

**Access to Antiretroviral Therapy in Developing Countries:
A Continuum of Care Approach**

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GUIDELINES AND POLICY ISSUES

Summary Report of the Workshop

Access to Anti-Retroviral Therapy in Developing Countries

Report of a Workshop supported by CI/CIDSE members
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1 EXECUTIVE SUMMARY

Faith-based organisations and NGOs, in particular those belonging to the networks of Caritas Internationalis (CI) and CIDSE (International Cooperation for Development and Solidarity, Brussels) are encouraged to support their partners in developing and fast developing countries to establish programmes leading to improved access to antiretroviral drugs (ARVs). During a Workshop financially supported by CAFOD and CORDAID and organised by the Medical Mission Institute in Wuerzburg, Germany, representatives from the above mentioned organisations discussed with partners from developing countries suggestions for policy guidelines, agreed upon technical, ethical and organisational standards and strongly recommended to proceed with concrete programmes.

Despite the decrease in the purchasing price of ARVs, there remains a heavy demand on resources, if a continued supply of quality drugs is to be assured. Organisations committed to improve the care of the HIV infected should neither withdraw resources from ongoing programmes of proven efficacy nor create false hope through misinformation that ARVs can cure. Patients can only adhere to life-long treatment with ARVs, when health services reach out to their communities in order to create a supportive environment. Safety and efficacy of use of ARVs demand good quality health services including basic laboratory services. Knowledge and experience regarding the use of ARVs for patients suffering from dual HIV and TB infection, for children and for pregnant HIV infected women are still insufficient. Research for safer, more efficient and cheaper drugs has to continue.

2 INTRODUCTION

HIV/AIDS continues to be one of the major challenges confronting contemporary society and the Catholic Church, having now become the second-greatest epidemic in human history. With more than 22 million deaths and more than 58 million cumulative infections, it is anticipated that HIV will supersede the medieval 'Black Death' as the most serious infectious threat that has ever faced the human community.

The disproportionate impact of the HIV/AIDS epidemic on developing countries, most especially affecting Africa but increasingly seen to threaten the vast populations in Asia, raises heart-rending questions regarding the distribution of resources to care for those impacted by the epidemic. While advances in HIV therapy have brought dramatic improvements in quality of life and life expectancy to those living in industrialised settings, numerous factors have made it difficult for those in resource-poor countries to gain access to these interventions which have the potential to diminish the destructive impact of the epidemic on individuals, families and communities.

3 THE RESPONSE OF CI/CIDSE

The AIDS Funding Network Group (AFNG) and the Caritas Internationalis AIDS Task Force (CI-ATF) have long promoted the integration of HIV/AIDS interventions among their partners, and in many locations have initiated comprehensive programmes of HIV-related care. At the same time, many church-related funding agencies have thus far not supported the provision and use of antiretrovirals (ARVs) in these programmes, largely for financial reasons. However, many factors are now contributing to a change in perspective on this question. These include a growing recognition of the pandemic's devastating impact on developing countries, recent decreases in the cost of ARVs, and the fact that the presence of these drugs – even in resource-constrained settings – is now “a fact on the ground.” In this context, many agencies are now acknowledging the need to assist health care partners in understanding how these drugs can be used effectively, and in developing the capacity to provide ARVs where possible.

During their meetings in early 2001, the members of the CI-ATF and the AFNG expressed the desire to reflect more deeply on the implications of the use of ARVs in the context of a workshop. An organizing committee was nominated and the meeting was scheduled for the 27th till the 29th of August, 2001 in Wuerzburg. The Medical Mission Institute (MI), in particular the Unit for Health Services and HIV/AIDS, took responsibility to plan and host the conference whose aim was to explore theological, ethical, medical, pharmaceutical and public health issues relevant to developing ARV programmes. Participants for the workshop included international experts, members of the CI-ATF and the AFNG, and CI/CIDSE partners with specific experiences from India and Africa (South Africa, Zambia, Kenya, Uganda, Nigeria). Much of the conference work was done in four smaller working groups which focused on relevant issues from the perspectives of ethics and theology, clinical care, pharmaceuticals, and public health. The output from the workshop is this document which describes ethical and theological underpinnings for undertaking ARV initiatives, as well as common strategies, policies and guidelines which should be suggested to CI/CIDSE constituencies. Given the rapid pace of change both in HIV research and in the pricing of ARVs, this document will be relevant for a limited period of time, and these issues will need to be revisited within two years.

4 THE LIFE AND EXPERIENCE OF JESUS: OUR STARTING POINT AND OUR GOAL

4.1 HUMAN SUFFERING

The role of Jesus Christ, both in the literal and metaphorical senses, is critical to Christians wrestling with the problem of human suffering. By becoming human in Jesus Christ, God entered fully into the human and cosmic condition, including that of suffering – whether at human hands or through natural processes like hunger and thirst. The extent of divine sharing in human suffering (even unto death) was fully revealed on Calvary. Yet this compassion – God suffering with humanity – was not just an example inspiring us to patience in adversity. In his ministry, Jesus spent much time and energy relieving the sufferings of the sick, the hungry, the bereaved, and he did so sometimes in violation of the sacred laws of the Sabbath.

4.2 THE “GOOD NEWS”

Jesus came to bring the “good news” to the deprived and excluded, to heal them and set them free, to establish through them the new community, the new humanity, the new creation. In pursuit of this mission he inevitably alienated the religiously and politically powerful. He foresaw this alienation and was willing to lay down his life for the sake of the new community, for his friends, and indeed for his lethal enemies for whose forgiveness he prayed on the cross. Suffering unto death was Jesus’ final response to the horrors of suffering inflicted and endured by human beings, and to the universal pain of human mortality. He evoked from the Father-God the gift of Resurrection, of true and eternal life where suffering would have no more place, and his gift would be shared with all human beings. Even now as suffering and death are overcome in principle by the Spirit of Christ, his disciples are called to continue his ministry of compassion and healing with all the God-given resources of creation, redemption, and resurrection.

4.3 NEW LIFE AND LOVE

Coping with the suffering and evil of HIV/AIDS calls for reflection on and imitation of God’s response to human suffering in Jesus Christ. By sharing as far as possible the multiple pains of people with AIDS in their physical and mental distress, in their social exclusion and personal depression – while striving to overcome these pains as far as possible – Christians are helping to transform sheer human tragedy into the possibility of new life and love. These Christians may be the first beneficiaries themselves as their struggle to help enables them to encounter the compassionate God present – if not always evident – with the suffering. The witness of the “carers” may evoke in the “cared for” a sense of this divine presence, and of the hope, beyond immediate evil, which had been almost extinguished. Of course, in many such cases, the attentive Christian may be the one inspired by the reaction of the sufferer or by the dedicated and tender caring of a partner or friend, threatened perhaps by the same affliction.

4.4 FROM COMPASSION TO COMMUNITY

In the face of the impenetrable problem of an evil such as the current pandemic, where intellectual effort falters, it is enriching and enlightening to look to the story of Jesus' ministry, death, and resurrection, and to its compassionate rehearsals in the mutually caring relationships the pandemic so often permits. The gospel accounts of Jesus' practice of healing at different levels – from simple fever and leprosy, to demonic possession and the forgiveness of sins – form the basis for the Christian commitment to caring for the sick and disabled. In feeding the hungry, Jesus revealed a further dimension of the call to his disciples. He also demonstrated the true human dimensions of such service in his meals with the socially excluded: publicans, prostitutes, and sinners. All of this was directed to establishing a new and inclusive community of friends (John 17), of brothers and sisters of Jesus, of daughters and sons of His Father (Paul *passim*). This new community, indeed this new creation (Paul: II Cor 5) would be an anticipation of the final community of the Reign of God. The call of Christians in the face of the HIV/AIDS crisis is to seek to care for, to heal, and to include people with HIV/AIDS and, in the same Spirit of Christ, to assist in preventing the further spread of this devastating disease. In responding to this call, Christians will need to meditate on the Scripture texts themselves, to pray over them in order to penetrate their depths, and to be enlightened by the immediate example and teaching of Jesus.

4.5 CATHOLIC SOCIAL TEACHING: THE CENTRAL FOCUS FOR OUR ANALYSIS AND ACTION

4.5.1 The Tradition

The century-long development of Catholic Social Teaching, from the encyclical *Rerum Novarum* (*On the Condition of Workers*), by Pope Leo XIII, in 1891, to the encyclical (*Centesimus Annus* *On the Hundredth Anniversary of Rerum Novarum*), by Pope John Paul II in 1991, has expanded and modernised that powerful call for justice in society which originated with the prophets of Israel and which was deepened and transformed by Jesus' teaching of the Reign of God.

