Policies to prevent HIV transmission through breast-feeding in Latin America

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Fundación Mexicana para la Salud
Institución privada al servicio de la comunidad

SIDALAC
Iniciativa Regional sobre SIDA para América Latina y el Caribe

Joint United Nations Programme on HIV/AIDS
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First edition, September 1999

ISBN 968-5018-13-8

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Fundación Mexicana para la Salud, AC
Periférico Sur 4809, Col. El Arenal, Tepepan
14610 México, DF

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Editorial Coordination: José Antonio Izazola Licea
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Editorial Assistance: Victoria Castellanos
Design: Laura Novelo Q.
Production: *Grafia*

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Printed and made in Mexico

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Presentation

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It is a widely accepted principle that breat-feeding should continue to be protected, promoted, and supported in all countries of the region. However, recognizing of the fact that Human Immunodeficiency Virus (HIV) can be transmitted through breast milk, it is desirable the informed decision-making from the seropositive women to decide for the good of the newborn and diminish the probability of vertical transmission.

It is recommended that when there can be ensured the uninterrupted access of the children stemming from seropositive women to nutritionally adequate, prepared and administered substitutes of breast milk in a hygienic form, these substitutes should be utilized instead of the lactation to the maternal breast.

In conclusion, only as an exception, and in view of the risk of vertical transmission of HIV, it will be recommended to the seropositive women with newborn not breast-feeding their children when there exists an adequate substitute dietary source.

The ethics associated with this recommendation makes it necessary not to utilize campaigns directed to the general population nor to women in childbearing age to discourage the lactation to the maternal breast, and only leave the decision to utilize substitutes of breast milk to women who have the possibility of acceding to these means without interruption.

The use of antiretrovirals should be promoted widely in accordance with national guidelines adapted to the national health systems, its financing and its other national policies.

The detection of the state of infection of women in childbearing age will respond then, basically, to the policies of use of antiretrovirals.

It is not acceptable the proposal that breast-feeding substitutes are utilized because of the risk of women to be infected with HIV; neither

the utilization of these substitutes is acceptable as long as it is not demonstrated through laboratory tests that women are seropositive to HIV. What determines the utilization of the substitutes it is the risk of transmission of the seropositive verified mother who breast-feeds to her child and, naturally, this indication is subject to the availability of the substitutes.

Executive summary

*José Antonio Izazola Licea**

* Executive Coordinator Regional AIDS Initiative for Latin America and the Caribbean (SIDALAC)

Introduction

SIDALAC is the regional initiative for Latin America and the Caribbean that was initially promoted by the World Bank, and now forms part of the strategy of the joint and cosponsored United Nations AIDS Program (UNAIDS).

The creation of SIDALAC has among its objectives to contribute to the mobilization of national and international efforts against AIDS in Latin America and the Caribbean through an enhanced awareness of decision makers in the region, and the support and development of a new generation of control programs with a specific regional scope for Latin America and the Caribbean.

SIDALAC organized a "Workshop on HIV transmission through Breast-feeding", held in Brasilia, Brazil, November 17-18, 1997. The workshop was a satellite to the Second Brazilian Congress on HIV/AIDS Prevention and had the support of the General Coordination of the Brazilian National AIDS Program, UNAIDS Geneva, the Population Council and the Harvard AIDS Institute.

The main purpose of the workshop was to promote the discussion of current policies and practices regarding breast-feeding among HIV infected women in Latin America, and in order to carry this out, the directors of eleven National AIDS Programs in the region, representatives of three international organizations and experts from two African countries that have faced HIV vertical transmission were assembled.

The workshop was divided into three sessions. During the first session, an examination of the HIV/AIDS epidemiology in the region was conducted, as well as a study of the benefits of breast-feeding vis a vis infant mortality from respiratory and gastro-intestinal infections, and the consequent decrease in infant mortality in the region.

Studies were presented demonstrating how breast feeding is one of the main causes of vertical transmission of the HIV virus from an infected women. These studies contained experiences from two African countries, Soweto, Botswana; Nairobi, Kenya; and a multi-center study carried out in Sao Paulo State, Brazil.

According to those case studies, the HIV vertical transmission rate (in-utero, at delivery or through breast feeding) varies from 16 to 43%. With these vertical transmission rates, the portion attributable exclusively to transmission through breast feeding corresponds to 14-19%, which means that between 30-50% of HIV infections in children fed from maternal milk by their HIV/AIDS infected mothers can be attributed to breast feeding.

During the second session, the existing policies of the countries in the region regarding this subject were examined, emphasizing the fact that most of the participating countries have a policy that discourages and even contraindicates breast feeding by HIV infected women. Only the representative of one participating country, Honduras, confirmed that this type of policy does not exist in his country.

