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Strategic Approaches to the Prevention of HIV Infection in Infants

Report of a WHO meeting, Morges
Switzerland, 20-22 March 2002



World Health Organization

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WHO Library Cataloguing-in-Publication Data

Strategic approaches to the prevention of HIV infection in infants : report of a WHO meeting, Morges, Switzerland, 20-22 March 2002.

1.HIV infections – prevention and control 2.HIV infections – transmission 3.Disease transmission, Vertical 4. Pregnant women 5.Postnatal care 6.International cooperation 7.Developing countries I.World Health Organization.

ISBN 92 4 156242 0

(NLM classification : WC 503.6)

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Typeset and printed in France.

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Executive summary

WHO convened a meeting in Morges, Switzerland, from 20 to 22 March 2002 to discuss the expected contribution of various programme approaches to preventing HIV infection in infants in different epidemiological situations and service delivery settings and to provide guidance to WHO on priority areas of work it should address to optimize its contribution to global efforts in this area.

The participants emphasized that a comprehensive approach was required to reach the goals specified in the Declaration of Commitment on HIV/AIDS of the United Nations General Assembly Special Session on HIV/AIDS: reducing the proportion of infants infected with HIV by 20% by 2005 and by 50% by 2010. They confirmed a strategic approach that includes:

- ▶ primary prevention of HIV infection;
- ▶ preventing unintended pregnancies among HIV-infected women;
- ▶ preventing HIV transmission from HIV-infected women to their children; and
- ▶ providing care for HIV-infected mothers and their infants.

This strategic approach recognizes the importance of **primary prevention** in efforts to reach the goals of the United Nations General Assembly Special Session on HIV/AIDS. The participants agreed that preventing HIV infection in women represents an efficient way of preventing secondary transmission to infants and provides several other important benefits to the population at large. They reflected that infants are exposed to the mother-to-child transmission of HIV as a consequence of failure to make the most of previous opportunities to protect women and their partners from infection. However, women who become infected despite prevention efforts need access to a range of care and support services, including reproductive health services and services to prevent the transmission of HIV to their infants.

This approach also acknowledges that **preventing unintended pregnancies among HIV-infected women** could contribute significantly to preventing HIV infection in infants. This component, which is currently often overlooked, requires strengthening family planning programmes, especially in high-prevalence settings, providing family planning clients access to HIV testing and counselling services and supporting HIV-infected women in making informed choices about their reproductive lives.

The participants discussed how a package of **interventions to prevent HIV transmission from infected women to their**

children, including antiretroviral drug use, safer delivery practices and infant feeding counselling and support, has decreased the mother-to-child transmission of HIV to very low levels in some countries. The participants considered the many challenges that need to be addressed to successfully implement this package in resource-constrained settings. Health systems need to be strengthened to redress programme inefficiency and to ensure wider access to and uptake of testing and counselling and the use of antiretroviral drugs by those in need. Approaches to make infant feeding safer in the context of HIV also requires urgent attention, especially in areas where replacement feeding is not acceptable, feasible, affordable, sustainable and safe for all mothers.

The participants recommended that a fourth component, **care for HIV-infected mothers and their infants**, be added to the three-pronged strategy supported to date by the United Nations agencies, to take into account the reality that programmes for preventing HIV among infants identify large numbers of HIV-infected women who should gain access to a long-term programme of care, treatment and support. On humanitarian grounds, it is difficult to defend providing a short course of antiretroviral drugs to save a child but denying basic care and, when indicated, antiretroviral treatment to the mother. Care and support services for mothers and exposed infants should also contribute to increasing the uptake and impact of key interventions for reducing the mother-to-child transmission of HIV.

The meeting participants encouraged WHO to actively promote this strategic approach for preventing HIV infection among infants, including all four of its critical components. The balance between intervention areas should be determined in each country based on data on epidemiology and on service delivery and use. The participants felt that WHO has an important role to play in several key areas, including reviewing and interpreting existing and emerging research in this field; collecting strategic information to guide programme design and implementation; providing technical guidance on key issues such as HIV counselling and testing, choice and use of safe and effective antiretroviral drug regimens, infant feeding counselling and support and care; and treatment and support for women with HIV and their children.

Of note is the participants' call to integrate key interventions for preventing HIV among infants into existing health services, in order to strengthen links between programme areas, to make the most of potential synergy, to reduce costs and to rapidly increase coverage. WHO is well placed to support the integration of key interventions in health systems towards the broader goal of improving maternal and child health in the context of HIV/AIDS at the global level.

1. Introduction

In the year 2001 alone, 800 000 children became infected with HIV.¹ The overwhelming majority of them acquired the virus from their mothers. The transmission of HIV from an infected mother to her child can be prevented almost entirely and has become rare in industrialized countries. However, it still occurs very frequently in developing countries, especially those hardest hit by the AIDS pandemic, where preventive interventions have not yet been implemented on the scale required.

The United Nations General Assembly Special Session on HIV/AIDS (UNGASS) met in June 2001 and set challenging goals for the global fight against HIV/AIDS. The prevention of mother-to-child transmission of HIV featured prominently. The UNGASS Declaration of Commitment on HIV/AIDS includes specific goals for the prevention of HIV infection in infants:

By 2005, reduce the proportion of infants infected with HIV by 20 per cent, and by 50 per cent by 2010, by ensuring that 80 per cent of pregnant women accessing antenatal care have information, counselling and other HIV-prevention services available to them, increasing the availability of and providing access for HIV-infected women and babies to effective treatment to reduce mother-to-child transmission of HIV, as well as through effective interventions for HIV-infected women, including voluntary and confidential counselling and testing, access to treatment, especially antiretroviral therapy and, where appropriate, breast-milk substitutes and the provision of a continuum of care.²

Reaching this goal requires addressing several challenges, developing strong partnerships and raising and allocating substantial resources.

To further guide its contribution to global efforts to reach the UNGASS goal, WHO organized a meeting from 20 to 22 March 2002 with the following specific objectives:

- ▶ to review the likely contribution of current strategic approaches to preventing HIV infection in infants and young children in different epidemiological situations and settings for service delivery;
- ▶ to provide guidance to WHO on priority areas of work for preventing HIV infection in infants within the frame of its mandate, strategic directions and core functions.