4.5.2 Unity of the Human Family: Dignity of Human Person

In face of the HIV/AIDS pandemic, the sufferings it involves and the injustices it exposes, certain relevant guidelines emerge clearly from this body of teaching. The unity of the human race as the one family of God, and the unique value and divine destiny of each human being, together provide the basic standard in evaluating responses to the AIDS epidemic and to the other great social challenges of today. The divine creation of human persons as members of the one human community inevitably and immediately involves rights and responsibilities for each and for all. The basic equality of all, and their call to share equitably in the gifts of creation, indicates the direction of human development towards that fulfilment of creation which Jesus called the Reign of God.

4.5.3 Participation

In the further spelling-out of the implications of this divine plan in an AIDS-afflicted world, the Catholic Tradition of social analysis and teaching offers several significant guidelines. In a family where all enjoy equal dignity and distinctive gifts, an ethos and practice of participation must be continuously promoted. Only in this manner will each individual be enabled to develop as a person and to contribute in turn to the community's development at local, national, and international levels. In a situation of social sin where there exist inequitable power structures, oppression, or exploitation on the basis of race, gender, or wealth, true participation is impossible. The critical analysis and reform of

these power structures is a continuing challenge. Where the generally exploited groups are for that reason also the more vulnerable to HIV/AIDS, and are also the last to benefit from prevention and care programmes, the moral call to change the oppressive structures towards a more participatory pattern becomes more urgent, and programmes designed for prevention and care must themselves insure that they are genuinely participatory.

4.5.4 Solidarity, Option for the Poor, and Subsidiarity

Within the Catholic Social Tradition, some further insights and key words enable us to delineate these general guidelines in a more detailed fashion. We live in a broken world where suffering and oppression may never be eliminated, so the call to solidarity with all persons in this broken human family seeks priorities in the use of limited time, energy, and resources. In that situation, choices should be made, as far as possible, in favour of the less powerful and more deprived. This preferential option for the poor, as it is termed, demands careful examination of situations and resources. It requires a sympathetic and imaginative sharing of the real sufferings of these people, as well as a compassionate solidarity with them, after the fashion of Jesus. In this way motivation, effectiveness, and sustainability may be achieved in sharing resources. Such sharing may not be imposed, but should be posed by the developing conversation and consensus between would-be partners so that the dignity of the obviously needier is fully respected, and to allow the seemingly powerful to be enriched by the more human relationships emerging. Partnerships of this kind recall another insight of the Catholic Social Tradition – that decisions should be taken as close as possible to the people most affected. This principle of subsidiarity has clear implications for decisions to be made in response to people infected and to those immediately affected by HIV/AIDS.

4.5.5 Values

Fundamental values from the Catholic tradition of social teaching and practice should be central in the design of HIV treatment programmes. These values include the following:

- The equal dignity of each human person as a member of the one human family
- The unity of that human family and its consequent call to equity in sharing the resources of creation in solidarity
- The rights and responsibilities of each member within the whole family
- The participatory nature of that family
- The call to overcome inequities, exclusions, discriminations, conflicts and violence which continue to mar the history of the human family
- The priority of the poor in the call to solidarity
- The value of subsidiarity in a shared tackling of human needs at the level nearest to those most affected.

4.5.6 Foundation and Application

This outline of rational moral values and insights must be related back to the person and teaching of Jesus for final validation. As Jesus understood, living such values will be costly. This is evident in a variety of ways in the AIDS context, ranging from the concept of “social mortgage” spoken of by Pope John Paul II in relation to all property (including intellectual property), to the more painful sacrifices which persons, communities, corporations, and nations may be called to make for the sake of the deprived. Values and insights must also encounter openly and imaginatively the actual situation of people affected by HIV/AIDS, the resources available to help them, and the experience already gleaned by the engagement of the Church and other bodies involved with the pandemic over the last decades. Only then can the values and insights be effectively applied and gradually expanded.

5 ARV PROGRAMMES FROM A PUBLIC HEALTH PERSPECTIVE

Important elements of the rationale for providing quality HIV-care in faith-based and NGO health services, including the introduction of ARVs, include the following:

- It can contribute to reduce the negative impact of catastrophic illness on human development through aggravation of poverty and disintegration of families, communities and the society as a whole.
- It is capable of improving quality of life and life expectancy, as measured by numerous scientific studies.
- It can help to reduce global inequity, especially regarding access to treatment.
- It is a response to increased demand by society, and to felt needs expressed by patients and service providers.
- It can reinforce efforts to prevent HIV transmission by creating an additional motivation for voluntary counselling and testing (VCT).
- It can reduce the number and severity of HIV-related complications and associated medical care, which will reduce the burden on health services and health workers.
- Recent dramatic reductions in the price of ARVs have now made provision of these services conceivable.

5.1 GUIDING PRINCIPLES

An uncontrolled introduction of ARVs could have devastating consequences for the effectiveness of HIV treatments, including the rapid development of drug resistance as the result of poor adherence to treatment or improperly designed drug regimes. It could also have a negative effect on other health care services, as for example if funds used to supply anti-malaria and anti-tuberculosis drugs were shifted to support HIV treatments. The uncontrolled introduction of ARVs could also jeopardise successes achieved to date regarding HIV prevention, if improper education creates the illusion that ARVs cure HIV infection. This could lead to a resumption of sexual behaviours which can transmit HIV.

- Faith-based organisations should have clear approaches to address issues concerning inequity and gender in order to insure that the community as a whole will have access to treatments, and that certain persons or groups will not have privileged access (e.g. the "better-off", men, people with a certain religious background, etc.)
- Communities have to be sensitised to the real benefits and limitations of ARVs in order to avoid "false hope," and to insure that prevention measures continue to be encouraged and observed

5.2 RESOURCES FOR ARV PROGRAMMES

Funding organisations and partner health care agencies must recognise that if the decision is made to increase access to these therapies, building the capacity to provide these drugs and to maintain ARV programmes will be complex and costly. Careful preparation and ongoing evaluation will be required to ensure the quality and continuity needed for safe and effective use of these drugs. It must also be recognized that due to financial constraints, all persons who are in need will not have access to ARVs. Some programmes will be able to provide the necessary resources and to train staff before others. Even within specific programmes, decisions will need to be made to use resources, including ARVs, in a fair, just and equitable manner.

Where decisions are made to institute ARV programmes, they should be thought of as ‘pilots’ in the sense that they are new, and that their planning should be carefully done and well documented. However, they should not be thought of as ‘pilots’ in the sense that their development should proceed slowly, given the need to make decisions about providing these interventions as quickly as is feasible.

- 1) Resources for ARV therapy must be *new*, and should be considered as only an initial step of committing more resources. ARV programmes must not drain resources from existing health care services, nor should there be an abandonment of existing HIV prevention and care activities which have been shown to be effective.
- 2) Given the substantial financial resources needed to support ARV programmes, funders will likely need to consider creating funding consortia which would include gaining access to public funds for ARVs, e.g., the Global Health Fund.
- 3) Alliances with other actors e.g. pharmaceutical companies, the business sector, other churches, UNAIDS, WHO, and NGOs need to be developed and enlarged. In this regard, the profile of the Church’s work ‘on the ground’ needs to be raised, collaboration with Government committees and similar bodies needs to increase, and global Church networks need to be strengthened.
- 4) Resources will be required to fund ARVs, to monitor drug toxicity, and to support interventions that enhance treatment adherence. Funders must also take account of the fact that providing ARVs will likely increase the overall workload of hospital staff by 10-20% related to coverage, the service package provided, and utilisation.
- 5) Facilities and funders desiring to establish ARV programmes should guarantee that they are able to sustain the program for a minimum of three years, with planning occurring annually to continue the program’s viability. Patients beginning ARVs should be fully informed of the fact that the program’s continuity can only be guaranteed for a finite amount of time (hopefully to be renewed each year), and that the program’s capacity to treat patients may be limited to a certain number of patients per year.
- 6) ARV therapy requires that there be a functioning system that reaches out to and depends upon active involvement by the community, as it is not feasible to suggest that a given church/ mission health care facility is responsible for or capable of providing all needed support. Faith-based and NGO health services should complement provisions made by Governments. ARV programmes must credibly interface with local health services and should have well established links with community-based organisations.

5.3 COVERAGE

The ultimate aim is to enable all faith-based and NGO health services to provide comprehensive HIV-care, including the provision of ARV for management of AIDS, for prevention of mother-to-child-transmission (PMTCT), and for post-exposure prophylaxis (PEP); (see below for further discussion of PMTCT and PEP programmes).

In the face of limited resources, decisions regarding access to care are complex. Criteria for gaining access to care, especially as these programmes will initially be able to serve only a small proportion of those needing care, will need to be developed in light of the theological considerations noted above, and in consultation with the local community.

5.4 IDENTIFYING PROGRAMMES TO PROVIDE ARV THERAPY

It is critical to recognise that to be most beneficial, antiretrovirals (ARVs) ideally should be administered as life-long treatment. ARVs therefore should begin only when adequate resources are available

to insure that interventions are medically sound, well monitored, and financially sustainable. Patients must also be aware that while HIV treatments can help to improve their quality of life, they cannot cure individuals of their HIV infection.

