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Joint United Nations Programme on HIV/AIDS

Prevention of HIV Transmission from Mother to Child

Planning for Programme Implementation
Report from a Meeting,
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INTRODUCTION

Over 12 million women of childbearing age are now living with HIV and AIDS, and nearly 600,000 children were born with HIV infection in 1997. Since the introduction of zidovudine based preventive therapy in 1994, HIV transmission from mother to child has been brought largely under control in developed countries. Few women in developing countries have access to this therapy, however, because of the complexity of the regimen, cost, the absence of appropriate counselling and testing services, and low rate or late attendance in reproductive health services. Several trials are now underway to examine the effectiveness of a shorter and less expensive regime to prevent mother to child transmission of HIV. Recent findings from one of these studies suggest that more affordable and acceptable medical interventions for prevention may soon become available. Government departments, development agencies and NGOs have therefore begun to consider their role in the prevention of mother to child transmission

In the light of the above, the Joint United Nations Programme on HIV/AIDS (UNAIDS), in collaboration with two of the six co-sponsoring agencies, WHO and UNICEF, hosted a meeting to plan for programme implementation to prevent mother to child transmission of HIV. The principal objectives of the meeting were:

- * to review the latest information on interventions for the prevention of mother to child transmission of HIV;
- * to identify and discuss the implications for programme implementation and resource allocation in developing countries;
- * to exchange information on plans for operations research and programme implementation from selected countries and donors; and
- * to identify an international agenda for planning towards programme implementation.

OPENING AND WELCOME

Dr Awa Coll-Seck (Director, Department of Policy, Strategy and Research, UNAIDS) welcomed participants to the meeting and introduced Dr Peter Piot (Executive Director, UNAIDS). Dr Piot emphasised the need to respond positively and urgently to findings from recent trials of a shorter and less expensive regimen of zidovudine (ZDV) as a means of preventing mother to child transmission in developing countries. There is also an ethical imperative for people in the countries in which trials have been conducted to benefit from the knowledge generated.

The following questions are central to any discussion of these issues:

- (a) Is it possible to move from studies and trials to broader scale efforts to interrupt mother to child transmission of HIV?
- (b) Where and how is it most cost effective to focus our efforts?
- (c) How rapidly can (and should) an initial focus be expanded to larger scale programmes and interventions?

- (d) What are the critical steps that will make interventions available for larger numbers of women?
- (e) What are the key operational questions that should be prioritised?
- (f) Who are the 'critical partners' that need to be mobilised in order to have the greatest impact on the epidemic in the shortest period of time?

A clear plan and a time line are needed for operational studies and for the development and dissemination of good practice in four mutually reinforcing arenas of intervention:

- 1) promoting primary prevention among women during pregnancy and while breastfeeding;
- 2) ensuring access to voluntary counselling and testing (VCT). VCT is important not only for interventions to prevent mother to child transmission and as entry point to access care, but may have an important independent preventive effect against HIV;
- 3) ensuring better access to antiretroviral therapy in the perinatal period; and
- 4) ensuring access to safe and affordable breast milk substitutes for women infected by HIV.

Following Dr Piot's presentation, Dr Turmen (Executive Director, Family and Reproductive Health, WHO/FRH) welcomed participants to the meeting on behalf of WHO, and expressing the hope that progress would be made towards reaching agreement on a series of important but complex concerns.

INTERVENTIONS TO PREVENT MOTHER TO CHILD TRANSMISSION OF HIV

Kevin de Cock, Centers for Disease Control, Atlanta, USA.

Dr de Cock provided an introductory overview of interventions to prevent mother to child transmission of HIV. Globally, it has been estimated that some 600, 000 new infections occur every year, that 1.1 million children are living with AIDS, and that 8.2 million children have been orphaned as a result of AIDS. It is important to recognise, however, that the epidemic is heterogeneous. While some countries have reported HIV prevalence rates among pregnant women as high as 35%, others have reported much lower rates of infection. Efforts have been made to estimate the likelihood of mother to child transmission of HIV. A 15-25% rate is perhaps fairly typical for industrialized countries in the absence of interventions but this rate is typically higher (reaching 25-45%) in the developing world. HIV has both direct and indirect effects on infant mortality and morbidity. The impact of HIV on child survival can be substantial and a doubling of the mortality rate for children aged under 5 is already observed in most affected areas.

Transmission can take place at three main points - in pregnancy, during labour and delivery, and post partum. A number of factors make it more likely that a mother will transmit HIV to her child. These include advanced disease, a high viral load and advanced immuno-suppression. Vitamin A deficiency and conditions such as chorioamnionitis have been implicated in infection.

Delivery factors including mode of delivery (vaginal vs by Caesarean section), premature delivery, prolonged rupture of the membranes, and the use of medical instrumentation have also been identified as factors increasing the likelihood of HIV transmission.

In 1994, the ACTG 076 clinical trial provided clear evidence that a ZDV regimen given ante-partum and intra-partum to the mother, and to the new born infant for six weeks after birth, could reduce the risk of mother to child HIV transmission by approximately 60%. Largely as a result of the introduction of such treatment, there was a 40% reduction in paediatric cases of AIDS in the US between 1992 and 1998. Clinical interventions of this kind are, however, costly (approximately \$800 per woman) and complex (1 tablet taken five times daily for 2-5 months ante-partum, intravenous infusion during labour, and syrup to newborn for 6 weeks), and there is little data of the safety and tolerance of ZDV among women in developing countries where anaemia (itself a side effect of ZDV treatment) may be more prevalent.

In principle, mother to child transmission of HIV may be prevented in five ways: by preventing primary infection in women, through the use of antiretroviral therapy before during and after birth, by reducing the baby's intra-partum exposure to HIV, by treating micronutrient deficiencies in the mother, and by avoiding the infant's exposure to breast milk. Primary prevention must of course remain a first priority, and the utility of other interventions depends heavily upon local availability, acceptability and cost. Reducing exposure to breast milk is perhaps one of the most contentious issues since breastfeeding is widely recognised as nutritious, economic and convenient. Breast milk provides some immunological protection, reduces the infant's exposure to pathogens, and prolongs birth spacing.