Annexes 1 and 2 outline the meeting agenda and list of participants. The first day, participants reviewed programme experiences related to preventing HIV infection in infants and young children and discussed how the strategy of the United Nations agencies in this area could be refined and strengthened. Some historical background on the development and implementation of intervention to prevent the mother-to-child transmission of HIV was briefly reviewed (section 1). Through plenary presentations, group work and plenary discussions, the elements of a comprehensive strategic approach were defined (sections 3 and 4). During the second day of the meeting, participants focused their attention on the specific role of WHO in global efforts to achieve the UNGASS goal (section 5).

¹ UNAIDS and World Health Organization. *AIDS epidemic update – December 2001* (http://www.unaids.org/epidemic_update/report_dec01). Geneva, UNAIDS, 2001 (accessed 29 March 2003).

² *General Assembly of the United Nations. Declaration of Commitment on HIV/AIDS* (<http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html>). United Nations General Assembly Special Session on HIV/AIDS, 25–27 June 2001. New York, United Nations, 2001 (accessed 29 March 2003).

2. An evolving policy framework

A brief historical review of knowledge and experience related to preventing HIV infection in infants and young children was provided, indicating how the policies and actions of the United Nations have developed over the years.

2.1 Adapting United Nations policy to rapidly changing knowledge : HIV transmission through breastfeeding

AIDS in children was first recognized in 1983, and it was concluded that vertical transmission of HIV could occur from an HIV-infected mother to her infant during pregnancy and delivery. Two years later, the possibility of HIV transmission through breastfeeding was also acknowledged. In 1987, WHO organized a consultation and published a first statement on breastfeeding and HIV,³ which assessed the limited information available at that time on the risk of HIV transmission through breastfeeding. In 1992, WHO and the United Nations Children's Fund (UNICEF) reviewed new data on breastfeeding and HIV and produced a consensus statement⁴ recommending that breastfeeding should remain the standard advice for pregnant women, including those who are known to be infected with HIV, in settings where the primary

causes infant deaths are infectious diseases and malnutrition. In other settings, women known to be infected with HIV should be advised not to breastfeed but to use a safe feeding alternative for their infants. In 1997, the Joint United Nations Programme on HIV/AIDS (UNAIDS), UNICEF and WHO issued a revised policy statement on infant feeding and HIV⁵ that represented a shift from a population-based policy to one based on a human rights perspective. The statement indicated that women should be empowered to make fully informed decisions about infant feeding and suitably supported in carrying them out. This recommendation, which remains valid, was further clarified during a technical consultation convened by WHO on behalf of its partner United Nations agencies in 2000.⁶

³ *Statement from the Consultation on Breast-feeding/Breast Milk and Human Immunodeficiency Virus (HIV), Geneva 23–25 June 1987.* Geneva, World Health Organization, 1987 (WHO/SPA/INF/87.8).

⁴ Global Programme on AIDS. Consensus statement from the WHO/UNICEF consultation on HIV transmission and breastfeeding. *Weekly Epidemiological Record*, 1992, 67:177–179.

⁵ UNAIDS, UNICEF and WHO. *HIV and infant feeding. A policy statement developed collaboratively by UNAIDS, UNICEF and WHO* (<http://www.unaids.org/publications/documents/mtct/infantpole.html>). Geneva, UNAIDS, 1997 (accessed 29 March 2003).

⁶ WHO. New data on the prevention of mother-to-child transmission of HIV and the policy implications : conclusions and recommendations. WHO technical consultation on the behalf of the UNFPA/UNICEF/WHO/UNAIDS Inter-Agency Task Team on Mother-to-Child Transmission of HIV, Geneva, 11-13 October 2000. WHO/RHR/01.28

2.2 New prospects: antiretroviral drugs

The year 1994 was a turning point, as the results of the Pediatric AIDS Clinical Trials Group (PACTG) protocol 076 demonstrated for the first time the efficacy of zidovudine administered to HIV-infected women throughout pregnancy, labour and delivery and to the newborn for 6 weeks after delivery in reducing vertical HIV transmission by 68%.⁷ The ACTG 076 regimen was rapidly introduced as standard practice for reducing the mother-to-child transmission of HIV in western Europe, Australia and North America but remained too complex and costly to be proposed for use in most developing countries. Research to test the efficacy of shorter and less complex regimens was undertaken in several countries. In February 1998, the results of a trial of a short course of zidovudine conducted in Thailand were released,⁸ bringing new hope that the use of antiretroviral drugs to prevent peripartum transmission of HIV was also feasible in resource-limited settings. The following month, UNAIDS, UNICEF and WHO organized a meeting to review the latest information on interventions for preventing the mother-to-child transmission of HIV and to plan for programme implementation.⁹ The decision was taken to implement pilot programmes providing short-course antiretroviral drug regimens and infant feeding counselling and support in several developing countries. Since then, further clinical trials have been conducted, expanding the choice of antiretroviral drug regimens that are safe and effective for preventing HIV transmission to infants in developing country settings.

2.3 Combining interventions : the three-pronged strategy

The meeting of United Nations partners in 1998 showed that mother-to-child transmission of HIV could be reduced most effectively if all available intervention approaches were combined. This led to the definition of a three-pronged strategy comprising of:

- ▶ primary prevention of HIV infection among parents-to-be;
- ▶ preventing unwanted pregnancies among HIV-infected women; and
- ▶ preventing transmission from HIV-positive women to their offspring.

The same year, an Interagency Task Team on the Prevention of Mother-to-Child Transmission of HIV was created, comprising the UNAIDS Secretariat, the United Nations Fund for Population Activities (UNFPA), UNICEF and WHO. It was formalized in 1999 by the Coordinating Committee on Health, providing a common platform for action and a clear distribution of roles and responsibilities between the different United Nations agencies for the promotion of the three-pronged strategy. In early 2001, the Interagency Task Team was reconfigured to include the World Bank and renamed the Interagency Task Team for the Prevention of HIV in Pregnant Women, Mothers and Infants, to reflect the need to intensify activities for primary prevention among women.

⁷ Connor EM, Sperling RS, Gelber R et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. Pediatric AIDS Clinical Trials Group Protocol 076 Study Group. *New England Journal of Medicine*, 1994, 331:1173–1180.