Health care facilities that would be appropriate for administering ARV include those second-line health care facilities which are willing to undergo the necessary preparation, which have adequate laboratory services and sufficient medical, nursing, pharmacy and counselling staff experienced in HIV and TB management and care, and who are ready for training in the administration of ARVs. In addition, introducing an ARV programme to a facility will require the hiring of additional staff.

The health care facility should have good working relationships with first-line health care facilities, community-based health care programmes, government health care authorities, and with civil service organisations such as faith-based groups. The facility should be experienced in palliative care, and should have active links with home-based care programmes in the community.

Not all faith-based and NGO health services have developed non-ARV HIV care and support services equally, and the introduction of ARVs into some of these services might not be feasible at the moment due to lack of human resources, structures, etc.. ARV therapies should be incorporated into the continuum of comprehensive primary health care, and should not be imagined or administered as stand-alone or vertical programmes. Facilities should attempt to avoid duplication of HIV services which are already available locally.

Possible ARV intervention sites should be selected on the basis of criteria that enhance the chances of success. The likelihood of successful implementation will be increased when the following essential care and support elements are in place within a continuum of care:

- Clinical management for diagnosis, testing, rational treatment, prophylaxis and follow-up care of tuberculosis (including appropriate laboratory services and management using the DOTS strategy)
- Nursing care to promote and maintain hygiene and nutrition, to assist the family in day-to-day care, to teach necessary precautions against HIV transmission, and to give health education
- Counselling services, including well developed VCT programmes
- Psychological, pastoral and spiritual support
- Social support, including material support when necessary
- Mutual support groups (patient groups, groups of people infected and affected by HIV/AIDS, advocacy groups, etc.)
- Referral systems between all different elements of the network
- Treatments for pain, diarrhoea, dehydration, opportunistic infections, and sexually transmitted diseases

Other essential qualities of ARV programmes are:

- There should be no financial, geographical or other barriers for persons living with HIV/AIDS (PLHA) and their families to move freely from one service component to another.
- Services should be continuous, affordable, accessible and acceptable.
- ARV programmes should make therapy equally available to women and men, with possible priority given to lone parents.
- Clinical programmes should carefully monitor clinic attendance, medication dispensation, feedback from community-based programmes intended to support ARV adherence, and feedback from patients receiving ARVs. Operational charts (described below) should be summarised and analysed as a monitoring tool in tracking program efficacy.
- Church-related institutions and other NGOs who sponsor ARV initiatives should also support surveillance of HIV drug resistance in the programme catchment area. These should be done at the program's baseline, and periodically thereafter, to monitor the level of drug resistance in the community in order that the program can be modified if necessary. It is critical that competent techni-

cal assistance be engaged in designing these surveillance programmes and in interpreting their data.

- In addition to monitoring individual patients, programmes implementing ARVs should as well be supported in operational research which monitors program-wide statistics such as the number of patients receiving VCT and ARVs, the clinical stages of patients being seen, the proportion who are receiving ARVs, drug combinations being used, and gender distribution of ARV recipients. In addition, program quality and efficacy should be monitored and evaluated by following trends in the incidence of opportunistic diseases, side effects being caused by ARVs, the impact of ARVs on quality of life and survival, the number of patients who continue on treatment after initiation, etc.. In this area there may be great benefit in obtaining external technical assistance.
- The health care facility should have access to laboratory assays which include HIV testing, haemoglobins, white cell counts, liver functions and amylase tests, as well as basic microscopic analyses of sputum, urine, stool and cerebrospinal fluid. The laboratory facility and health care facility staff should also be skilled in the diagnosis and management of tuberculosis, STIs, and other frequently encountered HIV-related co-infections (with treatment as appropriate by local standards).

General programme characteristics elements that can enhance successful implementation include the following:

- An integrated approach (integration of ARV services with those sponsored by Government and/or other NGOs)
- A project that is also a potential learning site (for other projects)
- An approach/ policy that insures access to the services by the poor, women and other socially disadvantaged groups

When a decision is made to introduce an ARV program, reaching the following goals within two years would be reasonable signposts of success:

1. Access to ARVs for persons living with HIV/AIDS will be improved*
2. The capacity of health care facilities to provide continuous, comprehensive and holistic quality care will be improved .
3. The health care of people living with HIV/AIDS will be part of a continuum of care.

6 CLINICAL MANAGEMENT GUIDELINES

- **HIV testing for diagnostic purposes.** Based on WHO recommendations a positive HIV test should depend on two positive results of antibody tests based on assays employing different methodologies. Western blot testing should not be considered as a standard ‘confirmatory assay’ because of the cost involved. Where CD4 testing may be available, CD4 tests should not be used as a surrogate means of doing HIV testing.
- **What criteria should be established for eligibility for ARV?** Ideally, decisions to initiate ARVs would be made on the basis of CD4 counts and viral load measurements, with treatment being initiated for persons having a CD4 count less than 200 cell per ml or a viral load greater than 50,000 viral copies per µl. However, recognising that CD4 counts (and even more, viral load measurements) are not generally available for financial and technical reasons, ARVs can be initiated on the basis of a confirmed positive HIV test and certain clinical indicators. With the exception of symp-

* “Access” has operational dimensions which include availability, accessibility, service provision, continuity and acceptability.

omatic patients who are in terminal stages, ARV therapy would be appropriate for patients who meet WHO HIV clinical stages 3 or 4 (see Appendix on page 23).

- **Patient capacity to be adherent to drug regimens.** Patients to be considered for ARV therapy should demonstrate some minimal capacity to be adherent to their medications, as for example by being able to be compliant with a specified number of clinic appointments before drugs are initiated. On the other hand, eligibility for ARVs should not be based on any social criteria or behaviour, as for example people who are alcoholics, drug users or commercial sex workers should not be discriminated against.
- **What regimens should be considered for initiation?** Extensive clinical experience has demonstrated that only drug regimens which include 3 potent ARVs are effective in long-term HIV suppression and in avoiding drug resistance, and are considered the standard of care. These combinations of three drugs are referred to as highly active anti-retroviral therapy, or HAART. Appropriate HAART in developing countries should generally be restricted to nucleoside reverse transcriptase inhibitors (NRTIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs), with little support given for protease inhibitors (PI's) due to their complicated administration schedules, high pill burdens, and toxicities. Three NRTIs or two NRTIs and one NNRTI are both acceptable initial therapies, with various arguments that can be made in support of either approach as a first regimen (see Appendix on page 23). Local decisions about which combinations are most appropriate can be made based on cost, availability, local experience, patient preference, etc.. It should be kept in mind that promoting high-quality, long-term provider-patient relationships and continuity of care is as important as the combination of drugs which are chosen.
- **Patients infected with HIV-2.** Not all ARVs are effective against HIV-2 (e.g. NNRTIs), and in areas with a significant prevalence of HIV-2, appropriate antibody tests should be used to identify these patients to insure that appropriate drug regimens are chosen when ARVs are initiated.
- **Patients in the terminal stage of AIDS** will not benefit from ARVs. However, these patients should be prioritised as recipients of palliative care including symptom relief and psychosocial, pastoral, nutritional and community-based support. (It is recognised that the determination of 'terminal stage' can be difficult, and will depend upon clinical experience and professional judgement.)
- **Pregnancy.** HIV-infected women in WHO defined HIV clinical stages III or IV should be offered ARVs, whether or not they are pregnant. However, pregnancy in itself does not provide an indication for provision of long-term ARVs. Women of childbearing age who are contemplating initiation of ARVs also need to be counselled regarding the potential risk to a foetus while receiving ARVs, and what their family planning options are. Women of childbearing age who are receiving ARVs should consider discontinuation of ARVs during the first trimester to prevent possible harm to the foetus (especially in the case of efavirenz). If a woman is receiving ARVs and becomes pregnant, consideration should be given to temporarily discontinuing ARVs during the first trimester for the same reason.
- **Initiation of ARVs in patients with HIV and TB.** Patients should generally have TB treatment completed before considering ARVs. However, if during the course of TB treatment the patient's response is less than expected, or the patient has signs and symptoms which are not usually associated with TB, initiation of ARVs should also be considered while TB therapy is ongoing.
- **ARV toxicity.** Patients on ARVs should be monitored periodically (within two – four weeks of initiation, then every 2-3 months) for common ARV-related toxicities. Haemoglobin tests should be done to detect anaemia. Patients receiving zidovudine should also have total white counts to detect leucopenia (low white cell counts), and patients receiving nevirapine should have periodic liver function tests done. All patients should also be monitored for signs and symptoms of diabe-

tes, and those receiving ddI, d4T or ddC should be monitored for signs and symptoms of pancreatitis, with serum amylase being studied in patients on these drugs who develop abdominal pain.