Findings from a recent trial of short course ZDV therapy in Bangkok have recently become available. Women were enrolled at 36 weeks of pregnancy (i.e. 4 weeks before the estimated delivery time) and randomised to receive either 300 mg ZDV before and during delivery, or a placebo. Among women receiving ZDV HIV transmission was reduced by approximately 50%, suggesting that this form of treatment is safe, well tolerated and effective, offering an alternative to the ACTG 076 regimen in countries where the latter cannot be implemented. It is important to recognise, however, that the women involved in this trial did not breastfeed their babies. Given that the additional risk of post-partum HIV transmission through breast milk from mother to child has been estimated to be around 14%, alternatives to breastfeeding need to be available to prevent HIV transmission after birth following the use of a short course pre-partum and intra-partum regimen such as the above. Interventions to reduce HIV transmission from mother to child through breast milk include (i) breast milk substitution (e.g. infant formula), (ii) modifications of breastfeeding (e.g. early weaning), (iii) the use of alternative sources of breast milk (e.g. an HIV negative wet nurse or donor milk) and (iv) the treatment of expressed breast milk (e.g. pasteurization). Limitations of availability, acceptability and cost are associated with each of these options. Additionally, women who do not breastfeed their infants may experience serious stigmatization in some communities.

Research priorities linked to the above include assessing whether other short course regimens can be as effective as those tried in Thailand; whether there exist other less costly interventions to prevent mother to child transmission; what the efficacy is of existing interventions in contexts where breastfeeding occurs; what the best infant feeding options are; and whether HIV infected women can breastfeed more safely. Given variability in maternal and child health services, in HIV-related counselling and testing services, and the difficulties of integrating these two very different kinds of service provision, important challenges remain to be faced.

The key components of an effective mother to child HIV prevention programme include: (i) education, counselling and support for primary prevention, (ii) HIV testing and counselling, (iii) good quality prenatal care, (iv) pre-partum and intra-partum interventions using ZDV, (v) infant feeding counselling and support along with access to maternal breast milk substitutes, (vi) the presence of trained health care workers, (vii) education for women and (viii) procedures to monitor interventions and their impact. It is important that future pilot projects and other activities are conducted according to the highest ethical standards and emphasize the principles of autonomy, beneficence, non maleficence and justice. There is a need to scale up the use of interventions to prevent mother to child transmission even if there remain some programmatic obstacles and scientific uncertainties.

In discussion the following issues were raised:

More evidence is needed about the independent effects of changes in procedures surrounding birth on mother to child transmission (independent that is of ZDV therapy).

More research is required on safer methods of breastfeeding, including drug based and vaccine based interventions to reduce the likelihood of HIV transmission through breast milk. The impact of ZDV and 3TC treatment on viral load in maternal milk also needs to be assessed.

Preliminary evidence from Uganda suggests that few women are likely to give up breastfeeding even in circumstances when they know the risks. This tendency may be especially acute when not breastfeeding a child may be tantamount to admitting publicly that you are HIV positive.

More research is needed into the reasons why often substantial numbers of women tested for HIV during pregnancy do not return to receive their test results (anecdotal evidence suggests that for some women coping with knowledge of HIV seropositivity in the absence of proper support may be too stressful during pregnancy);

Recent research in Kenya suggests that the impact of voluntary testing and counselling on feeding practices depends on how information is delivered and the context within which information is provided. Counselling does not simply involve telling mothers not to breastfeed, it involves supporting women in finding alternatives and sustaining their use of breast milk substitutes. Attention needs to be given to the distress many women may experience when not breastfeeding, especially in communities where this is expected.

The relative costs of different intervention regimens need to be assessed, especially the costs of providing ongoing counselling and support.

COSTS AND COST EFFECTIVENESS OF INTERVENTIONS TO PREVENT MOTHER TO CHILD TRANSMISSION COMPARED WITH OTHER HEALTH INTERVENTIONS

Dr E. Marseille, UCSF, USA

Dr Marseille provided an outline description of the economics of preventing mother to child transmission of HIV in low and middle income countries. He presented findings from (i) cost effectiveness analyses of anti-retroviral therapy for pregnant women in two contrasting settings -

a middle income setting such as urban Thailand and a low income setting such as rural Tanzania (ARV model) and from (ii) cost effectiveness analyses for formula feeding versus breastfeeding for HIV infected mothers in these same two settings assuming that an anti-retroviral therapy programme is already in place (FF model). The implications of these two analyses for possible anti-retroviral and formula feeding programmes in different settings in low and medium income countries were discussed. Estimates of the budget requirements for an anti-retroviral programme in a hypothetical population of 10 million in both settings were made.

With respect to both models, estimates of key parameters affecting ARV cost effectiveness and FF effectiveness were obtained from a range of published and unpublished sources. A ZDV cost of 25% of the current price in the developed world was assumed in the ARV model (reduction based on recent Glaxo-Wellcome announcement).

In comparing the cost effectiveness of health interventions, the World Bank has suggested that interventions costing below \$50 per DALY compare favourably with other uses of health resources in low and middle income countries. Interventions costing \$100 per DALY may also be cost effective in some middle income countries.

An estimated cost of \$30 per DALY was generated by the ARV model when applied to rural Tanzania, a figure which compares favourably with other HIV and non HIV-related interventions in sub-Saharan Africa. In Thailand, the HIV prevalence is lower and therefore costs of counselling and testing per infected woman identified are higher. Consequently the ARV programme was judged to be less cost effective at an estimated \$363 per DALY. Such a programme could be made more cost effective, however, by applying it only in regions of high HIV prevalence (e.g. the Phayao region of Thailand where seroprevalence has been estimated at 5.2%, and where the cost effectiveness of the programme would be \$145 per DALY) or by providing ZDV only to mothers already known to be HIV positive (with the assumption that counselling and testing services are available for the whole population); the cost effectiveness of the programme would thus be \$39 per DALY).

Formula feeding (FF) for six months achieved acceptable levels of cost effectiveness (at \$39 per DALY and \$31 per DALY respectively) when modelled for both urban Thailand and rural Tanzania. A combined ARV and FF programme would prove competitive with other health interventions in rural Tanzania and in Thailand, assuming in the latter case that it were implemented either in a high prevalence area or in the absence of additional counselling and testing interventions.