⁸ Shaffer N, Chuachoowong R, Mock PA et al. Short-course zidovudine for perinatal HIV-1 transmission in Bangkok, Thailand: a randomised controlled trial. Bangkok Collaborative Perinatal HIV Transmission Study Group. *Lancet*, 1999, 353:773–780.

⁹ UNAIDS, UNICEF and WHO. *Prevention of HIV transmission from mother to child: meeting on planning for programme implementation, Geneva, 23–24 March 1998* (<http://www.unaids.org/publications/documents/mtct/meetingmarch98.html>). Geneva, UNAIDS, 1998 (accessed 29 March 2003).

3. The need for a comprehensive approach

After considering this background information, the participants discussed the expected contribution of various programme approaches to preventing HIV infection in infants in different epidemiological situations and service delivery settings. This reflection was stimulated by the results of a modelling exercise and country experiences.

3.1 Balancing priorities

The results of a modelling exercise that sought to assess the contribution of various intervention approaches to preventing HIV infection in infants was summarized. The model estimated the cost-effectiveness of an antiretroviral drug-based intervention for HIV-infected pregnant women taken to the national level in eight African countries. This was used as a base case against which other intervention approaches were compared. Calculations were made of the reductions in HIV prevalence in women and in the number of pregnancies in HIV-infected women required to reduce HIV incidence in infants equivalent to that of the antiretroviral drug intervention in each country. Programmatic data were obtained from the multi-site UNICEF-supported demonstration project for the prevention of mother-to-child transmission conducted in sub-

Saharan Africa. The antiretroviral drug regimen in each site varied. In Botswana, Côte d'Ivoire, Zambia and Zimbabwe, short-course zidovudine was the regimen of choice, and in Kenya, Rwanda, Uganda and the United Republic of Tanzania, short-course zidovudine was used with nevirapine provided as a back-up to women who could not complete a course of zidovudine for any reason. The model considered the use of nevirapine only. Although this was not the drug regimen of choice in all countries, the rate of acceptance and uptake of counselling and testing and initiation of drug prophylaxis was assumed to be similar to what would be obtained with the nevirapine regimen. Among pregnant women who attend antenatal care clinics, significant dropout has been observed at each of the following key steps:

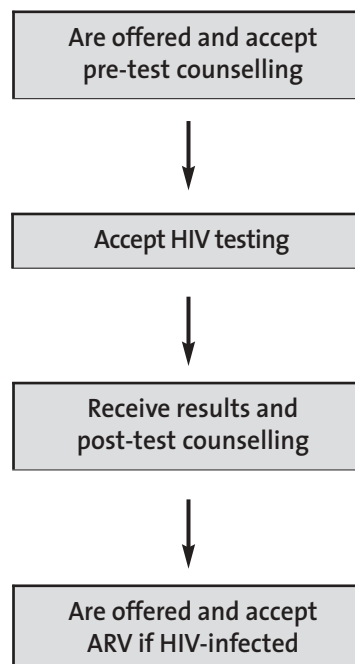
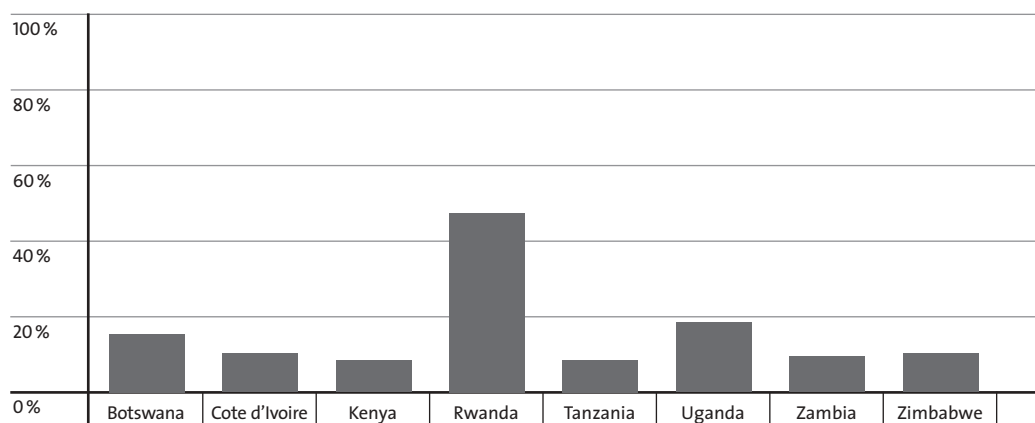


Fig. 1 shows the proportion of HIV-infected women seeking antenatal care in the demonstration projects who were provided an antiretroviral drug. Reports from the field indicate that reasons for failure of uptake of services include women actively declining key interventions such as HIV testing; limitations in the capacity of antenatal care clinics to provide the needed services because of shortages of supplies or staff; and the inability of many women to take advantage of the services that are offered. Health systems have significant costs in developing basic infrastructure and training of staff to provide the interventions needed all along the line. Many of these costs are incurred in serving women who do not, in the end, receive the antiretroviral drug.

Figure 1. Percentage of woman attending antenatal care who are provided antiretroviral prophylaxis



The results indicate that a small percentage reduction in HIV prevalence among pregnant women would result in an equivalent reduction as in the base case in every country. For example, in Côte d'Ivoire, the prevalence among women would have to be reduced from 10% to 9% to avert the same number of cases of HIV infection in infants as in the base case scenario. An added benefit of primary prevention is that a reduction in the HIV prevalence among women is associated with fewer HIV cases among adults.

Similarly a moderate reduction of the number of pregnancies among HIV-infected women would yield an equivalent reduction in the number of infants infected with HIV. For example, in Botswana, the pregnancy rate among HIV-infected women would have to be lowered by 11% to yield the same reduction in infant infections as the antiretroviral drug intervention.

The results suggest that specific interventions to prevent HIV infection in infants, including the prophylactic use of antiretroviral drugs, have only a limited impact under current programme circumstances. The efficiency of specific programme approaches based on the use of antiretroviral drugs needs to be improved, in particular by increasing client uptake and adherence and by developing and applying more effective regimens. However, the number of HIV-infected women who require the intervention should also be reduced.

The participants agreed that only a comprehensive approach that includes primary prevention and reproductive health services for HIV-infected women would lead to the required reductions in HIV infection in infants. This implies significant investment in enhancing health systems to address programme constraints and to effectively deliver a range of interventions to those in need.