- **Assessment of treatment effectiveness.** Individual clinical response can be assessed based on changes in a number of parameters which include weight, frequency of opportunistic infections, diarrhoea, fevers, and the capacity to carry on activities of daily living. Changes in the findings of physical examination, such as size of lymph nodes, muscle mass, rashes, skin pigmentation, etc., can also be used to monitor patients on HAART. Simple, decision-oriented patient records which can track these parameters and can be easily be used by multiple providers may provide great assistance to the health care team in managing individual patients.
- **Especially complex questions.** Several special cases exist for which consensus has not yet developed regarding the best approach. These include ARVs in children, programmes designed for prevention of mother-to-child-transmission (PMTCT), and the use of ARVs after exposure to HIV infection. The latter category encompasses both occupational exposure (as in the case of accidental needle sticks by health care personnel) and non-occupational exposure (through sexual intercourse – whether consensual or not – or through sharing of needles during injection of recreational drugs).
 - o **HIV-infected children.** Because of the persistence of passively-acquired maternal antibodies against HIV it is not possible to use standard antibody tests to accurately diagnose HIV in children born to HIV-infected mothers until 18 months after birth. In addition, there is little clinical experience of providing ARVs to children in resource-poor situations. In the context of ARV scarcity, some would argue that adults should be given priority for access to therapy because of the dependence of other family members on them, while others would assert that the equal value and dignity of all human lives argues for equality in access. Decisions in this area must be made in careful consultation with the community.
 - o **Prevention of MTCT.** Recent studies have indicated that brief, simple and low-cost interventions (such as 1 dose of nevirapine to mother and child around the time of delivery) can significantly reduce the incidence of perinatal HIV transmission when breastfeeding is not done. However, some studies have also shown that when breastmilk substitute is not provided and children are breastfed, HIV prevalence rates at 18 months rise to levels seen in children in which no intervention was done. Thus, PTMCT programmes would appear to require a component supplying breast milk substitute in order not to counter the benefit of nevirapine or other drugs. However multiple complicating factors attend the use of breast milk substitutes. Mothers who do not breastfeed can be subject to stigmatisation both because they are not breastfeeding and because they are suspected of being HIV positive. In addition, preparing breast milk substitutes requires the presence of clean water (which may be scarce, or which will require the use of cooking fuel for purification by boiling). Many studies have also shown that children who do not receive the immunologic protections provided by breastfeeding are at high risk for death from diarrhoeal diseases. Finally, economic factors present an enormous hurdle, as nevirapine is cheap or even free, but breast milk substitutes can cost an average of US \$ 2 per day and are needed for a period of 6 months. Again, no consensus currently exists on the allocation of resources to PTMTC programmes, and dialogue between scientists, funders and each local community will be necessary in making decisions in this area.
 - o **Post-exposure prophylaxis (PEP).** International studies of health care workers who have taken AZT following occupational exposure to needlesticks have demonstrated an 80% reduction in the likelihood of becoming HIV infected. As a result, much interest has been generated in making PEP programmes available in the health care setting, and even in the case of exposure to HIV from sexual intercourse or shared needle use. (Usual PEP courses include two drugs [such as AZT and 3TC] given for a 1 month period.) However, because the risk of transmission in the case of needlesticks is very low (approximately 0.3%), only 1 case of HIV infection will be prevented for every 300 persons treated. Given the cost-benefit relationship of this intervention, again it is critical to be in dialogue with the community about allocation of

resources for PEP in any given circumstance. (It should be noted that in some areas, national or local laws and regulations may require health care facilities to make PEP available in the case of health care workers with occupational exposure.)

6.1 INSURING QUALITY OF ARV PROGRAMMES

The quality of various service components represents one of the main determinants of success of an ARV program. Some of the issues related to quality can be looked at before the introduction of ARVs, while other quality issues will have to be included over time, i.e. during the implementation of the intervention. The following quality issues should be considered:

- Technical support by experts on a regular basis (local, if available)
- ARV introduction projects should be well planned and organised, preferably using the Project Cycle Management methodology, including:
 - Appropriate project proposal
 - Continuous monitoring and evaluation of inputs, processes and outputs,
 - The use of objectively verifiable indicators (both quantitative and qualitative)
- Use of appropriate (specific) Health Information Systems and Management Information Systems, including standardised patient records, reporting forms, etc.
- Continuous education and training
- Standards for patient management
- Availability of sufficient human resources to undertake all tasks
- Regular supply of drugs and appropriate management of drugs
- To insure equal access to ARVs, the treatment should ideally be free of charge. However, payment of a nominal fee could be considered at local level (especially where for cultural reasons a nominal fee is important in order that a service is valued), as long as this does not have a negative impact on the poor.

6.2 ADHERENCE

One of the major indicators for a successful ARV programme is adherence to treatment. Adherence to any treatment is influenced by many factors, and programmes should consider adherence issues as critical to program development and planning. Adherence in the case of ARVs presents particular challenges in that treatments are theoretically lifelong, and because temporary interruption of treatment can cause drug resistance which makes further treatment (with the same drug regimen) less effective or even useless. Adherence to a treatment regimen is determined by many factors. These include the following:

- System related factors
 - Continuous availability of drugs
 - Patient-friendly services
 - High-quality and trusted services
- Drug related factors
 - Side-effects (fatigue, nausea, muscle aches, headache, etc)
 - Relationship with dietary intake
 - Drug interactions (e.g. fluconazole, miconazole)
 - Drug-dosing regimen (timing, number of pills, relationship to meal times)

- Psycho-social conditions and patient related factors
 - o Awareness and education regarding the nature of HIV, the possible effectiveness of therapy, drug-related side-effects, etc.
 - o Social support (e.g. peer groups etc.)
 - o Welfare support (e.g. food supplements)
 - o Stigma

The first period of the treatment (initial phase) can be the most difficult, as the majority of side effects occur in this period and increase the chance that the patient might interrupt treatment. Close monitoring of side effects and drug-intake is therefore extremely important. The following approaches can enhance adherence to treatment:

- Close and frequent contact between the patient and the care provider
- Special counselling regarding adherence
- Directly-observed therapy (by family or community member)
- Blister-packs
- Single dose treatment
- Incentives for volunteers (treatment supervisors)
- Pre-filled pill boxes
- Pillbox timers or beepers

7 PHARMACEUTICAL CONSIDERATIONS

While governments have the lead responsibility and role in providing guidelines and in supplying anti-retroviral drugs and essential drugs for the treatment of opportunistic infections (“ARV plus[†]”), church-related health services which are responding to the needs of people affected by HIV/AIDS will follow such national guidelines as a minimum standard.

Church-related health services should apply the principles of the WHO Essential Drugs Programme to the development of ARV services (although ARVs are not currently listed, with the exception of zidovudine and nevirapine for the exclusive use of prevention of MTCT).

Church-related health services should establish a steering committee inside each country which should deal with the following tasks:

- Obtain information on existing care programmes which include the use of ARVs
- Negotiate agreements and contracts with governments or pharmaceutical companies to achieve best possible price reductions
- Assess and develop training activities and promote these throughout the network
- Lobby governments and the pharmaceutical industry with the aim of improving access to treatment, e.g. for the inclusion of ARVs in the National Essential Drug List.

Networking could be done by a pharmaceutical church-related organisation like the EPN (Ecumenical Pharmaceutical Network, previously called Pharmaceutical Advisory Group). Such a body would have to be supported by development and donor agencies in developed countries.

[†] The term ‘ARV plus’ comprises essential pharmaceuticals to treat opportunistic infections, provide palliative care and includes antiretroviral drugs.

7.1 PROCUREMENT OF DRUGS

Only those anti-retroviral drugs (“ARV plus”) should be procured which

- comply with international quality standards (for details see Annex 1)
- meet the legal requirements of the government or any other relevant authority (e.g. Medicines Control Council or similar body)
- are registered in the country concerned, or
- for which a special authority has been granted by the Government concerned.

For the time being, the following sources can be used – listed in descending order of preference:

- In those countries where “ARV plus” drugs are procured by Government as part of its National AIDS Control Programme or as a result of a specific agreement between Government and the pharmaceutical industry, the church-related health service should seek agreement with government to receive such drugs at the same conditions as applying to government.
- In those countries where the government does not procure such drugs but has established guidelines, these guidelines should be followed.
- Where there are no government guidelines, reference should be made to the CI/CIDSE guidelines.
- If the above does not apply, centralised procurement should be encouraged, wherever possible, through:
 - o Existing central medical stores serving church services of a country or a region, or where such a store does not exist, separate church health services should seek cooperation with each other and – where possible - also with other relevant non-governmental bodies and form a network to negotiate directly with pharmaceutical companies.
- Where the above described conditions do not exist, a church-related health service may approach a reliable overseas partner to negotiate on its behalf with the pharmaceutical supplier(s).
- Finally, a church health service could negotiate directly with a company or rely on a sustainable donation from a reliable overseas partner (see “Drug Donation Guidelines”).