The programme budget required to serve a population of 10 million in Tanzania and Thailand would be approximately \$4.6 million and \$2.2 respectively. In the medium to longer term it might be plausible to reduce some of these costs through the bulk purchasing of drugs and test kits, by focusing efforts on areas of high prevalence, and by streamlining service delivery.

In discussion the following issues were raised:

What are the likely determinants of programme development and implementation, and what issues arise when ARV and FF programmes are implemented in situations where the health care infrastructure is weak?

How reasonable are the estimates included in the various models, and are they the highest values we might expect?

How realistic is it to assume that women are able and willing to use breast milk substitutes. What political, moral and ethical concerns might the introduction of FF programmes raise?

In a more sophisticated modelling of the cost effectiveness of ARV interventions to prevent mother to child transmission, might it not be appropriate to assign counselling and testing costs to the various components of HIV prevention? Do counselling and testing costs vary according to how VCT is carried out, and what savings can be obtained through more innovative forms of counselling (e.g. group based counselling or video based counselling)?

INTEGRATING INTERVENTIONS TO REDUCE MOTHER TO CHILD TRANSMISSION OF HIV

Dr S. Holck (WHO/RHT)

Dr Holck identified a range of issues that need to be taken into account when integrating interventions to prevent the mother to child transmission of HIV into existing maternal health care service provision. At a minimum, the following prerequisites are necessary for this to occur: access to and use of antenatal, intra-partum and post-partum care with skilled health workers trained to provide the necessary interventions to prevent mother to child transmission; adequate counselling services and reliable and affordable HIV testing; available and affordable supplies of ZDV; safe alternatives to breastfeeding for at least six months after delivery; and good quality delivery and post-partum care.

Present constraints on the effective use of anti-retroviral therapy to prevent mother to child transmission include aspects of the intervention itself as well as the health services necessary to deliver it effectively. These barriers include: low use of antenatal care in developing countries; lack of facilities for voluntary testing and counselling; lack of facilities to support the provision and monitoring of anti-retroviral therapy; lack of safe and acceptable alternatives to breastfeeding; high costs to women, families and the health care system; and lack of information to pregnant women, their families and communities concerning anti-retroviral therapy and its potential benefits.

Two major barriers to accessing antenatal care for many women are distance and transport. Common barriers to the use of antenatal care when access is not a problem, include poor understanding of possible benefits, the absence of family permission, and child care responsibilities. Existing maternal health services may need to be expanded and re-oriented if anti-retroviral therapy is to be made available to a wider range of women. Voluntary counselling and testing (VCT) for HIV also needs to be available, acceptable, reliable and affordable. VCT should be provided by trained health care workers wherever possible, and in circumstances where confidentiality can be guaranteed.

The success of anti-retroviral therapy to prevent mother to child transmission is also dependent on the existence of reliable and affordable laboratory facilities (including trained personnel) to monitor health status, and affordable and consistently available ZDV in a regimen which can be adhered to by women who may have many other responsibilities. Safe alternatives to breastfeeding, accompanied by counselling in their use, needs to be available for at least six months after birth. Major challenges lie in promoting the acceptability of not breastfeeding in circumstances where breastfeeding is the norm.

Women's informational needs are many. They include (i) knowing the basic facts about HIV transmission, (ii) knowing about the availability and advantages of VCT, (iii) knowing about potential risks to the newborn child, (iv) being aware of options for reducing risks to the newborn, (v) knowing of the availability and cost of services, and (vi) being aware of the costs and availability of safe alternatives to breastfeeding.

Implementing anti-retroviral interventions to prevent HIV transmission requires a strengthening of existing maternal health services including antenatal, delivery and post-partum care. It also means equipping health workers with HIV counselling skills, offering reliable and affordable VCT services, and providing safe alternatives to breastfeeding along side continuing support for mother and infant. While maternal health service offer an important entry point for interventions to prevent mother to child transmission, many existing services need strengthening if we are to offer effective forms of provision.

In discussion, the following issues were raised:

The futility of promoting interventions to prevent mother to child transmission before and during birth only to witness children being infected after birth through breast milk.

The possible reluctance of some obstetricians to play a part in implementing anti-retroviral therapy in circumstances where hitherto they might have recommended the termination of pregnancy.

The challenge of integrating STD and maternal health services, and the difficulties in overcoming the stigma associated with using the former.

The challenge created by poor levels of maternal health care generally. Even where there is a supportive HIV/AIDS programme, more general systems of health care provision may be seriously deficient.

The importance of identifying opportunities for effective work, and the importance of considering where ARV interventions should be placed in the hierarchy of other needs, along with the possibility of stimulating improvements in other services.

The challenge of forging effective links between ARV interventions for prevention and other recent initiatives in the field of maternal and child health (e.g. Baby Friendly Hospitals).

The challenge of dealing constructively with the existing separation of services and the verticality of many programmes. The opportunity to move beyond seeing work on maternal and child health as somehow separate from that of STD prevention and treatment.

A SIMPLIFIED SERVICE-BASED OPERATIONAL MODEL FOR THE PREVENTION OF MOTHER TO CHILD TRANSMISSION

Dr I. de Vincenzi (UNAIDS)

Dr de Vincenzi introduced a model by which to map the process of implementing interventions to reduce mother to child transmission of HIV, and to identify the interventions which are critical and/or most cost effective. She began by emphasizing how important it is for mother to child

interventions to be part of a comprehensive approach to HIV prevention and care, and mother and child care. Primary prevention should remain a top priority alongside work to ensure the non-stigmatisation of women who are HIV positive. The health and well being of women and children should not be adversely affected by the introduction of ARV and other interventions for HIV prevention, and these interventions should not be provided at the expense of basic antenatal care and related programmes.

A multi-levelled model was described which identifies several environments in which intervention to prevent mother to child transmission can take place. Interventions to prevent infection may be directed towards: (i) all pregnant women; (ii) pregnant women receiving adequate and early antenatal care; (iii) pregnant women counselled and tested; (iv) HIV positive women who know their serostatus

In principle, the model holds the potential to quantify the gaps between different steps in the intervention process, to identify the interventions necessary to fill these gaps, to stimulate the design of a programme of inter-related interventions, to assess the effectiveness of these programmes, and to measure the cost effectiveness of work carried out.