3. The need for a comprehensive approach

3.2 Programme experiences

Five country presentations (Brazil, Côte d'Ivoire, South Africa, Thailand and Ukraine) on progress and challenges in implementing programmes for the prevention of HIV infection in infants provided fruitful input to the discussion.

All these countries have accelerated programme activities in recent years, although progress has been uneven and they are now at various stages of implementation. Thailand and Brazil have made the greatest strides over the years and are seeking to extend services to all pregnant women with HIV. Thailand has now achieved very high levels of coverage of antiretroviral drug use among HIV-positive pregnant women to prevent HIV transmission to their infants. In Brazil, although coverage is increasing, it varies considerably from one region to another, with a national average of 40%. Ukraine is currently scaling up its programme to the national level. Other countries now plan to rapidly move from demonstration projects to wider implementation.

The organization of health services and capacity for programme implementation vary between countries, but some common issues arise. In the countries concerned, utilization of antenatal care services is generally high, though in all settings, a varying proportion of women at risk have poor access to antenatal care and HIV/AIDS services, for various reasons. The widespread introduction of voluntary counselling and testing in antenatal care settings has faced many difficulties. Even when voluntary counselling and testing are in place, uptake remains low in many areas. Further, among women agreeing to be tested for HIV, the proportion of those testing positive who receive specific services to prevent transmission to their infants is insufficient, at least in the sites in Africa, which suffer from weak infrastructure and staff capacity. Community support for the programme is often inadequate, and stigma and discrimination remain major barriers to the uptake of services.

The main emphasis in most countries is on providing specific interventions to prevent transmission from HIV-infected pregnant women to their infants, although other programme efforts have been ongoing and programme areas are increasingly being linked. For example, in Thailand, opportunities for strengthening primary prevention are being sought by enhancing HIV prevention services in antenatal and postpartum settings for HIV-negative women and their partners. In Brazil, links are being developed with care, treatment and support programmes for people living with HIV. Most settings, however, still have limited success in increasing the access of HIV-positive women to reproductive health services, including family planning services in the postpartum period.

The importance of a supportive policy environment was emphasized. Political support at the highest level and a sufficient resource base for scaling up seem to be critical to success. Strong partnerships between implementing agencies and links across sectors are also key to ensure the consistency of programme approaches and policy and technical guidelines on difficult issues such as infant feeding in the context of HIV. Vigorous and successful programmes as documented in Thailand and Brazil have benefited from political support at the highest level and have been quick to adapt their strategic approaches in response to research and evaluation data to better meet local conditions, solve implementation problems and innovate in response to new challenges, such as the need to increase access to care for people living with HIV.

4. The elements of a comprehensive strategy

The participants reviewed and discussed the key components of a comprehensive strategy to prevent HIV infection among infants. The main conclusions reached during the plenary and group sessions are summarized below.

4.1 Primary prevention of HIV infection

There was general agreement that primary prevention is a key component of a global effort to prevent HIV infection in infants as guided by the UNGASS goal. The model described in section 3.1 indicates that preventing HIV infection in women is an efficient approach to preventing secondary transmission to infants and provides several other important benefits to the population at large. Continuing increases in the number of women who acquire HIV infection, as observed in many parts of the world, could rapidly overwhelm the capacity to deliver specific services to prevent transmission of HIV from infected mothers to their infants.

The participants reaffirmed that primary prevention works if applied correctly and at a sufficient scale (as demonstrated in Thailand and Uganda, for example, which also have invested in programmes to prevent the mother-to-child transmission of HIV). The data presented from Thailand indicate that the present success in reducing the number of infants infected with HIV can be attributed both to strong primary prevention efforts, which have been successful in reducing the prevalence of HIV infection in women of childbearing age, and to introducing specific efforts to prevent transmission from infected women to their infants.

Priorities for primary prevention within the context of programmes to prevent HIV infection in infants and young children were discussed, specifically addressing the following areas.

Advocating for the expansion and intensification of HIV prevention efforts

Those concerned about preventing mother-to-child transmission of HIV must emphasize the need for increased attention to preventing HIV infection among women (especially young women, who have high fertility rates as well as high HIV prevalence rates) and their partners, highlighting the strong and direct relationship between primary prevention activities (or the lack of them) and the number of infants

infected. Services to prevent HIV among women and men directly benefit the beneficiaries and prevent transmission to their future sexual and injecting partners as well as their offspring. The expected benefits at a population level are considerable. The prevention of HIV infection in infants should therefore be firmly placed within the context of HIV prevention programmes that reach women, especially young women, and their partners. Participants considered a number of programme approaches that have been shown to be useful in this regard, such as the promotion of dual protection¹⁰ in family planning settings, especially in areas of high prevalence of sexually transmitted infections, including HIV.

Strengthening links between programmes to prevent the mother-to-child transmission of HIV and other HIV prevention efforts

All opportunities to strengthen primary prevention services in the context of programmes that address the prevention of mother-to-child transmission of HIV should be explored and assessed.

In particular, providing counselling and testing services in antenatal care settings presents a critical opportunity to identify women who are uninfected and to support them in remaining so. Even in areas with high HIV prevalence, most women attending antenatal care services will test HIV-negative and would benefit from prevention services.

When vulnerable but marginalized groups are affected, such as injecting drug users, street youth or people who sell sex, interest in preventing HIV infection in infants may offer impetus and support for extending comprehensive prevention and care services to these groups. For example, in many countries in Europe, most cases of HIV infection among women are found among injecting drug users or their partners. Services for injecting drug users need to be strengthened, such as drug dependence treatment and other forms of harm reduction, and strong links need to be built between these services and other

¹⁰ Dual protection is an approach that can both reduce the risk of unintended pregnancy and the risk of sexually transmitted infections, including HIV, either through the use of a dual-purpose method such as a male or female condom that can offer protection against both risks or through dual-method use including simultaneous use of a condom and a contraceptive.

4. The elements of a comprehensive strategy

existing services such as reproductive health care for women, to prevent the spread of HIV associated with drug use to infants.

Building a special focus on HIV prevention during pregnancy and lactation

Pregnant and lactating women are not generally considered an important target group for efforts to prevent HIV infection. However, because viral loads are higher and infectivity greater in the initial stage of infection, primary HIV infection during pregnancy and breastfeeding, which can be frequent in some areas, poses an increased threat of mother-to-child transmission.