7.1.1 Procurement Concerns at the Health Facility Level

In the interest of quality and continuity of care it is recommended that ARVs should be procured or distributed, respectively, only where

- a suitable programme for diagnosis and treatment of symptomatic HIV infected persons exists, and
- the personnel engaged in programme implementation have been properly trained, and
- where sustainability of drug supply can be assured with reasonable certainty, and
- at first and second level provision there should be a pharmacy and therapeutic committee to establish protocols for diagnosis and treatment. There should also be an established system for monitoring and investigating adverse reactions to drugs.

Drugs are offered in brand-named and in generic form. Comparison of prices should be done in drug selection. Prescriptions should use generic names. As regards details about drugs, generic and brand names, dosages, effects and side-effects see Annex 2 “Features of ARVs and Combination Therapies”.

7.2 ACQUISITION, STORAGE AND DISTRIBUTION OF DRUGS

The selection of the type of drugs to be purchased rests with the committee-in-charge of the ARV programme. In order to guarantee an uninterrupted supply of the selected drugs on the one hand and to avoid overstocking on the other, the following issues need special attention:

- The number of patients who are registered in the ARV programme must be known to the person in charge of the pharmacy at any time.
- There should be enough ARV drugs in stock at any time to cover the treatment of all registered persons for a definite period to be determined according to local circumstances regarding availability of supplies and speed of procurement.
- Additional ARV-naïve patients should only be started on ARV treatment once financing and supplies are assured. The amount of drugs held in stock for these additional patients should be determined according to local circumstances regarding availability of supplies and speed of procurement.

ARVs should be stored in a high security area, e.g. in the narcotics cupboard, to avoid misuse. A separate register must be maintained and ARVs should be stored and dispensed like narcotics.

ARVs should be stored at the hospital (central unit) and at health facilities where personnel have received training for the implementation of the ARV programme in order to ease access to supplies for registered patients.

ARV drugs should be packed in such a way that the correct intake is made easy (Blister-pack or similar arrangements). Insofar as possible, pills which combine 2 or more ARVs should be used (e.g., Combivir® [Retrovir and Efavirenz] or Trizivir® [Retrovir, Efavirenz and Abacavir]). Not more than one month's supply should be handed out to a patient at any one time. Where possible, some form of DOT-approach should be considered.

7.3 COMMUNICATION

Proper communication between the pharmacy staff and the individual patient is very important. The pharmacy staff must be trained and motivated to give specific information to the individual patient, particularly regarding the manner of drug taking, the need for compliance, and possible side-effects. This information must be given in a language the patient understands well, and the staff member must have the time and patience needed to give this information effectively.

Pharmacy staff should also be involved in relevant health education in the community. Important issues to be stressed are the fact that ARVs do not cure the infection, have to be used correctly, continuously and conscientiously, and may have side-effects. It is also necessary to stress that the risk of transmission continues and that measures to prevent transmission must continue.

Selected pharmaceutical staff also need to be given counselling training.

7.4 AVOIDANCE OF MISUSE OF PHARMACEUTICALS

Optimal sharing of correct information with all members of staff and the community should be the first step. Patients should be reminded again and again that ARV treatment is not a cure for HIV/AIDS, and that erratic and/or unsupervised use is detrimental to health.

ARVs must be handled like scheduled narcotic drugs, and close supervision should be implemented. It is important to raise awareness among staff and patients about the danger of interrupted and/or incorrect treatment.

Staff must be motivated and supported in efforts not to give in to pressure and/or bribery (including pressure from persons of a high status in society) regarding distribution of ARVs.

7.5 TRAINING

Staff working in the pharmacy of a health service which introduces an ARV programme must be particularly briefed about the proper acquisition, storage and issuing of these drugs, the avoidance of misuse, and their obligation to provide proper information to patients. Pharmacy staff must also be adequately supervised and supported.

7.6 EVALUATION

Management and administration of pharmaceuticals should form part of the evaluation of an ARV programme.

7.7 WHO DRUG DONATION GUIDELINES

Donations may play a part in the sourcing of antiretrovirals and other costly drugs for the treatment of opportunistic infections in PLWHAs. The existing WHO Drug Donation Guidelines cover relevant aspects and should be strictly adhered to. The collection of samples or leftover drugs from PLWHAs and other well wishers overseas must be totally discouraged.

8 NETWORKING AND CO-OPERATION

Given the complexity of providing ARVs and the potential for drug side effects and the development of resistance, programmes should insure that ARV prescribers are adequately trained and continually updated. Educational curricula should include an adequate understanding of the natural history and clinical manifestations of HIV, the natural history, clinical manifestations and treatment of HIV-related opportunistic infections, the mechanisms, interactions and potential toxicities of ARV drugs, and ongoing developments occurring in the field of HIV basic science and therapy. In addition to these technical areas of expertise, ARV providers must also be educated in appropriate counselling and communication skills, and the treating team must be committed to maintaining the quality and longevity of the provider-patient relationship. Church-related health facilities and their donors should insure that ARV training programmes for physicians, nurses, pharmacists and lab personnel are available in the region, and that ongoing refresher courses are available and utilised by the ARV team. These educational programmes should be seen as integral to providing ARVs, and will require earmarked funding by church agencies. Health care facilities and funding agencies may find many previously developed curricula (such as those prepared by the International Association of Physicians in AIDS Care [IAPAC] and the International AIDS Society [IAS]) very useful, although it is likely that local adapta-

tions will be necessary in many instances. Church funding agencies are encouraged to support the development of these educational curricula to be adapted for regional and local use.

Mechanisms should be in place for regular exchange between church funders and their partners to insure that lessons learned at the local level result in a continuing dialogue and in the ongoing evaluation of program and funding designs.

9 ETHICS AND THEOLOGY

9.1 THE CHURCH FACING THE CHALLENGE OF ACCESS TO ANTI-RETROVIRAL TREATMENTS

The Church has a constructive role to play in increasing PLWHA access to ARVs in resource-poor countries. In order to carry out this role effectively, many challenges must be faced. These challenges are for the whole Church and not just the Church in the South or the North. They include the following:

9.2 TRAINING

The greatest resource to be tapped is the community, made up of many individuals who have much to contribute and who need education, training, and re-training:

- PLWHAs
- Volunteers, counsellors, community health workers, medical and nursing staff, laboratory workers, and pharmacists
- Pastoral workers, psychologists, social workers, traditional healers. etc.
- Community leaders
- Church leaders, parish groups (e.g. St Vincent de Paul)
- Orphans and vulnerable children
- Teachers and parents
- Youth and youth leaders
- Trade Unions
- Employers

9.3 ENGAGING THE CHURCH IN ADVOCACY

- Within the Church, the issues of silence, discrimination, judgmental attitudes, integration of sexuality, and stigma must be addressed
- The Church has the responsibility to speak on behalf of the marginalized to raise awareness of the effects of global inequity and injustice. More importantly, the Church should allow space for the marginalized to empower and speak for themselves.
- The Church should be a strong voice advocating changes in legislation which discriminate against PLWHAs and their access to prevention, care, treatment, and employment.

9.4 ADDITIONAL ISSUES TO BE CONSIDERED

It must be kept in mind that HIV/AIDS is not a condition which only affects individuals, but which affects as well families, communities, whole nations, and the entire global community. Therefore, all decisions related to provision of ARV treatment and other HIV/AIDS services need to include participation from the various social sectors. It is recognised that ARV treatment programmes will require substantial additional resources. As long as such resources remain limited, difficult and complex decisions will need to be made with regard to a number of vital issues. Some initial reflections are offered here, but they will require additional prayerful and honest dialogue by Church-related organisations on various levels, but especially on the level of the local community:

- **To whom should treatment be offered?** This topic gives rise to some haunting questions: for example, in a family where the man and the woman are infected and also some of their children - who is to get the treatment when there is not enough for all of them? Is it ethical to implement PMTCT programmes when, in the long run, these programmes only benefit the child and not the mother? Would making ARVs available to only a proportion of the HIV-infected members of a community possibly threaten the success and integrity of currently well-functioning HIV care programmes which do not yet provide ARVs? In seeking a solution to such questions, Catholic social teaching and principles as outlined above can provide some guidance, including respect for the sacredness of human life at all stages, giving priority to the most vulnerable, and acknowledging the need for participation by the members of the human family in decisions which most directly affect them.
- **Which organisations or persons are best qualified to give ARV treatment?** Very often, this type of decision is made by donors alone. Within the Catholic tradition, which stresses solidarity, all actors in such situations should be involved in policy-making, and these endeavours should be seen as true partnerships.
- **Socio-economic issues.** ARVs are becoming cheaper, but are still too expensive for the vast majority of people who need them most. If people have to pay for the drugs they may be impoverished in the process (selling cattle, land, using up their savings, etc.). There is an argument, therefore, that these drugs should be provided without charge as far as possible, otherwise many people will only be able to access the treatment for short periods of time. While this “extra” time could be crucial for a family and particularly its children, it is not an ideal situation. ARV treatment programmes cannot be designed in isolation from other development programmes.
- **Gender:** Women have less access to health facilities already. Women will increasingly face problems in accessing these expensive drugs. Treatment management, quality control, standards, confidentiality and resource management have to be improved. Where possible, victims of rape should be given access to post-exposure prophylaxis (PEP).
- **Voluntary Testing and Counselling:** Voluntary counselling and testing services may need to be expanded and strengthened in relation to ARV treatment programmes. Under no circumstances should people be tested mandatorily or without their knowledge.