Activities to increase the proportion of women receiving adequate early antenatal care include the development and application of standards of care applicable to all women, the review of existing obstetric procedures, and the wider diffusion of information concerning the benefits of early antenatal care including its potential to prevent mother to child transmission.

Activities which may increase the proportion of women who know their HIV serostatus include increasing access to VCT services, integrating such services into systems of antenatal care, developing communication programmes to promote the use of VCT, developing support services for people with HIV and AIDS, staff education and training in VCT, and the more widespread use of rapid HIV test kits.

Activities which may increase the proportion of women receiving anti-retroviral treatments include lowering the cost of these drugs through negotiations with manufacturers, organizing more effective and sustainable distribution systems, training health workers in the prescription and monitoring of ARV treatments, and informing women about the availability and advantages of ARV therapy.

Activities which may increase the proportion of women using safe breastfeeding alternatives include making these alternatives available and affordable, researching systems of replacement feeding other than the use of infant formula, promoting an overall environment which empowers women to act on the basis of their decisions about safe feeding, and providing feeding counselling and support for HIV infected mothers.

In principle, the above model can be used to undertake local situation assessments; prioritize interventions; develop and adapt national and international policies; develop training programmes for health care workers; ensure the availability of drugs, services and materials; develop new education and communication programmes; ensure follow up after discharge from maternal and child health services; and promote better networking between health and NGO provided services. Efforts to use the model in scenario planning suggest that it holds the potential to predict the decreases in child mortality expected in a range of situations.

In discussion, the following issues were raised:

What kinds of ongoing support and care should be offered to mothers who have received ARV for the prevention of mother to child transmission, but for whom such therapy may no longer be available after the birth of their child?

How can the existing model be modified to allow for the fact that in some countries substantial numbers of women seek antenatal care from traditional birth attendants rather than from health services?

How can all the different levels of provision suggested by the model be offered in resource poor settings without making cuts to existing services?

SITUATION ANALYSIS FOR AFRICAN COUNTRIES

Dr E. Mercier, UNICEF

Dr Mercier described the readiness of countries in Africa to respond positively to efforts to introduce interventions to prevent the mother to child transmission of HIV. He began by emphasizing the need to take into account variability in health service provision between and within countries. The introduction of such programmes should begin immediately, not least because unless action is taken quickly ill conceived interventions and programmes may be implemented. A learning by doing approach was advocated, and a range of factors need to be taken into account when selecting possible intervention sites. These factors include the quality of local medical and social services, resources for VCT, and the availability of alternatives for infant feeding.

Factors affecting the success of a particular intervention include how well informed health practitioners are, the availability of local counselling and testing services, the quality of counselling available, and political factors. There is a need to start small but to think big in relation to the opportunities that exist. These include the chance of significantly reducing levels of mother to child transmission, improving the quality of mother and child health services, increasing access to HIV testing and counselling, and developing a more comprehensive approach to care.

Programmes to prevent the mother to child transmission of HIV are, however, likely to have to compete with (i) other HIV and AIDS prevention and care priorities, (ii) more general health priorities, (iii) other development priorities. A coherent international strategy may therefore be needed to support work in this field. This involves demonstrating that interventions to prevent mother to child transmission can be successful and are cost effective.

In discussion, the following issues were raised

For the purposes of advocacy, it is important to emphasize the likely costs of **not** taking action. A relatively short but sharp intervention implemented immediately may have important long term benefits.

In some countries, there are constraints on implementation caused by poor health service infrastructure. This has important consequences for priority setting.

Clarity is needed in relation to the setting up of new (and expanded) programmes. A clear rationale is needed for such work.

There may be value in integrating HIV counselling and testing at the point of initial contact with family planning services

Greater effort is needed to identify best practice in service provision. It may be valuable to look beyond purely government sponsored interventions to consider new possibilities involving greater collaboration with the private sector. The main issue is not whether interventions to prevent mother to child transmission should be made, but how they are to be implemented and scaled up.

COUNTRY REPORTS

A series of country reports were given by representatives from South Africa, Thailand and Zimbabwe. These detailed activities undertaken to date, as well as future plans and priorities.

South Africa

Dr D. Wilkinson (Centre for Epidemiological Research in Southern Africa, South Africa) described findings from a recent study to estimate the cost effectiveness of short course ARV therapy for pregnant HIV positive women in a rural health district in South Africa. HIV prevalence among pregnant women in this district was estimated at 26% in 1997. The number of paediatric infections averted in the district, and their cost, was assessed under two scenarios compared with a no intervention control. The first scenario consisted of the short course regimen prescribed in recent Thai trials delivered with current infrastructure. The second scenario consisted of this same regimen delivered through an enhanced infrastructure including community based health promotion to encourage early attendance for antenatal care, on-site HIV testing and counselling, an assured drug supply, extra staff to provide a 24-hour maternity service, and the selective avoidance of breastfeeding. Outcome measures included the number of paediatric infections averted, the cost of infections averted, and the cost-effectiveness of the interventions themselves.

Modelling under the first scenario predicted a 11% reduction in infections over one year, and under the second scenario a 37% reduction in infections over this same period. In the second and more effective scenario, the cost per year of potential life gained was \$38. While cost effective, an intervention of this kind would consume approximately 5% of the 1997 district health budget. This, together with possible difficulties in recruiting trained staff to work in rural areas, raises important questions about the manner in which such programmes and interventions should be introduced and extended. Operational research is therefore needed before ARV programmes to reduce mother to child transmission are implemented. Politicians and programme managers need to determine the priority which should be afforded to a reduction in the vertical transmission of HIV at a time of competing health needs and constrained budgets.

Zimbabwe

Dr I. Chistike from the University of Zimbabwe described a framework for the implementation of interventions to reduce mother to child transmission of HIV. The Government of Zimbabwe has recently established a Prevention of Mother to Child Transmission Taskforce to develop comprehensive strategies to prevent mother to child transmission, establish and sustain relevant partnerships, and identify the feasible models of intervention. Specific objectives of the pilot

work underway include making VCT available to all pregnant women and determining the feasibility of providing a short course ZDV regimen for reducing mother to child transmission.