The information provided also shows that although 40% of the countries do not have a legislation to prevent HIV transmission, in almost all of these countries there is ample access to zidovudine during pregnancy, in accordance with the ACTGO 76 protocol, even when there are differences in coverage; for example, in the Dominican Republic and Honduras it is not administered to pregnant HIV infected women in public hospitals even when this drug is available in the market.

Moreover, all the participating countries stated that they possess maternal milk substitutes, but Honduras.

In addition, the experience of the milk banks in Brazil was studied, as a possible alternative to commercial products, in the fight to prevent vertical HIV/AIDS transmission.

Finally, through a methodological decision process, the evaluation of the possible impact of programs and policies on breast feeding and HIV infections was examined, at the end of which several elements were discussed on how to avoid maternal HIV transmission and the corresponding activities that should be implemented in the region.

The conclusions and recommendations reached by the workshop, which compile the opinions expressed therein, are presented in the following paragraphs. The idea is that these results be propagated and taken into consideration when designing health policies.

Technical recommendations of the Workshop

The participants recognized that breast-feeding increases the risk of infection to the newborn. They also agree on pursuing the objective to prevent HIV vertical transmission in Latin America, in both prenatal and postnatal periods. The use of antiretrovirals during pregnancy, delivery and for the newborn is a priority, and protocol ACTG 076 represents the current standard of core.

Given that maternal breast-feeding is the best choice for newborns and infants, it must be encouraged as a general principle in the region. Nevertheless, the medical recommendation is that when a woman is infected with HIV or has AIDS, nursing of the newborn should be contraindicated, and the baby should receive alternative nourishment that is both safe and nutritional. Economically, it is less expensive for a country to provide substitutes of breast milk and prevent the HIV vertical transmission than to give antiretrovirals to the infected infant. Children of HIV-infected women may receive maternal milk only if it has been previously pasteurized.

Recognizing the subregional differences in Latin America, the policies and strategies designed to prevent the HIV vertical transmission must either include very specific aspects about the rights of the HIV positive women.

As a fundamental principle, women (and their partners) must decide if they should nourish their infants with breast milk, taking into account the risk of HIV infection. Health personnel must provide counseling to prevent the perinatal transmission of HIV, i.e., women must be counseled not to breast-feed their infants if a continuous source of adequate nutrition is guaranteed; with HIV infection, a contraindication for breast-feeding must be considered.

In short, the possibility of decreasing the transmission of HIV through maternal milk using the current technology available and the accumulated knowledge in Latin America is a matter of ethics.

Agenda of activities

To achieve the objectives outlined above, the participants proposed the following activities:

a) Activity agenda for national AIDS/STD

1. To extend testing and counseling services to all pregnant women, recognizing that these services must be confidential and practiced with the informed consent of the pregnant women. These services must provide information regarding the risk of HIV transmission through maternal milk to the newborns when the mother is HIV infected.

2. To make HIV-screening procedures available to pregnant women, with pre- and post-test counseling from the first prenatal visit to the doctor.

3. To incorporate HIV prevention into primary health care services, including training.

4. To provide counseling on the prevention of STDs and about diagnostic tests for women of reproductive age in primary health care units.

5. To extend the former services according to the local infrastructure and to the stage of the AIDS epidemic in each country.

6. To provide the ACTG 076 protocol as a "gold standard" for the prevention of perinatal transmission. However new regimens should be considered in due course, as more information regarding the use of combinations becomes available.

7. If the ACTGO 76 protocol cannot be implemented, the standard of care for seropositive women during treatment with zidovudine (AZT) should be conducted after the fourteenth week of gestation, and for newborns, during six weeks in infants less than one week old.

8. To discourage breast-feeding by women with HIV-infection and to provide their children with substitutes of maternal milk or pasteurized human milk.

9. Whenever possible, promote and support nourishment of children with milk from seronegative women.

10. To promote research in the region to obtain information according to the regional context, by mobilizing local/regional resources

and promoting horizontal technical cooperation among countries of the region.

11. When HIV testing is not universally available for all pregnant women, the participants suggest the evaluation of a sequential procedure of testing, in which the serological tracking of pregnant women with special risk conditions should be considered, for example:

- Screening for another STD or VDRL positive test
- To have a partner who is HIV infected or an Intravenous Drug User
- To be an Intravenous Drug User
- To have background of blood transfusion
- To have multiple sexual partners

12. To disseminate the former recommendations, the responsibles should initiate a series of joint awareness and training programs to adopt these recommendations, working in coordination with the reproductive health and maternal-child programs in each country.

b) Activity agenda for national governments

1. To guarantee universal access to HIV testing in prenatal clinics, with pre- and post-test counseling.

2. To guarantee a supply of breast milk substitutes, with counseling about their adequate preparation and requirements for sustained and adequate feeding of newborns and infants.

3. To promote milk banks in the maternal-infant units, when that is possible and feasible according to the national policies of each country.