9.5 SUSTAINABILITY OF PROGRAMMES

Sustainability is the ability of the project/ programme to produce the desired outputs on a continuous basis. An empowering environment enhances the sustainability of the project/programme. Sustainability has many components, e.g. financial and human resources, institutional and organisational co-operation, community involvement and advocacy. General principles on sustainability apply as well to ARV intervention projects and will not be detailed here. However, there are a few issues that need attention:

- **Financial resources:** It is unlikely that these projects/programmes will become financially sustainable, without external financial support, as long as global economical inequalities persist. The fi-

financial sustainability of ARV intervention projects is therefore very vulnerable. Possible ways to overcome this vulnerability are:

- o Additional funding
- o Long term commitment
- o Multiple and diverse donors, which may include non-traditional donors such as businesses, foundations, international funds, governments of developed countries
- o Local fundraising
- o Local contribution from the community in cash and kind
- o Sound financial management
- o Voluntarism (professional and non-professional)

Apart from general issues on human resources in relation to sustainability, the following should be considered:

- On-going training
- Incentives to retain and motivate staff (both professional and volunteers)
- Community ownership and participation strengthens the ability to attract and retain local available human resources, both paid and unpaid

9.6 FINAL REMARK

Church-related organisations engaged in ARV treatment programmes will face new and ongoing challenges of great complexity and grand scale. The Church's teaching, experience and tradition offers many resources for careful planning and continuous refinement. The Church must not become discouraged with the size of the problem or with the cost of the work – whether personal or financial. Participation of people living with HIV is vital and will insure quality programmes that meet the real needs of communities. The Church is part of a global community, and developing partnerships with other groups and individuals can make a difference. While the Church does not have answers to all the questions, it does have a role to play based on its previous extensive experience with HIV prevention and care programmes. The risks of treatment are real and must be addressed honestly, but without making these an excuse for denying people access to treatment. We must never forget that the message of Jesus Christ is a message of healing and of hope.

10 APPENDIX

10.1 GLOSSARY

Item	Explanation
AIDS	Acquired Immune Deficiency Syndrome
AFNG	AIDS Funding Network Group
ARV:	Antiretroviral. Refers to drugs for treating HIV, a member of the retrovirus family.
CIATF	Caritas Internationalis AIDS Task Force
DOTs	Directly Observed Treatment – short course
HAART:	Highly Active Anti-Retroviral Therapy. Refers to combining three or more highly active antiretrovirals in order to fully suppress viral replication, thereby minimising the risk that drug resistance will develop.
HIV - 1	Human Immunodeficiency Virus The strain of HIV which represents the vast majority of HIV infections in the world.
HIV - 2	A strain of HIV found mostly in western equatorial Africa. The HIV-2 epidemic is vastly smaller than that of HIV-1. HIV-2 is transmitted in the same manner as HIV-1 and also causes AIDS, but appears to do so in a smaller proportion of persons than does HIV-1, and may take longer to do so.
INGOs	International Non-Governmental Organisations
NNRTI:	Non-nucleoside reverse transcriptase inhibitors. Refers to ARVs which inhibit HIV's reverse transcriptase, an enzyme which is essential for viral replication. In contrast to nucleoside inhibitors (see below), non-nucleosides directly inhibit the reverse transcriptase by binding directly to the enzyme.
NRTI:	Nucleoside analogue reverse transcriptase inhibitors. Refers to drugs which inhibit HIV's reverse transcriptase by mimicking naturally occurring nucleosides – the letters of the genetic code which the transcriptase copies. Nucleosides are the four letters of the genetic code (represented by the letter A, C, T, G) which code for protein structure. Reverse transcriptase copies nucleosides from an RNA strand to a DNA strand, allowing the cell to synthesize viral proteins. Nucleoside analogues are modified nucleosides. When they are introduced as letters into a growing DNA strand (by reverse transcriptase), the modification of the nucleoside's structure causes a termination of the growing DNA strand, thus arresting the reverse transcription process. For example, AZT is a modified T (thymidine), and when introduced into a DNA strand the AZT causes DNA strand termination.
PEP:	Post-exposure prophylaxis. Refers to the administration of ARVs to persons who have potentially been exposed to HIV infection through occupational exposure (such as needlestick injuries by healthcare workers), or from non-occupational exposure (such as sexual intercourse or shared needle use during injection of recreational drugs).
PLHA:	Persons Living with HIV/AIDS
PMTCT:	Prevention of Mother-To-Child Transmission
STIs	Sexually transmitted infections
UNAIDS	United Nations AIDS Organisations
VCT:	Voluntary counselling and testing (refers to the needed educational and counselling process that should accompany HIV testing).
WHO	World Health Organisation

10.2 TABLES

Table 1: World Health Organization Classification System for HIV Infection

Clinical Stage 1

1.
Asymptomatic infection

2.
Persistent generalized lymphadenopathy

3.
Acute retroviral infection

Performance Stage 1: asymptomatic, normal activity

Clinical Stage 2

4.
Unintentional weight loss < 10% body weight

5.
Minor mucocutaneous manifestations (e.g., dermatitis, prurigo, fungal nail infections, angular cheilitis)

6.
Herpes zoster within previous 5 years

7.
Recurrent upper respiratory tract infections

Performance Stage 2: symptoms, but nearly fully ambulatory

Clinical Stage 3

8.
Unintentional weight loss > 10% body weight

9.
Chronic diarrhoea > 1 month

10.
Prolonged fever > 1 month (constant or intermittent)

11.
Oral candidiasis

12.
Oral hairy leukoplakia

13.
Pulmonary tuberculosis within the previous year

14.
Severe bacterial infections

15.
Vulvovaginal candidiasis

Performance Stage 3: in bed more than normal but < 50% of normal daytime during the previous month

Clinical Stage 4

16.
HIV wasting syndrome

17.
Pneumocystis carinii pneumonia

18.
Toxoplasmosis of the brain

19.
Cryptosporidiosis with diarrhea > 1 month

20.
Isosporiasis with diarrhea > 1 month

21.
Cryptococcosis, extrapulmonary

22.
Cytomegalovirus disease of an organ other than liver, spleen or lymph node

23.
Herpes simplex virus infection, mucocutaneous

24.
Progressive multifocal leukoencephalopathy

25.
Any disseminated endemic mycosis (e.g., histoplasmosis)

26.
Candidiasis of the oesophagus, trachea, bronchi, or lung

27.
Atypical mycobacteriosis, disseminated

28.
Non-typhoid Salmonella septicaemia

29.
Extrapulmonary tuberculosis

30.
Lymphoma

31.
Kaposi's sarcoma

32.
HIV encephalopathy

Performance Stage 4: in bed > 50% of normal daytime during previous month

Table 2: Summary of currently suggested initial ART regimens for low income settings*

Advantages	Disadvantages
2 NRTIs + 1 NNRTI	
<ul style="list-style-type: none"> • Low pill burden • Equal potency to PI regimens 	<ul style="list-style-type: none"> • Limited long-term data • Compromises future NNRTI regimens
3 NRTIs	
<ul style="list-style-type: none"> • Defers 2 classes (PI, NNRTI) • Low pill burden 	<ul style="list-style-type: none"> • Lower potency in patients with high baseline viral load • Limited long-term data • May compromise future NRTI regimens • Potential convergence of mitochondrial toxicity

* adapted from: Carpenter et al. JAMA, January 19, 2000: 283 (3); 384.