At this time, women are generally encouraged to take measures to reduce their risk of acquiring HIV and other sexually transmitted infections during pregnancy and lactation, especially in areas with high prevalence and incidence of HIV infection. However, there is little documented experience to draw on in this area, and condom use during pregnancy in particular still remains uncommon. More information is needed on the magnitude of mother-to-child transmission associated with primary infection during pregnancy and lactation in different settings and on approaches to preventing it. Both women and men may be more willing to adopt HIV prevention measures if they are informed of the increased risk of vertical transmission during this period and motivated to protect themselves and their child.

Promoting the involvement of men

The burden of HIV prevention should not be placed solely on women's shoulders. Opportunities to reach, motivate and support men in efforts to change behaviour need to be sought. Programmes to prevent HIV infection in infants may provide specific opportunities for this through public education and community mobilization efforts and related services that provide information about the routes of transmission of HIV, motivation for HIV counselling and testing and support for changing behaviour. As mentioned above, knowledge about mother-to-child transmission of HIV could act as a motivating factor for both women and men. Some (limited) evidence indicates that men may be more willing to use condoms with their partner while she is pregnant or breastfeeding, out of concern for the child. This initial change in behaviour could lay the foundations for prevention over the longer term.

4.2 Preventing unintended pregnancy among HIV-infected women

Preventing unintended pregnancy among HIV-infected women could contribute significantly to preventing HIV infection in infants, yet this element of the strategy is often overlooked. The participants considered programmatic approaches that need attention.

Strengthening family planning programmes, especially in high-prevalence settings

There is a large unmet need for family planning services. This is a particular problem in sub-Saharan Africa, where high fertility rates and high HIV prevalence rates converge, leading to a high burden of HIV infection in infants. Family planning programmes need to be strengthened so that all women can receive support and services to prevent unintended pregnancy. Most HIV-infected women in developing countries are unaware of their HIV status. Although efforts are required to scale up testing and counselling programmes, increasing access to family planning services for all women will reach many infected women who still do not know their status and need family planning.

Increasing access of family planning clients to HIV counselling and testing

Efforts should be made to increase the access of family planning clients to HIV counselling and testing, especially in high-prevalence settings, by integrating HIV counselling or HIV counselling and testing within family planning services or through links with external HIV counselling or testing services. This would allow family planning advice and services to be tailored to the specific HIV risk situation and needs of clients. In this way, providers can make the most of the opportunity to help uninfected women at risk stay uninfected by using dual protection. They can also identify women who are already infected and who require specific care and support services, including counselling on their reproductive choices.

Providing services to HIV-infected women that support their reproductive choices

Comprehensive care and support services for HIV-infected women should include reproductive health counselling and related services that enable them to make informed choices about childbearing in the context of HIV and to carry them through.

Wider access to HIV counselling and testing services would enable more infected women to learn about their status in time to plan their reproductive lives, including whether they wish to bear a child and, if so, when. For those whose HIV infection is only identified in early pregnancy, post-test counselling should include full information about the risk of mother-to-child transmission of HIV and the interventions available to reduce this risk. When appropriate, and in settings in which it is legal and safe, termination of pregnancy should be discussed as an option in a noncoercive and supportive manner (as for other women, regardless of their HIV status). In later pregnancy and after delivery, HIV-infected women should be provided family planning counselling and services to enable them to make decisions on preventing or delaying future pregnancies. Unfortunately, programmes to prevent mother-to-child transmission that fully integrate these client-friendly counselling and family planning services are still the exception. In some settings, a coercive approach has been taken in which health providers impose termination of pregnancy, tubal ligation or other interventions on HIV-infected women. In other settings, family planning services are simply not available to them.

What is required is a much greater integration of HIV concerns into reproductive health services in general and family planning services in particular. To achieve this, reproductive health service providers, including those working in nongovernmental organizations and the private sector, should be sensitized to the difficult issues raised by HIV/AIDS and provided guidance and support in dealing with them. Similarly, health providers involved in programmes to prevent the mother-to-child transmission of HIV must receive training in family planning.

Providing safe and effective contraceptive methods for HIV-infected women

Current guidelines¹¹ indicate that, in principle, women living with HIV may use all contraceptive methods offered to uninfected women. However, caution is recommended in the use of intrauterine devices, as their use is not encouraged among women who are at risk of sexually transmitted infections. Also, care should be paid in some situations to the possible pharmaceutical interaction of hormonal contraceptives with antiretroviral drug therapy.

In addition, sexually active women with HIV should always be encouraged to use male or female condoms to protect themselves against new sexually transmitted infections and to limit ongoing transmission to their sexual partner(s). In this regard, the participants discussed how the concept of dual protection has been broadened in some settings, mainly in Africa, and is now often applied to women known to be HIV-infected, not so much to reduce their risk of acquiring other sexually transmitted infections but to reduce the risk of transmitting HIV to others.

4.3 Preventing HIV transmission from HIV-infected mothers to their infants

A package of specific interventions has been identified to prevent HIV transmission from an infected mother to her child. It includes antiretroviral drug use, safer delivery practices and infant feeding counselling and support. Here too, voluntary counselling and testing play a key role so that HIV-infected woman can learn their status in good time to draw the full benefits of this package. Although the use of this package has decreased the transmission of HIV from HIV-positive women to their infants to very low levels in the most advanced health systems, many challenges remain to implement these interventions in resource-constrained settings.

Specific interventions to reduce the mother-to-child transmission of HIV

Antiretroviral drug use.¹² A number of antiretroviral drug regimens – based on zidovudine, zidovudine and lamivudine, or nevirapine, or combinations used in highly active antiretroviral therapy – have been shown to be effective in reducing the mother-to-child transmission of HIV. The choice of antiretroviral drug regimen should be made locally, taking into account issues of feasibility, efficacy and cost.

Safer delivery practices. Caesarean section has been shown to help to reduce the risk of transmission during delivery. This, however, may not be an appropriate intervention in resource-constrained settings, because of limited availability, cost and the risk of complications. Invasive obstetrical procedures, such as artificial rupture of membranes, fetal scalp monitoring and episiotomy, may increase the risk of transmission to the infant. Their use should be limited to cases of absolute necessity.