A brief situation analysis was presented. Infant mortality rates in Zimbabwe showed a sustained decline until the late 1980s when they began to increase. The under 5 mortality has doubled in Harare between 1990 and 1996. Antenatal services are reasonably accessible and nearly 80% of pregnant women report making at least one visit to such services. Nationally, just over 70% of women have an institutional delivery. Some testing and counselling services exist but are not easily accessible for women in the pilot areas. A low rate of return for test results (circa 33%) has been reported in some studies (Some additional women returned after delivery saying that they were not able to cope with the results during pregnancy). The majority of antenatal clinics have nursing staff who received some training in counselling.

Issues relevant to the setting up of interventions to prevent mother to child transmission in Zimbabwe include (i) the costs of such programmes relative to provision for competing health needs; (ii) difficulties of promoting alternatives to breastfeeding in Zimbabwe; (iii) provision for the care of children orphaned as a result of HIV and AIDS; and (iv) provision for the care and support of mothers and families prior, during and subsequent to participation in the programme. However, the ethics of withholding treatment in circumstances where it has been shown to be effective have been raised.

Important developmental work is therefore needed. This will include deciding where and how to introduce the intervention, and how to mobilize the resources necessary to initiate and sustain the work.

Thailand

Presentations were made by Professor Praphan Phanuphak, Dr Vallop Thaineua and Dr Siripon Kanshana. ZDV is available for purchase in Thailand since 1988. While the cost of the drug is lower than in many other parts of the world, implementing a programme to reduce mother to child transmission based on the ACTG 076 protocol would be prohibitively expensive, consuming an estimated \$6.6 million per year. Antenatal testing of mothers is routinely carried out but a substantial number of obstetricians still advocate the termination of pregnancy in the case of a mother with HIV infection.

As part of its HIV and AIDS related activities, the Thai Red Cross Society and Chulalongkorn University have recently stopped a clinical trial of short course ZDV to prevent mother to child transmission because it was considered better to study the efficacy of interventions under real life conditions. Consequently, a fund raising campaign was started to pay for the ZDV administered as part of an intervention project. Since its start, more than 1500 women benefited from donated ZDV, and preliminary findings suggest that the intervention may be successful in reducing the number of infections that occur. It also shows that an initiative such as this, which relies upon charitable donations, may be successful in the Thai context.

Dr Vallop Thaineua described how AIDS is now the leading cause of death for children under 5 in northern Thailand. There is an urgent need therefore to identify practicable and affordable ZDV regimens for the prevention of mother to child transmission. In Phayao province, a three component pilot programme has been introduced to prevent mother to child transmission. This involves the screening of all pregnant women, the provision of anti-retroviral therapy to mothers before and during birth and to the child after birth, and longer term care for infants and counselling for mothers. Nested within regular mother and child health activities, the programme

aims to complement other HIV prevention activities nationally and locally (including condom promotion campaigns). Preliminary evaluations suggest that the programme is well received with very high rates of acceptability of VCT, ZDV and replacement feeding, and sustainable.

In discussion, the following issues were raised

Given different experiences in monitoring adherence to ARV treatment, how best can we ensure that women who commence therapy adhere to it over time.

Perhaps the majority of existing trials and interventions have assumed that mothers are mobile and relatively healthy. What are the key issues to be taken into account when mothers are less mobile and/or ill?

How does the stigmatization of women who do not breastfeed affect participation in trials and interventions? How can women's commitment to not breastfeeding be maintained over time? If the use of breast milk substitutes is to be encouraged, what might be the response of Baby Friendly Hospitals to HIV positive mothers who do not breastfeed?

A series of discussions is currently underway between UNICEF, WHO and UNAIDS about how best to approach HIV transmission through breastfeeding. Two documents (one for policy makers and another for health care workers managers) are in the process of preparation. If a mother knows she is HIV positive then she must receive counselling to explore options to breastfeeding. Decisions must be made in the light of individual circumstances.

There is a need to look more closely at counselling provided in the context of 'shared confidentiality' and to re-evaluate when best to include the spouse and other relatives in discussions about infant feeding.

The importance of planning for future interventions was stressed. Where safe alternatives to breast milk exist they should be promoted for HIV positive mothers. A major challenge lies, however, in supporting breastfeeding in HIV negative women while making alternatives available for women who are HIV positive. The role of animal or modified animal milks needs perhaps more adequate exploration.

Caution is needed with the setting up of demonstration programmes and projects. Unless ZDV, HIV test kits and breast milk substitutes can be consistently available, efforts may fail. To ensure the consistent availability of supplies, links might usefully be forged with essential drugs programmes. There is a serious shortage of skilled personnel in some countries. It is important, therefore, to implement programmes in contexts with the capacity to support the work.

It is important to retain a clear focus at all times on what women actually want. Women need a chance to talk about their experiences of programme implementation. There are important human as well as scientific dimensions to work to prevent mother to child transmission, and these should not be marginalized or ignored.

WORKING GROUPS

Dr T Mertens (WHO/ASD) introduced the three working groups to develop recommendations on (i) Planning and Advocacy for Implementation, (ii) Technical and Operational Issues and (iii) Social, Cultural, Legal and Ethical Issues respectively. Each group was encouraged to re-visit the critical questions highlighted at the beginning of the meeting, namely (a) what is operationally feasible, (b) where and how is it most cost effective to focus our efforts, (c) how rapidly is it possible to expand the initial focus to larger scale operations, (d) what are the critical steps to ensuring interventions are affordable for larger numbers of women, (e) what unanswered operational questions should be prioritised, and (f) who are the critical partners to mobilize in order to have the greatest impact on the epidemic in the shortest period of time? More specific questions to be addressed by each group were as follows:

Planning and advocacy issues linked to the implementation of interventions to reduce mother to child transmission including the timing of any scaling up of activities, key players and roles, and international support mechanisms.

Technical and operational issues including a consideration of the ultimate aims of interventions, the steps to be followed in striving to attain these goals, and the monitoring and evaluation systems which will provide insights into effectiveness.

Social, cultural, legal and ethical issues including a consideration of the extent to which these create barriers and opportunities, how best to reduce stigma and discrimination, how best to change the climate of health seeking behaviour, and how best to share the responsibility for not breastfeeding a child.