Table 3: Overview of available antiretroviral pharmaceuticals

Compound/Short/ Brand name/ Patent holding Company	Tabl. Size/ Rec- ommended dos- age per day / Tabl. per Day	Advice	Special features and <i>major side effects</i>	Suit- able [‡]
NRTI and combinations of NRTIs				
Abacavir/ ABC / Ziagen®/ Glaxo Well- come	300 mg/ 2 x 300 mg/ 2	None	Used in combination – see Trizivir®, / in 5% hypersensitivity reaction in the first six weeks of treatment - immediate as- sessment necessary; diarrhea may need treatment, screen liver enzymes	++
Zidovudin/ AZT / Retro- vir®/ Glaxo Wellcome	250 mg, 100 mg, 300 mg/ 2 x 250 mg/ 2 [the rec- ommended dose in the U.S. is 300 twice daily]	None	Active in central nervous system / headache, fever, may cause anemia and granulocytopenia, should not be given with d4T	++
Zidovudin + Lamivudin/ AZT + 3TC / Combivir®/ Glaxo Wellcome	300 mg + 150 mg/ 2 x 1 Tablet/ 2	None	See AZT and 3TC / the use of 2 drug combinations is dis- cussed in the paper 'Medical Aspects') if possible it should be combined with a third drug	+++

[‡] Suitable in this table means: judgment according to experts attending the CI/CIDSE ARV Workshop for use in projects of church

Lamivudin/ 3TC / Epivir®/ Glaxo Wellcome	150 mg/ 2 x 150 mg/ 2	None	Rapid development of resistance (only one mutation necessary, should be combined either with AZT, ddl, abacavir or D4T, active in central nervous system, also used to treat Hepatitis B infection <i>/ very well tolerated substance, evtl. muscle pain</i>	
Zidovudin + Lamivudin+ Abacavir/ AZT + 3TC + ABC / Trizivir® / Glaxo Wellcome	300mg + 150 mg + 300 mg/ 2 x 1 Tablet/ 2	None	See drug components <i>/ it might be difficult to assess which drug is responsible for side effect and toxicities</i>	++
Zalcitabin/ ddC / Hivid®/ Hoffmann - La Roche	0.75 mg, 0.375 mg/ 3 x 0.75mg/ 3	None	Active in central nervous system, <i>/ peripheral neuropathy, pancreatitis, oral ulcers, lactic acidosis, regular screening of liver and pancreas enzymes</i>	+
Didanosin/ ddl / Videx®/ (Enteric Coated - capsule)/ Bristol Myers Squibb®	400 mg, 250 mg, 200 mg, 125 mg/ 1 x 400 mg or 2 x 200 mg/ 1 or 2	One hour before or two hours after eating	Not sufficiently active in central nervous system; bad taste <i>/ lactic acidosis; peripheral neuropathy in 30% of patients, liver and pancreas damage, in 16% diarrhea needing treatment, ulcerations in the mouth</i>	-
Stavudin/ D4T / Zerit®/ Bristol Myers Squibb	30 mg, 40 mg, 15 mg, 20 mg/ 2 x 30 mg or 2 x 40 mg/ 2	None	Active in central nervous system, very often used <i>/ Lactic acidosis; peripheral neuropathy, regular screening of liver and pancreas enzymes</i>	++
NNRTI				
Delavirdin/ DLV / Rescriptor®/ Pharmacia Upjohn	100 mg/ 3 x 400 mg/ 12	None	Used in combinations; Rapid development of resistance (only one mutation necessary) <i>/ interactions with antacida, resistance against DLV in less than two month; rash, metabolized by cytochrom P450 – attention to drug interactions e.g. Rifampicin</i>	+
Efavirenz/ EFV / Sustiva® or Stocrin®/ Dupont Pharma	200 mg, 100 mg, 50 mg/ 1 x 600 mg or 2 x 300 mg/ 3 or 4	None	Can only be used in combination with other drugs, Rapid development of resistance (only one mutation necessary) <i>/ sleeping disorders, nightmares, dysphoria, should not be used during pregnancy, metabolized by cytochrom P450 – attention to drug interactions e.g. Rifampicin, live threatening interactions known for antihistaminica, benzodiazepines and cisaprid</i>	+/-
Nevirapin/ NVP / Viramene®/ Boehringer Ingelheim	dosing is one 200 mg pill daily for 14 days, then 1 pill twice daily (metabolism is induced)	None	Must be combined with other drugs (except when used to prevent MTCT), very active in central nervous system; Rapid development of resistance (only one mutation necessary) <i>/ in 20% rash, in 3% Steven-Johnsons-Syndrome; regular screening of liver enzymes necessary; should not be combined with SQV-hgc</i>	++
PI (or combination of 2PIs)				
Amprenavir/ APV / Agenerase®/ Glaxo Wellcome	150 mg, 2 x 1200mg or 2 x 600mg when combined with 2 x 100 mg RTV/ 16 or 10	None	Not used for first line treatment; easy to swallow, may be combined with RTV, mutations causing resistance different from other drugs, fat disorders rare <i>/ diarrhea, metabolized by cytochrom P450 – attention to drug interactions</i>	+/-

Indinavir/ IDV / Crivivan®/ MSD	200 mg, 400 mg/ 3 x 800 mg or 2 x 800 mg when combined with 2 x 200 mg RTV/ 12 or 6 and 8	Should be taken with a low-fat meal; drink >1.5 l per day	Often combined with RTV / in 15% hyperbilirubinaemia, kidney stones (especially where dehydration is a risk); risk of fat and glucose metabolic disorders; drug interactions possible but less frequent than for RTV (if taken in combination with ritonavir, food restriction and increased fluid requirement are less important)	+/-
Lopinavir + Ritonavir/ LPV + RTV / Kaletra®/ Abbott	133mg LPV + 33mg RTV/ 2 x 3 Tablets/ 6	With a meal	Fixed drug combination, if combined with ddl drug intake must be separated for 2 hours; drug very effective and good to tolerate; if taken with efavirenz, dose should be 4 tabs twice daily because of impact of efavirenz on p450 system / in 22% diarrhea, risk of fat disorders, deterioration of liver function in patients with Hepatitis B or C infection, risk of pancreatitis; contraceptives less effective	+
Nelfinavir/ NFV / Viracept®/ (Agouron) Hoffmann - La Roche	250 mg/ 3 x 750 mg or 2 x 1250 mg or 2 x 750 mg when combined with 2 x 400 mg RTV/ 9 or 10 or 14	With a meal	Effective only when combined with RTs, not active in central nervous system / diarrhea, metabolic disorders, interactions with rifampicin and contraceptives;	
Ritonavir/ RTV / Norvir®/ Abbott	100 mg/ 2 x 600 mg/ 12	With a meal	Often used to improve plasma level of other PIs ('booster'), beginning of treatment with increasing dosages, cold chain necessary for storage / diarrhea, asthenia - fatigue, bad taste, parallel use of the following drugs is contraindicated: antihistaminica, hypnotica, ergotamin or neuroleptic drugs	
Saquinavir soft gel capsule/ SQV – sgc / Fortovase®/ Hoffmann - La Roche	200 mg/ 3 x 1200 mg/ 2 x 600 mg when combined with 2 x 400 mg RTV/ 18 or 14	With a meal	See IDV, improved bioavailability, cold chain necessary for storage; / in 20% of patients diarrhea needing treatment, lipodystrophia, drug interactions see IDV	
Saquinavir - hard gel capsule/ SQV – hgc / Invirase®/ Hoffmann - La Roche	200 mg/ 3 x 600 mg/ 9	Right after a meal / better uptake with grapefruit juice	Should only be used in combinations, especially with RTV; poor bioavailability / often diarrhea needing treatment, may contribute to fat and sugar metabolic disorders; many interactions especially with ARVs, metabolized by cytochrome P450 – attention to drug interactions e.g. Rifampicin;	

Table 4: Drug Charge in combination therapies with reverse transcriptase inhibitors

Combination	Brand Names	Recommended Dosage	Tablets per Day-	Cost	Suitable
AZT + 3TC + ABC	Trizivir	2 x 1	2		+++
AZT + 3TC + ABC	Combivir Ziagen	2 x 1 2 x 1	4		++
D4T + 3TC + ddl	Zerit Epivir Videx	2 x 1 2 x 1 1 x 1	5		++
D4T + ddl + ABC	Zerit Videx Ziagen	2 x 1 1 x 1 2 x 1	5		++
D4T + 3TC + ABC	Zerit Epivir Ziagen	2 x 1 2 x 1 2 x 1	6		++
AZT + 3TC + NVP	Combivir Viramune	2 x 1 2 x 1	4		+++
AZT + 3TC + EFV	Combivir Sustiva	2 x 1 1 x 3	5		++
D4T + ddl + NVP	Zerit Videx Viramune	2 x 1 1 x 1 2 x 1	5		+++
D4T + ddl + EFV	Zerit Videx Sustiva	2 x 1 1 x 1 1 x 3	6		++
D4T + 3TC + NVP	Zerit Epivir Viramune	2 x 1 2 x 1 2 x 1	6		+++
D4T + 3TC + EFV	Zerit Epivir Sustiva	2 x 1 2 x 1 1 x 3	7		+