¹¹ *Improving access to quality care in family planning: medical eligibility criteria for contraceptive use* (http://whqlibdoc.who.int/hq/2000/WHO_RHR_00.02.pdf). 2nd ed. Geneva, World Health Organization, 2001 (accessed 29 March 2003).

¹² WHO. New data on the prevention of mother-to-child transmission of HIV and the policy implications: conclusions and recommendations. WHO technical consultation on the behalf of the UNFPA/UNICEF/WHO/UNAIDS Inter-Agency Task Team on Mother-to-Child Transmission of HIV, Geneva, 11-13 October 2000. WHO/RHR/01.28

4. The elements of a comprehensive strategy

*Infant feeding counselling and support*¹³. All HIV-infected mothers should receive counselling that includes information about the risks and benefits of various infant feeding options and specific guidance in selecting the most suitable option for their situation. When replacement feeding is acceptable, feasible, affordable, sustainable and safe, HIV-infected mothers are recommended to avoid all breastfeeding. Otherwise, exclusive breastfeeding is recommended during the first months of life. To minimize the risk of HIV transmission, breastfeeding should be discontinued as soon as feasible, taking into account local circumstances, the individual woman's situation and the risks of replacement feeding.

Examples from several countries highlighted the major issues. For some years, the cost of antiretroviral drugs was seen as the key constraint to the wider implementation of interventions to prevent the mother-to-child transmission of HIV. Now, with the negotiation of lower drug prices, production of generic versions in some developing countries as well as large-scale donations of some drugs, access to antiretroviral drugs for this purpose has increased enormously. However, many hurdles to implementation still remain. The most important may be the inability of health systems in some of the countries that have been most severely affected to deliver the necessary interventions to those in need. First, access to or use of antenatal and delivery care is limited in many countries. For example, the percentage of women receiving antenatal care, defined as at least one visit, ranges from 20% to 99% in Africa, with an average of 62%. The percentage of women delivering with the help of a skilled attendant ranges from 2% to 99%, with an average of 36%. Many women therefore remain out of the reach of health services at the times when key interventions might be offered or applied.

Then, many settings in which the need is greatest have low provision and uptake of HIV counselling and testing – which is essential if women seeking antenatal care are to know their HIV status and make use of specific prevention and care interventions as required. In addition, not everyone who tests positive receives the test result and, of these, not everyone is offered or accepts the package of interventions. Data from demonstration projects suggest that these problems stem both from the inability of health systems to offer

the range of services required and from the reluctance of women to make use of them.

Finally, making breastfeeding safer remains a major challenge, especially in areas where replacement feeding is not acceptable, feasible, affordable, sustainable and safe for all mothers. Several issues should be urgently addressed. Better guidelines and tools are required for policy-makers, programme managers and health workers to develop appropriate policies and comprehensive programmes on infant feeding in the context of HIV and to counsel and support mothers. Practical and affordable options for replacement feeding need to be investigated at the local level to guide infant feeding choices. Infant feeding patterns and HIV transmission rates in relation to different modes of infant feeding, including exclusive breastfeeding, must be assessed to monitor progress. Every effort must be made to avoid any negative impact of programmes to prevent the mother-to-child transmission of HIV on breastfeeding practices among uninfected women or women of unknown HIV status.

These constraints to implementation must be addressed to enable wide delivery of the interventions needed to prevent HIV transmission from HIV-infected mothers to their infants and young children. At the same time, further research is required to develop more effective drug regimens that can be applied in resource-constrained settings. The participants stressed that the prophylactic antiretroviral drug regimens currently used in developing countries would only be able to prevent about half the peripartum transmission to infants, even if provided correctly to all women with HIV, and would have limited impact on postnatal transmission through breastfeeding.

4.4 Care for HIV-infected mothers and their children

The participants recognized that programmes to prevent HIV infection in infants and young children would identify many women living with HIV who need special attention. Strengthening the links between prevention and care programmes will ensure that these women, and their children, also access the services that they need. Care is the

¹³ WHO. New data on the prevention of mother-to-child transmission of HIV and the policy implications: conclusions and recommendations. WHO technical consultation on the behalf of the UNFPA/UNICEF/WHO/UNAIDS Inter-Agency Task Team on Mother-to-Child Transmission of HIV, Geneva, 11-13 October 2000. WHO/RHR/01.28

natural development of programmes to prevent HIV from being transmitted from HIV-infected mothers to their infants, as many mothers initially ask «What can you do for my baby?» but soon expect something to be done for them too. Meeting participants urged WHO to include care for women and their children as a critical component of programmes to prevent HIV infection among infants and young children for the following reasons.

- ▶ Programmes to prevent HIV among infants provide a critical opportunity to identify HIV-infected women who should gain access to a long-term programme of care, treatment and support. On humanitarian grounds, it is difficult to defend providing a short course of antiretroviral drugs to save a child but denying basic care and, when indicated, antiretroviral treatment to the mother.
- ▶ Care, treatment and support of the mother contribute to protecting the health and development of the child, as data indicate that the survival of the exposed child (even if uninfected) is compromised if the mother dies.
- ▶ Providing care for mothers should increase the uptake of counselling and testing and of services to prevent HIV transmission to infants and thus greatly increase

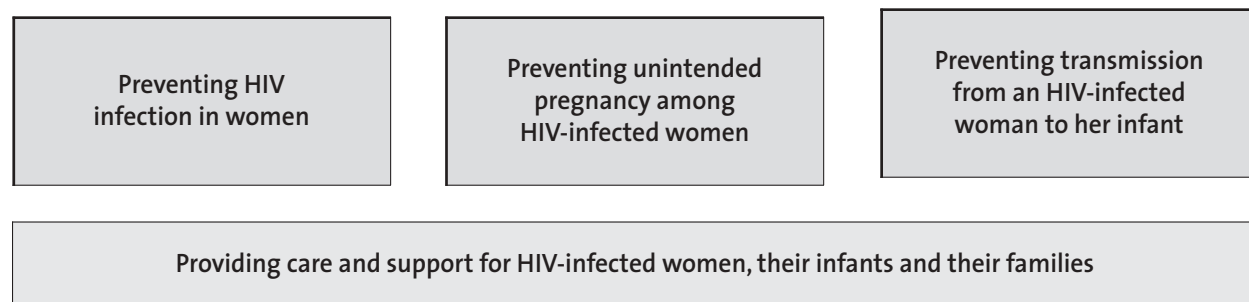
some may be infected and required specific care and support services.

