The challenge is how to gain as much as possible from as few resources as possible. Stepwise recognition, with three steps to hospital accreditation, has been implemented. The first step is to manage the outstanding risk, to review the problems or adverse events and to find ways to prevent them. The hospitals are guided in using various methods to review performance, such as risk analysis, user feedback, bedside review, reviewing medical records, reviewing critical incidents, reviewing referral, monitoring indicators, reviewing utilization and analysing gaps by comparing practice with scientific evidence. These reviews auto-

matically consider various dimensions, such as safety, accessibility, appropriateness, effectiveness and efficiency. During this step, the hospital staff can learn and practice basic quality concepts, especially the systemic approach to solving problems rather than blaming people. The second step is more systematic quality assurance and improvement to fulfil the purpose of various functions or units in hospitals. The third step is implementing the whole set of hospital standards in an integrated manner and becoming a learning organization.

The Programme mobilizes those who have experience in working with quality and are working in the health care system to assist hospitals in improving quality. Regular hospital visits by these experienced consultants and knowledge- and experience-sharing at the provincial level are used to encourage continuous improvement in 76 provinces.

Of 1300 hospitals, more than 700 are implementing some steps of the hospital accreditation programme. On 31 March 2004, 142 hospitals had passed the first step to hospital accreditation and 84 hospitals had been accredited (Fig. 1).

Fig. 1. Number of accredited hospitals in Thailand, 31 March 2004



Many community hospitals have developed good comprehensive HIV/AIDS care with a holistic approach towards the health problems in their catchment areas. The Ministry of Public Health has developed and regularly updated the guidelines for HIV/AIDS care since 1992; the last update was in 2002. Accessibility to antiretroviral therapy increases as the drug prices decline, thus changing the concept to lifelong therapy. The Programme promotes the use of scientific evidence or clinical practice guidelines in practice with two simple mechanisms: gap analysis and improvement by hospital staff; and external assessment by surveyors. Although there is no specific accreditation programme for HIV/AIDS care at the moment, the Thai Hospital Accreditation Programme plays an important role in improving the hospital care of people living with HIV/AIDS.

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Uganda

For the past decade, Uganda's Ministry of Health has been promoting the establishment of comprehensive HIV/AIDS care at home, in the community, in peripheral health units and in referral facilities at the health subdistrict, district, regional and national levels. Antiretroviral therapy has recently become a strong component of the care package. Because antiretroviral therapy is expensive and complex to deliver, there is national consensus on a tightly monitored system for delivering HIV/AIDS care to establish and maintain local and international norms and standards.

Plan for scaling up antiretroviral therapy services

Antiretroviral therapy services in the public sector, including private not-for-profit facilities, will be scaled up progressively. Phase 1 will include national and regional hospitals; phase 2, district and other hospitals,

including private not-for-profit health facilities; and phase 3, health centres grade IV. The private for-profit hospitals and health facilities must apply for accreditation when they are ready.

Accreditation

The facilities planning to offer antiretroviral therapy should be accredited before initiating services and thereafter as required to maintain accreditation status. Any centre must meet the minimum accreditation criteria to begin delivering antiretroviral therapy.

The National Advisory Board developed accreditation criteria and tools for health centres that would be authorized to prescribe antiretroviral therapy. The service delivery facilities were categorized into three groups (Box A1). Accreditation tools were developed for each category. All health units that want to start an antiretroviral therapy programme have to be accredited by the Ministry of Health. A team of experts on antiretroviral therapy selected by the Ministry carries out the accreditation. The Ministry is responsible for updating the accreditation criteria and developing the methods for assessing continued compliance with the standards, including frequency of renewal. This includes identifying an accreditation team, designing accreditation methods and tools and reviewing the reports on accreditation.

Accreditation tools are intended to facilitate capacity-building, to ensure capacity for initiation of treatment and to enhance support for adherence at lower facilities, including the community and household levels. The tools should be effective for ensuring adherence to performance standards and improving the quality of services provided in a continuous and sustained manner.

Annex 1. Country experiences in accreditation of health service facilities for HIV care

Box A1. Categories of antiretroviral therapy centres in Uganda, November 1997

Category A

Specialized laboratory work: CD4 and CD8 counts, viral load, enzyme-linked immunosorbent assay (ELISA), Western blot, tests for opportunistic infections, full chemistry including liver function tests, haematology and renal function tests, in addition to all tests falling under Category B centres.

Category B

Upgraded laboratory work to provide basic care: complete blood count and erythrocyte sedimentation rate. Tests for opportunistic infections including TB and cryptococcal infections. Basic chemistry, urinalysis and urine culture and sensitivity, basic microbiology and serology. Equipment needed includes a blood analysis machine, microscopes, chemistry machine, incubator and ELISA reader.

Category C

Access to laboratory facilities from Categories A and B centres. The targets are well-defined private practitioner's clinics that have already been rendering this kind of service.