WORKING GROUP REPORTS

Planning and Advocacy

A range of issues were considered by the working group on Planning and Advocacy for the implementation of interventions to prevent mother to child transmission. These included the question of how quickly it might be possible to move from studies and pilot projects to broader scale interventions; who should be the key players in promoting this ‘scaling up’ of activities, and what international mechanisms are needed to move the agenda forward. This latter discussion included a consideration of the ‘critical partners’ in such a process.

Overall, the group was convinced that it was feasible to begin to scale up the existing response and that there was an ethical imperative to do so. The success of such a process would, however, be dependent on political commitment and/or willingness, affordability and the presence of an infrastructure for service delivery. Political commitment might be enhanced by the dissemination of advocacy statements from UNAIDS and its cosponsors, by publicising the consequences of inaction and by identifying the added value that intervention might provide. Affordability could be enhanced through negotiations to lower the price of drugs, test kits and breast milk substitutes and by efforts to ‘de-medicalise’ existing counselling services. Some discussion took place concerning the prioritisation of sites in which to initiate an expanded response. The existence of an infrastructure to support interventions to prevent mother to child transmission was seen as a prerequisite for intervention.

A variety of forms of collaboration between international agencies was envisaged. This included agencies such as WHO, UNICEF and UNAIDS taking responsibility for particular forms of advocacy and negotiation (for example in relation to the pricing of HIV tests kits, drugs and breastfeeding substitutes), while allowing the proper involvement of bilateral agencies at country level. The key issue, however, was one of coordination. Without this, the response was almost certain to be uneven and unsustainable. UNAIDS was recognised as having a key role to play here, through acting both as a clearing house for information relating to the conduct of programmes and interventions, and as an agency with the potential to take the lead with respect to particular kinds of advocacy and negotiation.

Technical and Operational Issues

A wide range of technical and operational issues were discussed by including the pre-requisites for the setting up of programmes and interventions. These were seen as including: a national policy framework within which work would take place; a communication strategy for VCT and adequate numbers of trained counsellors; a sustained supply of relevant drugs, test kits and breast milk substitutes; and sufficient numbers of educated and trained health services personnel.

While there are still some unresolved research questions to be answered relating to the effectiveness of zidovudine in reducing levels of mother to child transmission among women who breastfeed, it was strongly recommended that short course zidovudine be made available to women irrespective of the mother's choice of feeding practices. In order to promote equity of access to maternal and child health services, the group recommended that the basic standards for maternal and child health services recommended by WHO be incorporated as an integral part of any strategy to reduce mother to child transmission. Any national strategy to control mother to child transmission should also be part of a broader strategy to prevent the further transmission of HIV and STDs which includes access to information on safer sex, access to condoms and access to reliable and confidential counselling and testing.

With respect to the development of programmes and interventions to reduce mother to child transmission, countries are likely to need support in developing a national strategy for this work; in ensuring that good links are made with existing maternal and child health services, and with STD services; in identifying and accessing reliable and consistent supplies of test kits, drugs and breast milk substitutes; in establishing the laboratory services able to provide rapid testing and results; in providing counselling and testing in ways specifically tailored to the needs of pregnant women; and in anticipating and responding to the human resources needs associated with this work.

Social, Cultural, Legal and Ethical Issues

A wide range of social, cultural, legal and ethical issues were discussed. Central among these was the need to take the perspectives and views of women themselves as the starting point for intervention and programme planning. Women have the right to protect themselves against HIV infection by having access to information about HIV and mother to child transmission and the means of prevention such as condoms and relevant HIV/STD health services. Women also have a clear right to decide whether or not, and when, to bear a child. This requires access to information about family planning and access to family planning services along with community and family acceptance of a woman's or a family's decisions.

Voluntary and informed consent is required for all aspects of HIV testing, counselling and treatment including choices made in the context of mother to child transmission. A supportive environment is needed for this which may involve reducing stigma and discrimination related to HIV and mobilising communities for support. It also includes improving access to health care, including voluntary counselling and testing, antiretroviral treatment in pregnancy, and treatment for opportunistic infections; and providing the conditions necessary to use safe alternatives to breastfeeding. Health care workers, including traditional health care workers, may require education and training in providing informed consent and protecting confidentiality.

Finally, programmes and interventions including operational research should be developed according to the highest ethical principles and with the participation of communities. They should be designed so as to avoid causing harm to and so as to stress the importance of confidentiality and informed consent. Findings from such research should be speedily disseminated to involved and affected communities.

MEETING STATEMENT

Following feedback from each of the working groups, a Meeting Statement was agreed (Appendix 1). This identifies a series of key priorities which need to be addressed including planning and advocacy issues, technical and operational matters, and social, cultural, legal and ethical concerns.

In discussion, the following issues were raised:

There is an urgent need to establish proper planning and coordination mechanisms involving donors and relevant UN agencies. Without this, the impetus for action might be lost. The possibility of establishing a virtual network for communication and planning was discussed as well as UNAIDS potential role in this process. The value of horizontal coordination and cooperation was stressed.

There could be value in establishing an international task force to oversee resource generation and resource mobilisation. This should seek to involve all relevant agencies including UNFPA and the World Bank. Meetings could perhaps be held regionally with the donor community being encouraged to participate actively in the process. Ongoing discussion might enable the structure and remit of such a task force to be more clearly identified.

CONCLUDING STATEMENTS

Dr P. Piot closed the meeting by thanking participants for assembling at short notice to discuss the prevention of mother to child transmission of HIV. Findings from recent studies compel us to act, and the meeting has provided guidance on the direction that future actions should take. There is a strong and clear rationale for urgently investing in VCT for pregnant women and in interventions to prevent mother to child transmission. Such interventions have clear benefits for women (in that they inform family planning and child health choices), for children (in that through these interventions morbidity and mortality may be significantly reduced), and for communities (in that current pressures on curative services for children may be reduced).

Efforts to promote the primary prevention of HIV infection among women, particularly during pregnancy and while breastfeeding, should be intensified. Women who are pregnant or planning to have a child should be encouraged to know their HIV status and its implications for their

health and the health of their child. Women who are infected with HIV should be provided with access to ZDV and other anti-retroviral drugs in the perinatal period in order to reduce the likelihood of mother to child transmission. Where women with HIV infection have access to affordable, safer and reliable alternatives to breastfeeding, they should be encouraged not to breastfeed and counselled in the appropriate choice and use of these alternatives. Finally, where women with HIV do not presently have access to such substitutes, urgent steps should be taken consistent with the International Code of Marketing of Breastmilk Substitutes to enable women to access safe alternatives to breastfeeding.