- ▶ Finally, care services that provide Highly Active Anti-Retroviral Therapy (HAART) to women for whom it is indicated reduce the viral load in the mother and may thus further decrease peripartum transmission and possibly transmission through breastfeeding, as compared with the short-course prophylactic regimens, thereby increasing the efficacy of the intervention. Research in this area is ongoing.

It was thus proposed to include the provision of care and support for mothers, their infants and family as a fourth element of the strategy to prevent HIV infection in infants, thus moving from a three-pronged strategy to a strategic framework with four cornerstones.

Although this proposal was generally supported, some participants expressed concern that advocating an immediate integration of care, treatment and support for mothers and their families in all programmes to prevent HIV infection among infants might weaken support for these programmes, given limited resources and uneven access to antiretroviral therapy. The best way to encourage govern-

A framework for a comprehensive approach to prevent HIV infection in infants and young children



the effectiveness of such programmes. Evidence from Brazil indicates that a strong commitment to care for mothers increases the support for and use of services to prevent HIV transmission to infants.

- ▶ Follow-up and, as necessary, care for exposed children is also needed, as all will be at increased risk and

ments to move may be to propose an incremental approach in which programmes for preventing HIV infection in infants and young children initially seek opportunities to link up with care, treatment and support programmes and work towards integration over the longer term.

5. Priority lines of action for WHO

There is now tremendous international interest in scaling up programmes to reduce HIV infection in infants. The main question discussed during the second day of the meeting was how WHO could best contribute to the overall drive to reach the UNGASS goals in this area. The participants provided specific guidance to WHO on the work that it might take up within the framework of its mandate, strategic directions and core functions.

5.1 Key functions

To guide the discussion, WHO's core functions and its specific roles and responsibilities in the UNAIDS global inter-agency initiative on the prevention of mother-to-child transmission of HIV, as endorsed by the WHO/UNICEF/UNFPA Coordinating Committee on Health in 1999, were recalled (Boxes 1 and 2). In this area of work, WHO has played a normative role, supporting the review of scientific advances related to preventing mother-to-child transmission of HIV, drawing out their implications for policy and programme development and providing technical guidance for programme design and implementation with a focus on key interventions and managerial approaches to programme implementation within public health systems.

Box 1. Core functions of WHO

- ▶ Articulating consistent, ethical and evidence-based policy and advocacy positions
- ▶ Managing information, assessing trends and comparing the performance of health systems
- ▶ Setting the agenda for, and stimulating, research and development
- ▶ Catalysing change through technical and policy support, in ways that stimulate action and help to build sustainable national capacity in the health sector
- ▶ Negotiating and sustaining national and global partnerships
- ▶ Setting, validating, monitoring and pursuing the proper implementation of norms and standards
- ▶ Stimulating the development and testing of new technologies, tools and guidelines for disease control, risk reduction, health care management and service delivery

5. Priority lines of action for WHO

Box 2. WHO's role in the UNAIDS global interagency initiative

- ▶ Provides technical support to and identifies gaps in the global research agenda, and promotes research to address them
- ▶ Reviews and disseminates information on scientific advances related to MTCT
- ▶ Develops technical norms and standards
- ▶ Provides technical support for local action and capacity-building
- ▶ Promotes integration within health systems of interventions to reduce MTCT
- ▶ Provides technical support to monitoring and evaluation of MTCT interventions
- ▶ Strengthens global surveillance of MTCT-related HIV trends
- ▶ Updates drug policies and strategies in order to promote access to HIV-related drugs and essential supplies

Source: *Global Interagency Initiative for the Reduction of Mother-to-Child Transmission of HIV. WHO/UNAIDS/UNICEF/UNFPA Coordinating Committee on Health, 2–3 December 1999.* Geneva, World Health Organization, 1999.

5.2 Specific actions

The meeting participants made a number of recommendations on actions that WHO should take in collaboration with its partners.

Promoting a comprehensive strategic approach to preventing HIV infection in infants

Participants encouraged WHO to actively promote the strategic approach for preventing HIV infection among infants discussed during the meeting, addressing all four of its critical components. WHO is engaged in policy and programme support across the board and thus is a critical and persuasive advocate for more comprehensive and effective strategic directions.

In particular, the importance of primary prevention in efforts to reach the UNGASS goals in this area needs to be emphasized. Exposure of infants and young children to mother-to-child transmission of HIV needs to be recognized as the consequence of failure to make the most of previous opportunities to protect women and their partners from HIV. However, women who become infected despite prevention efforts need access to a range of services that include repro-

ductive health care and other care and support services and services to prevent the transmission of HIV to their offspring.

Considerable efforts are required to build up all four cornerstones of the strategic approach, recognizing that investment in the third and fourth cornerstones are perhaps better justified on humanitarian grounds rather than on cost-effectiveness grounds alone. The exact balance to be achieved among priority actions should be guided by a careful analysis of epidemiological situations and trends and patterns of service delivery and use. WHO has an important role to play in supporting this analysis.

Developing the evidence base and the strategic information for programme design and implementation

There are still important gaps in knowledge on a range of issues such as: the safety of hormonal contraception in HIV-infected women; the impact of antiretroviral prophylaxis during pregnancy on future treatment options for women; and the effectiveness of approaches to reduce HIV transmission through breastfeeding. WHO's convening role in reviewing and interpreting the rapid epidemiologi-

cal and clinical research advances in this field and in building consensus on new research directions and methods is much valued and should continue.

This should be extended to collecting evidence on the contribution of all four components of the strategy to reduce the burden of HIV infection in infants and young children. This will entail further research to assess the effectiveness and costs of programmes and to define the necessary improvements in programme operations. WHO also needs to be more active in stimulating or supporting operations research on key issues, such as approaches to service delivery to improve the uptake of HIV testing and counselling in antenatal care settings and the provision of infant feeding counselling and support for HIV-infected mothers.