- ▮ functioning laboratory services that can conduct basic and minimum investigations as outlined in the national antiretroviral therapy guidelines;
- ▮ systems for procuring and safely storing antiretroviral drugs;
- ▮ a health management information system that keeps proper records for tracking people receiving antiretroviral therapy; and
- ▮ a follow-up and referral system, including arrangements for consultations with other antiretroviral therapy centres,

Accreditation of laboratories and pharmacies for antiretroviral therapy

When laboratories or pharmacies are part of the overall facility providing antiretroviral therapy, the accreditation may be bundled together. When the facility arranges for external laboratory or pharmacy services as part of providing antiretroviral therapy, these facilities are accredited for antiretroviral therapy on their own. The responsibility of the Ministry of Health involves defining criteria for accreditation, procedures, the composition of the accreditation team, methods, tools and reports and the methods and frequency of accreditation renewal. The National Drug Authority is involved in enforcing accreditation.

Accreditation criteria for antiretroviral therapy centres

The accreditation team visits a health unit and assesses what is available on the ground and recommends areas of improvement if necessary before accreditation can be given. The criteria examined during the accreditation visit include:

- ▮ trained staff in HIV/AIDS care: medical officers, nurses, counsellors, laboratory technicians, pharmacists, dispensers and social workers (optional);
- ▮ available or easily accessible voluntary counselling and testing services;
- ▮ available space for counselling and assessment that ensures reasonable confidentiality;

Human resources to deliver antiretroviral therapy

The Ministry of Health will estimate the numbers of personnel needed above those already available, taking into account attrition, to meet the plans for scaling up antiretroviral therapy. This will also require more supplies, more equipment and better systems for procuring, storing, distributing and monitoring drugs. Availability of the right type of personnel in adequate numbers is crucial for the successful delivery of antiretroviral therapy. The partnership between the public and private sectors has been encouraged, especially when a private team has more experience.

Future perspectives

The future perspectives for accreditation and quality assurance for HIV/AIDS care include:

- ▮ expanding the accreditation tools to include management and a community support system;
- ▮ forming an accreditation committee;
- ▮ establishing an accreditation newsletter; and
- ▮ strengthening the monitoring of the accreditation system.

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Annex 2. Sample brief list of standards for community-based health service facilities initiating and supervising antiretroviral therapy*

A. HIV testing and counselling

- ▶ The organization establishes and follows an HIV testing policy that reflects national laws and guidelines and the WHO guidelines on rapid testing.
- ▶ The staff obtain informed consent from each person tested, and test subjects and staff attest to the voluntary nature of HIV testing.
- ▶ The organization respects the confidentiality of test results.
- ▶ The organization provides pre-test and post-test counselling.

B. Provision of antiretroviral therapy

- ▶ The organization has a transparent process and a written protocol to identify those who will receive antiretroviral therapy.
- ▶ The organization follows standard diagnostic protocols for every person suspected of having HIV infection.
- ▶ The organization follows clinical management protocols based on national or WHO guidelines for all people living with HIV/AIDS.
- ▶ The organization provides adequate time for all staff to participate in relevant education and training opportunities.
- ▶ The trained and/or certified caregivers and health professionals monitor people receiving therapy for drug toxicity and adverse effects.
- ▶ The organization provides support to people receiving therapy to facilitate their adherence to the prescribed treatment.

C. Uninterrupted supply of drugs and diagnostics for antiretroviral therapy and opportunistic infections

- ▶ The organization stocks medicines for antiretroviral therapy and opportunistic infections listed in the national or WHO antiretroviral therapy guidelines and has them readily available.
- ▶ The list of medicines stocked in the organization includes other drugs, such as methadone for substitution therapy, appropriate for the services offered by the programme.
- ▶ The organization has an established monitoring process to ensure a continuous flow of supplies of key antiretroviral and opportunistic infection drugs and a process in place to protect drugs from loss, theft or misuse.

D. Secured and confidential clinical record system

- ▶ Staff obtain a basic health inventory for each person suspected of having HIV or AIDS.
- ▶ The organization maintains the confidentiality, security and integrity of data and information.
- ▶ The organization communicates test results to other people only with the consent of the person being tested, and only health-care professionals with a direct role in managing the person being tested have access to the results on a need-to-know basis.
- ▶ Clinical records contain sufficient and updated information to identify the person receiving treatment, support the diagnosis, justify the treatment, document the course and results and promote continuity of care among health care providers.

* The categories and standards included in this list are selected in accordance with the recommendations from the WHO/UNAIDS International Consensus Meeting on Technical and Operational Recommendations for Emergency Scaling-up of Antiretroviral Therapy in Resource-Limited Settings in November 2003⁽⁴⁾. This sample list is an example to show how countries can adapt the list of proposed standards for their use in each country. This list, however, by no means intends to exclude or suspend any existing health care facility that provides antiretroviral therapy and their activities but should be used to improve the quality of these facilities.

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ISBN 92 4 159255 9