There is a clear consensus that broader scale programming is necessary, and this should be our first priority. While uncertainties remain, to not act on the basis of recent research findings would be irresponsible, would undermine institutional credibility, and would lead to a worsening of the present situation. The challenge, therefore, lies in identifying a set of guiding principles to inform international concerted action. These principles include (i) enduring concern for the protection and promotion of human rights, including measures to reduce the stigmatization of women with HIV infection and women who may choose not to breastfeed; (ii) the need to ensure that interventions to prevent mother to child transmission of HIV form part of a more general strategic approach to strengthening ante-natal care services; (iii) a commitment to including affected communities in the planning and implementation of interventions; (iv) the need to secure an accelerated response informed by new research findings as and when they become clear.

Epidemiological and economic analyses confirm that interventions for prevention are likely to show greatest cost effectiveness in settings of high prevalence, particularly those where VCT is already available and where ante-natal care services for women exist. In relation to how to ensure that interventions for prevention become affordable for larger numbers of mothers, the evidence seems clear. In low prevalence areas, the cost of VCT is rate limiting whereas in higher prevalence settings it is the cost of drugs and safe alternatives to breastfeeding which is rate limiting. Efforts are needed, therefore, to reduce both of these costs, perhaps through the 'de-medicalisation' of VCT and through continuing negotiations with drug and breast milk substitute manufacturers.

Unanswered operational questions remaining on the research agenda include: how best to make primary prevention more effective among women, particularly during pregnancy and breastfeeding; how to improve and perhaps shorten courses of anti-retroviral treatment, how to reduce HIV transmission through breast milk, how to reduce 'drop outs' in testing and treatment, and how to encourage better communication between programmes and projects.

In relation to the critical partners who need to be mobilized so as to have the largest impact on the epidemic in the shortest period of time, it is clear that a concerted effort is required of organisations and agencies within the United Nations system, beyond this system including bilateral aid agencies and donors, and regionally and at country level. The scientific evidence is clear, we must act and we must act quickly. The challenge now lies in scaling up the present response so as to save countless thousand lives.

ANNEX 1 : MEETING STATEMENT

Background

Transmission of HIV from mother to child can occur during pregnancy and delivery, as well as through breastfeeding. Such mother to child transmission of HIV represents a major cause of morbidity and mortality among young children, particularly in developing countries with a high prevalence of HIV infection. Interventions to prevent mother to child transmission of HIV, including recent breakthroughs in antiretroviral therapy, offer immediate opportunities to : (i) save children's lives; (ii) reduce the impact of HIV on families and communities; and (iii) strengthen maternal and child health services.

In addition to the long regimen (ACTG 076) proven effective in 1994, a CDC-sponsored trial in Thailand demonstrated in February 1998 that the use of a shorter zidovudine regimen, which is more feasible and affordable in developing countries, is also effective. This shorter regimen, involving the administration of zidovudine to mothers during the last four weeks of pregnancy and during delivery, has been shown to reduce mother to child transmission by half among women who do not breastfeed. An integrated prevention programme which combines the use of this regimen and the use of safe alternatives to breastfeeding would be effective in reducing mother to child transmission of HIV among breastfeeding populations. Recent cost-effectiveness data suggest that in many developing countries this intervention is comparable to other public health interventions. It is clear that there is an urgent need to begin to implement such interventions to reduce the transmission of HIV from mother to child.

Taking interventions to scale

Any national strategy to prevent mother to child transmission of HIV should be part of broader strategies to prevent the transmission of HIV and STDs, to care for HIV-positive women and their families, and to promote maternal and child health. The ability to make widely available, and as soon as possible, the interventions to reduce HIV transmission from mother to child depends on political will, affordability of the interventions, and the strength of existing human resources and infrastructures. Powerful means of effecting change lie in demonstrating the success of interventions to reduce mother to child transmission of HIV, as well as the costs of not acting to prevent this kind of transmission.

Three factors that affect the affordability of interventions to prevent mother to child transmission are: (i) the cost of drugs; (ii) the cost of safe alternatives to breastfeeding; and (iii) the cost of HIV tests. WHO has added zidovudine for mother to child transmission to the Essential Drug List. Glaxo-Wellcome has recently offered zidovudine at substantially reduced prices. Further negotiations are planned to minimise the cost of each of these components.

Service delivery, including voluntary HIV counselling and testing, represents a further set of costs. In countries with well-functioning health systems, the additional service delivery costs of interventions to prevent mother to child transmission may be affordable. Other countries may require more substantial investments in order to strengthen their health infrastructure to allow for the incorporation of large-scale interventions. Where applicable, traditional health and community support systems should also be fully utilised. Such investments will have a broad beneficial effect on the health sector more generally and should be encouraged.

Optimum Context

The following parameters describe the optimum context in which to implement effectively the interventions necessary to reduce transmission of HIV from mother to child:

- All women should have knowledge about HIV, and should have access to the information necessary to make appropriate choices about HIV prevention and about sexual and reproductive health and infant feeding in the context of HIV.
- HIV counselling should be available for pregnant women and those contemplating pregnancy. Such counselling should address the needs of pregnant women and women living with HIV, including reproductive health issues such as family planning and safe infant feeding. Active referral and/or networking for follow-up counselling, comprehensive care, and social support should be available for the HIV positive woman and her family.
- Pregnant women, and those contemplating pregnancy, should have access to voluntary HIV testing, to test results with the least possible delay, requiring that appropriate laboratory services be available to process such tests, and to counselling.
- All pregnant women should have access to antenatal, delivery and post-partum care, and to a skilled attendant at birth. For the shorter zidovudine regimen to be effective, at least one antenatal visit with follow up is needed before 36 weeks, and preferably before 34 weeks, of gestation. In order to benefit from this intervention, women who access antenatal services prior to 36 weeks should have access to HIV voluntary counselling and testing. Skilled care during delivery is also needed; the shorter zidovudine regimen also involves administration of zidovudine during labour and delivery.
- There should be follow-up of children at least until 18 months, especially for nutrition and for childhood illnesses.