WHO should also continue to actively participate in global efforts to collect data relevant to HIV infection in infants, including monitoring progress towards the UNGASS goals. Activities are under way to define the information to be collected for monitoring and evaluation, to develop consensus around a set of core indicators and to set up systems for collecting, analysing and disseminating data. WHO should also work with partners to document country experiences, draw lessons learned and distil best practices.

Providing technical guidance

Participants also strongly encouraged WHO to continue its work in building on existing knowledge to provide technical guidance on critical issues related to preventing HIV infection in infants and young children. They noted, however, that more attention needs to be paid to ensuring wide dissemination of key materials, as many do not seem to reach the intended audiences. Several of the issues discussed require the attention of WHO and its partners. Issues on which technical guidance to countries is required as a high priority include:

- ▶ HIV counselling and testing, including models suitable for family planning and antenatal care settings and the use of rapid tests in such settings;
- ▶ peripartum interventions to prevent mother-to-child transmission, including choice and use of safe and effective antiretroviral drug regimens, approaches to use in specific situations (such as for women who present in labour, injecting drug users and adolescents) and safer obstetric practices, including caesarean section;

- ▶ infant feeding counselling and support, in the context of the global strategy on feeding infants and young children, including revising current guidelines for policy-makers and programme managers, developing decision tools to guide health workers on infant feeding options to recommend and developing tools for monitoring and evaluation;

- ▶ following up and ensuring early diagnosis of HIV infection in exposed infants;

- ▶ comprehensive care and support for women with HIV, including nutritional advice and care, especially for HIV-infected women who breastfeed; and

- ▶ comprehensive care and support for HIV-infected children.

Supporting the integration of interventions in health systems

The participants emphasized that the various components of the strategy should not be seen in isolation. They present a number of links that need to be clearly identified, as they provide opportunities for synergy. For example, the counselling and testing sessions could provide an opportunity to reinforce prevention messages for women who test negative. The infant feeding counselling sessions could also be taken advantage of to support women in using a family planning method of their choice. HIV-infected women should be supported in initiating interventions to prevent transmission to their infant as an entry point into long-term care, treatment and support for these women and their families. The current interest in preventing the mother-to-child transmission of HIV should be used as an opportunity to work towards the broader goal of globally improving maternal and child health in the context of HIV/AIDS. Making the most of this synergy, reducing costs and rapidly increasing coverage require integrating these interventions into existing health services. HIV is becoming an essential component of programmes related to such topics as Making Pregnancy Safer, family planning and child health and development.

6. Conclusions

The meeting participants recognized that this field is moving very rapidly, with a short time span from the emergence of research results to action in the field. The rapidity with which the findings of the «Thai short course» antiretroviral drug regimen made public in 1998 were applied in many public health systems in developing countries, with support from United Nations agencies and other partners, is remarkable. The demonstration projects in Africa and the national programmes in other countries such as Brazil and Thailand show that the mother-to-child transmission of HIV can be prevented. The challenge now is scaling up these efforts in the countries most affected by HIV/AIDS. This requires keeping on top of the emerging science, building on successes, learning from mistakes and developing innovative solutions to common implementation problems.

The participants reflected that the programme focus of programmes to prevent the mother-to-child transmission of HIV was often narrowly defined as delivering antiretroviral prophylaxis to HIV-infected pregnant women and their newborns. They emphasized that only a comprehensive strategic approach, building on the four cornerstones, would be likely to yield the results expected in terms of preventing HIV infection in infants, as specified in the UNGASS Declaration of Commitment on HIV/AIDS. They strongly recommended that the fourth component, related to providing care for HIV-infected mothers and their infants, be added to the three-pronged strategy supported to date by the United Nations agencies in this area. The participants also provided detailed comments and suggestions on the thrust and content of the four components, to serve as guiding principles to inform policy support and programme design. However, they emphasized that the balance between intervention areas should be determined in each country based on data on epidemiology and on service delivery and use.

Finally, the participants provided specific guidance to WHO on the key functions and activities that it might take up to optimize its contribution to global efforts for preventing HIV infection in infants. Of note is the particular role that WHO could play in supporting the integration of key interventions in health systems, towards the broader goal of globally improving maternal and child health.

Annex 1 - Agenda

20 March 2002

Opening remarks	<i>Bernhard Schwartländer</i>
Overview of the meeting	<i>Isabelle de Zoysa</i>
Participant introductions and expectations	<i>Doris Schopper</i>
Reception	
Dinner	

21 March 2002

How to prevent HIV infection in infants most efficiently: strategic approaches in different contexts

Plenary presentation UNGASS commitments to reducing HIV infection in infants	<i>Philippe Gaillard</i>
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The three-pronged strategy for the
prevention of HIV infection in infants

Group work. Defining the essential elements of each prong of the strategy	<i>All</i>
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Group 1: primary HIV prevention especially
among young women

Group 2: prevention of unintended
pregnancies among HIV-infected women

Group 3: specific interventions to reduce
HIV transmission from HIV-infected women
to their infants

Plenary presentation What is the expected contribution of each prong to the overall goal in resource-constrained settings? Presentation of a modelling exercise	<i>Michael Sweat</i>
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Plenary discussion Combining the three prongs, creating links and synergies, to optimize efforts to reduce HIV infection in infants	<i>All</i>
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Annex 1 - Agenda

21 March 2002 **Strategic approaches in different contexts**

Plenary presentation

The development and implementation of a countrywide strategy to prevent HIV infection in infants : priority interventions and implementation challenges

5 country presentations

• Ukraine

Natalia Nizova

• South Africa

James McIntyre

• Côte d'Ivoire

René Ekpini

• Brazil

Marco Antônio de Ávila Vitória

• Thailand

Siripon Kanshana

Plenary discussion

How to adapt the three-prong strategy to different epidemiological situations and service delivery settings

*Introduction by
Kevin O'Reilly*

22 March 2002 **WHO's future directions and priority areas of work for 2002–2005**

Plenary presentation

Summary of previous day and review of remaining issues

Jerry Hoosen Coovadia

Plenary presentation

WHO's mandate, strategic directions and core functions

Isabelle de Zoysa

Group work

Prevention of HIV in infants : what should WHO's contribution be ?

All

Plenary presentation of group work :

WHO's priority areas of work for 2002–2005

All

Plenary discussion and synthesis

Jerry Hoosen Coovadia

Concluding remarks

Isabelle de Zoysa

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ISBN 92 4 156242 0