Table 5: Tablet charge for combinations containing PIs

Combination	Brand Names®	Dosage	Tablets per Day	Suitable
IDV + RTV + AZT + 3TC	Crixivan / Norvir / Combivir	2 x 2 / 2 x 1 2 x 1	8	+
IDV + AZT + 3TC	Crixivan / Combivir	3 x 2 / 2 x 1	8	+
NFV + AZT + 3TC	Viracept / Combivir	2 x 5 / 2 x 1	12	+/-
RTV + AZT + 3TC	Norvir / Combivir	2 x 6 / 2 x 1	14	+
APV + RTV + AZT + 3TC	Agenerase / Norvir / Combivir	2 x 4 / 2 x 1 2 x 1	12	+/-
APV + AZT + 3TC	Agenerase / Combivir	2 x 8 / 2 x 1	18	+/-
LPV + RTV + AZT + 3TC	Kaletra / Combivir	2 x 3 / 2 x 1	8	+
IDV + RTV + D4T + 3TC	Crixivan / Norvir / Zerit / Epivir	2 x 2 / 2 x 1 2 x 1 / 2 x 1	10	+
IDV + D4T + 3TC	Crixivan / Zerit / Epivir	3 x 2 2 x 1 / 2 x 1	10	+
NFV + D4T + 3TC	Viracept / Zerit / Epivir	2 x 5 2 x 1 / 2 x 1	14	+/-
RTV + D4T + 3TC	Norvir / Zerit / Epivir	2 x 6 2 x 1 / 2 x 1	16	-
APV + RTV + D4T + 3TC	Agenerase / Norvir / Zerit / Epivir	2 x 4 / 2 x 1 2 x 1 / 2 x 1	14	-
APV + D4T + 3TC	Agenerase / Zerit / Epivir	2 x 8 2 x 1 / 2 x 1	20	--
LPV + RTV + D4T + 3TC	Kaletra / Zerit / Epivir	2 x 3 2 x 1 / 2 x 1	10	+/-
IDV + RTV + D4T + ddl	Crixivan / Norvir / Zerit / Videx	2 x 2 / 2 x 1 2 x 1 / 1 x 1	9	+
IDV + D4T + ddl	Crixivan / Zerit / Videx	3 x 2 2 x 1 / 1 x 1	9	+
NFV + D4T + ddl	Viracept / Zerit / Videx	2 x 5 2 x 1 / 1 x 1	13	+/-
RTV + D4T + ddl	Norvir / Zerit / Videx	2 x 6 2 x 1 / 1 x 1	15	+/-
APV + RTV + D4T + ddl	Agenerase / Norvir / Zerit / Videx	2 x 4 / 2 x 1 2 x 1 / 1 x 1	13	+/-
APV + D4T + ddl	Agenerase / Zerit / Videx	2 x 8 2 x 1 / 1 x 1	19	-
LPV + RTV + D4T + ddl	Kaletra / Zerit / Videx	2 x 3 2 x 1 / 1 x 1	9	+
IDV + RTV + AZT + ddl	Crixivan / Norvir / Retrovir / Videx	2 x 2 / 2 x 1 2 x 1 / 1 x 1	9	+
IDV + AZT + ddl	Crixivan / Retrovir / Videx	3 x 2 2 x 1 / 1 x 1	9	+
NFV + AZT + ddl	Viracept / Retrovir / Videx	2 x 5 2 x 1 / 1 x 1	13	+/-
RTV + AZT + ddl	Norvir / Retrovir / Videx	2 x 6 2 x 1 / 1 x 1	15	+/-
APV + RTV + AZT + ddl	Agenerase / Norvir / Retrovir / Videx	2 x 4 / 2 x 1 2 x 1 / 1 x 1	13	+/-
APV + AZT + ddl	Agenerase / Retrovir / Videx	2 x 8 2 x 1 / 1 x 1	19	-
LPV + RTV + AZT + ddl	Kaletra / Retrovir / Videx	2 x 3 2 x 1 / 1 x 1	9	+

Note: If indinavir is used without ritonavir, it must be given three times daily – the only drug for which this is necessary. ‘3x2’ in the table should not be misinterpreted as 3 pills twice daily, rather than 2 pills three times daily. This increased frequency has a powerful impact on adherence. If indinavir is used with ritonavir, it can be used twice daily.

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Meeting of the AFNG *Ad Hoc* Working Group on Access to Care Paris, 6th and 7th of April 2004

Introduction

- ▶ Well-designed and comprehensive treatment programmes run by faith based organisations (FBOs) have proven to be feasible, successful and beneficial to people and families affected by HIV and AIDS.
- ▶ Faith based organisations, including those related to the Catholic Church, are committed to contribute to the aims of the United Nations General Assembly Special Session on AIDS, and to set up treatment programmes, when conditions are favourable.

General Recommendations

- ▶ Catholic organizations not yet involved in treatment programmes are encouraged to consider whether and how they might collaborate with other civil society entities, governments and the U.N. to increase access to treatment and care.
- ▶ Planning should be done to facilitate a communications link that will allow Catholic organizations who have done pioneering HIV and AIDS work to share their experiences with other Catholic organizations, civil society entities, governments and the U.N.
- ▶ Catholic organizations should continue their advocacy on the lowering of costs for branded and generic pharmaceuticals.
- ▶ Although not generally considered as a precondition, laboratory monitoring of CD4 cell counts and virus load are considered in the mid term as essential for good quality care. In the long run (2-4 years) resistance testing will also likely need to become an integral part of structured treatment programmes.
- ▶ Through their constituencies Catholic organizations should actively promote the development of low-cost laboratory technologies. Preference is given to “open platform” methodologies and to those favouring technology transfer to resource constrained countries.
- ▶ It is recommended that more efforts be deployed to address the issues of HIV and TB, especially in areas with high HIV and TB prevalence. TB control and clinical care of other opportunistic infections are an essential component of HAART programmes. HAART programmes that do not have a TB-control component should be avoided. At the same time, HAART programs should not compete for resources with TB-control programs.
- ▶ Catholic organizations should encourage compliance with the Doha declaration of the World Trade Organisation in order to overcome constraints to accessibility of pharmaceuticals, reagents and laboratory equipment through intellectual property rights. The task force objects to the bypassing of this declaration through bilateral ‘free trade agreements’ by governments, and urges the pharmaceutical industries to provide more voluntary licences especially to resource constrained countries. It urges governments and international or civil service organisations to use generics of proven quality at the most accessible price whenever possible. (*consider adding text from Vatican intervention at this meeting*)
- ▶ Treatment literacy and education about treatment adherence are critical in preparing patients to begin and to maintain HIV and AIDS care.
- ▶ Clergy, religious and lay pastoral workers should have HIV-related capacity-building incorporated into their formation programs and continuing education.
- ▶ Attention to provider “burnout” is central (append to 5.1 in larger document)
- ▶ Advocacy, networking and partnerships (North-North, North-South and South-South) are central to planning, evaluating and expanding programs. (see section 7, 8.3)

- ▶ Catholic HIV and AIDS Programs will respect appropriate national and international guidelines and protocols.

TREATMENT OF CHILDREN

- ▶ Scientific knowledge has grown regarding how to treat children with HIV in resource constrained settings. Respecting the public health rational agreed upon at the Wuerzburg Conference in 2002, it is advised that efforts be made to include infants and children into the ongoing treatment programmes where possible.
- ▶ As operational experiences are insufficient , it is important to follow strictly the international guidelines on treatment for children established by the World Health Organisation.
- ▶ Specific attention needs to be given to the diagnosis of children living with HIV. Wherever possible, the use of sophisticated diagnostic methodologies e.g. Polymerase Chain Reaction Tests are recommended to assess HIV status of children younger than 18 month.
- ▶ Catholic organizations should increase advocacy efforts to make appropriate drug formulations for children available. The lack of pediatric drug formulations is a serious constraint to the treatment of children under the age of three.

POST-EXPOSURE PROPHYLAXIS

- ▶ As a matter of justice it is recommended that Catholic Health Institutions develop an ethically-based and scientifically sound policy and guidelines on:
 - 1) risk reduction for occupational exposure to blood borne infections including HIV, and that universal precautions be uniformly employed;
 - 2) making ARVs available for occupational post-exposure prophylaxis (PEP); the provision of ARVs to exposed health workers should not occur at their expense;
 - 3) the provision of PEP for non-occupational exposure (in the case of sexual violence, rape and abuse).

PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT) PROGRAMMES

- ▶ Catholic organisations need to recognize the growing scientific evidence documenting that single-dose nevirapine PMTCT could have a negative impact on subsequent treatment options for women through development of resistance. For this reason, especially where HAART is presently available or is anticipated to be available in the future, continued implementation of single-dose nevirapine programmes should be carefully reconsidered. Transient HAART during the last trimester of pregnancy and during breastfeeding should also be considered for mothers who would not otherwise be eligible for commencing HAART on the basis of their CD4 counts and/or HIV viral load.
- ▶ Efforts should be made to transform ongoing PMTCT programmes into PMTCT-plus programmes in which mothers, their infected partners and infected children have access to HAART.
- ▶ It is recommended that the issues of breastfeeding, breast-milk substitutes and non-mixed feedings be further studied, and that the experience and recommendations of appropriate agencies, national guidelines, and organizations with experience in this area be consulted.
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Paris, April 2004