Key principles

The following are some of the key principles that should underpin the implementation of all interventions to prevent mother to child transmission:

- The right to protect oneself from HIV infection, including through: (1) access to full information about HIV, including information on mother to child transmission, information from relevant research, and information concerning one's serostatus; and (2) access to the means of prevention, such as condoms and relevant HIV/STD health services. This requires the integration of HIV prevention, including prevention of mother to child transmission, into existing systems, e.g. education, health care (including traditional health care), and community and women's development (non-governmental and community-based organisations, traditional community leadership, etc.)
- The right to decide whether or not, and when, to bear a child. This requires access to information about family planning and access to family planning

services. It also requires community and family acceptance of a woman's or a family's decisions.

- The right to voluntary/informed consent and confidentiality in HIV testing, counselling and treatment, including choices made in the context of mother to child transmission. This involves training of health care workers, including traditional health care workers, in providing informed consent and protecting confidentiality, and should lead to voluntary, informed, and when possible, supported decision-making on these and related issues.
- The right to an environment which enables women, parents and families to make choices that protect their health and that of their loved ones, and to act upon these choices. This includes reducing stigma and discrimination related to HIV and to mobilising communities for support. It also includes improving access to health care, including voluntary counselling and testing, antiretroviral treatment in pregnancy, treatment for opportunistic infections, and to the conditions necessary to use safe alternatives to breastfeeding.
- The right to ethical research, including research that does no harm, is conducted with informed consent and with the participation of communities in research design and implementation, and involves the dissemination of research results to affected communities.

Unresolved issues

The efficacy of zidovudine in preventing HIV transmission to the child from an HIV positive mother who breastfeeds is currently not known. Zidovudine may provide some degree of protection, although probably less than the protection it provides to infants who are not breastfed. Since the majority of HIV positive women facing transmission from mother to child are women who breastfeed, it is critical to resolve this issue. It is also necessary to learn more about the effect on the morbidity and mortality of infants born to HIV positive women of introducing alternatives to breastfeeding.

Nevertheless, the greatest reduction in mother to child transmission of HIV is likely to occur when an integrated prevention programme is implemented which combines the provision of zidovudine and safe alternatives to breastfeeding. In some countries, it may prove to be impractical to implement simultaneously access to zidovudine and access to safe alternatives to breastfeeding. In these situations, the implementation of one prevention component should not be delayed until the other is feasible. Furthermore, if a woman chooses not to use both zidovudine and safe alternatives to breastfeeding, she should still have access to the intervention of her choice and should be supported to carry out the use of this intervention safely and effectively.

Other unresolved issues involve the efficacy of even shorter regimens of zidovudine than that used in the Thai study, and the efficacy of interventions which do not require knowledge of serostatus, such as Vitamin A supplementation and vaginal cleansing for prevention of mother to child transmission. Results from ongoing research will indicate whether or not these can be proposed as effective interventions on their own, or only as measures complementary to an antiretroviral regimen.

Additional research is also required on issues such as factors influencing the uptake of voluntary testing and counselling, not returning for HIV test results, adherence to the regimen, and acceptance of interventions to prevent mother to child transmission.

The Need for Action and Support

A global effort is needed to promote the updating and scaling up of interventions to prevent mother to child transmission of HIV. Furthermore, there is an ethical imperative to support the introduction of the shorter zidovudine regimen in countries in which trials have been completed, and to encourage the initiation of such interventions in countries which have the capacity and willingness to support them. Recognising the urgency of the situation and at the same time the fact that it will take time to mobilise new resources for these interventions, it is recommended that a phased approach be taken in the introduction of such interventions. Such an approach would tailor implementation to utilise fully and immediately existing national and local capacities, with a concrete plan to build on these initial efforts over time. Where the capacity to implement these interventions is limited, efforts should begin immediately to increase capacity, with a plan to introduce these interventions as soon as possible.

Coordination mechanisms

Mechanisms are being established through UNAIDS, in close collaboration with UNICEF and WHO, to coordinate and support efforts for accelerated capacity-strengthening and technical development, and to scale up the implementation of interventions to reduce mother to child transmission. These mechanisms will facilitate the exchange of information, mobilise resources, help to coordinate research, and resolve remaining policy, programmatic and technical issues. Key actors are presently discussing the nature and functioning of these coordination mechanisms.

ANNEX 2: AGENDA

Chair-person: A.M. Coll-Seck, UNAIDS

- 09:00-09:15 Welcome/opening - *P. Piot, UNAIDS*
09:15-09:50 Introduction of participants
09:50-10:15 Review of interventions to prevent MTCT of HIV – *K. De Cock, CDC*
10:15-10:40 Discussion
- 10:40-11:00 Coffee-break
- 11:00-11:20 Costs and cost-effectiveness of interventions to prevent MTCT of HIV, as compared to other health care interventions – *E. Marseille, UCSF*
11:20-11:45 Discussion
11:45-12:05 Maternal and newborn care services:
Integrating interventions to reduce MTCT of HIV- *S. Holck, WHO*
12:05-12:30 Discussion
- 12:30-14:00 Lunch

Chair-person: T. Turmen, WHO

- 14:00 -14:20 Reducing MTCT of HIV:
A simplified service- based operational model - *I. De Vincenzi, UNAIDS*
14:20-14:40 Discussion
14:40-15:00 Situation analysis for African countries – *E. Mercier, UNICEF*
15:00-15:20 Discussion
- 15:20-15:40 Coffee-break

Chair-person: D. Alnwick, UNICEF

- 15:40-16:25 Country reports on prevention of MTCT of HIV
South Africa - *D. Wilkinson, Medical Research Council- SA*
Zimbabwe - *I. Chistike, University of Zimbabwe*
Thailand – *P. Phanupak, T. Red Cross Society and V. Thaineau, MOH*
16:25-17:20 Discussion
17:20-17:30 Introduction to group work- *T. Mertens, WHO*

Chair-person: P. Piot, UNAIDS

- 08:30-11:30 Group work
11:30-12:30 Reports of group work and plenary discussion
12:30-13:30 Lunch
13:30-15:00 Drafting of recommendations and common statement
15:00-16:15 Plenary presentation of recommendations and common statement
16:15-17:00 Discussion
17:00-17:30 Closure

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