4. To guarantee adequate treatment for the reduction of perinatal transmission, searching for a way to buy antiretrovirals (ARVs) within a "common market".

c) Activity agenda for international agencies

1. Use specific and clear messages (a unified criterion on topics discussed and analyzed among different agencies). WHO (and its executive committee), UNICEF and UNAIDS should immediately incorporate the specific needs of Latin America and of middle income countries in general within their discussions, and include the results in their recommendations, acknowledging the current practices within the countries and the ability of the latter to reduce or eliminate perinatal HIV transmission.

2 Discuss, within the socio-political context of each country (differentiated recommendations), the possibility of dissuading only HIV/AIDS infected women from breast feeding their children.

3. To support as a general principle the breast-feeding programs, facilitating the concept of trans-disciplinary work (maternal-child health / family planning / adult health – infant health, etc.)

4. To make sure these recommendations are followed at national, regional and local levels.

Breast-feeding and reproductive health in the age of HIV/AIDS

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A current subject of major concern is the practice of breast-feeding with regard to the reproductive and maternal and child health in the context of the HIV/AIDS epidemic. The regional program of the Population Council is involved in research both on the subject of lactation and of HIV/AIDS. At the beginning of the AIDS epidemic it was not thought that these subjects were going to come together in as troubling way. The fact that the virus of HIV can be transmitted through breast milk has produced something close to the panic, both in the press and in the community well intentioned but not always well informed. This panic and the desire to protect women has created a situation of false emergency. The commercial interests can take advantage of an apparent gap to save the world with an old remedy: the cow's milk *maternized*. This remedy, prepared under conditions of poverty has cost the life of many children in the world, and has put their mothers at risk of pregnancies without adequate intervals. The purpose of this chapter is to review the situation of lactation in the environment of reproductive and maternal and child health, taking into account the context of the new threat to the health of the women and children that represents HIV/AIDS.

Advantages of breast-feeding

It has been known for a long time that the use of substitutes of breast milk in poverty represents a threat to the health of children. Breast milk provides immunological protection to the newborn, preventing diarrheal and respiratory diseases. In addition, breast milk diminishes the probability of allergies and of diabetes throughout life. These effects are the result of the nutrients, enzymes, hormones, immunological factors, and other com-

ponents of breast milk that were designed more than two hundred million years ago in order to ensure the reproductive success of mammals.

The evidence on the advantages of maternal lactation to ensure the survival and improve the health of children already is incontrovertible, and consists of epidemiological studies conducted in both the developing and industrialized countries. Notable recent studies include that of Popkin, *et. al.* (1990) in Philippines, that found a risk of diarrhea 17 times greater in children from 0 to 2 months old that did not receive breast milk, with regard to those which only received breast milk. In Brazil, César Victora, and colleagues (1987, 1989) found a protection factor 25 times greater in babies breast-fed with respect to the risk of death from diarrhea. The effects of the antidiarrheal protection can last longer in children who are breast-fed during a minimum of 3 months, according to a study conducted in Scotland (Howie). With regard to the respiratory diseases, both Victora and colleagues, as well as Villalpando in Mexico, have verified the effect of the maternal lactation in protecting against respiratory diseases.

Maternal lactation also helps considerably to prolong the interval between births. These results summarized by Audrey Naylor, pediatrician and director of Wellstart International, Center of Training in Breast-feeding, have to do with infant mortality, morbidity in otitis media, allergies, diabetes, disease of Chron, urinary infections. All these reports, that increase day to day, illustrate the most cost-effective intervention in the health of children that human beings have ever known.

Breast-feeding also benefits the health of women. Oxytocin stimulates uterine contractions, diminishes bleeding in the postpartum, and contributes to the involution of the uterus. Another effect of enormous importance during lactation is the infertility of women who breast-feed. This infertility is equivalent, in the first six months after giving birth, to use a modern contraceptive with an effectiveness of 98%. The mechanism consists of an interference with the ovulation. An increasing body of evidence suggest that lactation prevents posmenopausal breast, ovaries and matrix cancer, and of hip fractures.

From a public health standpoint, maternal lactation not only offers formidable benefits but its cost is almost null. In contrast, the cost of breast milk substitutes is very high. Annually 292 million children are born; each one requires from 400 to 500 liters of milk during the first two years of life for an optimal and healthy growth; if those liters are of substi-

tutes of the breast milk there is a need for systems of drinking water, fuel, feeding-bottles, publicity and networks of distribution.

The effects of breast-feeding also contribute to savings in contraceptive costs. It is estimated that breast-feeding exclusively could offer the same effect of all contraceptive programs currently available. For all these reasons, breast-feeding is much friendlier with the environment.

History of maternal lactation as a public health matter

During the 1950s and 1960s breast-feeding had an important decline, as a result of the availability of substitutes of milk, and feeding-bottles. First in the developed countries and afterwards in the developing countries, lactation was being abandoned with the false hope that cow's milk was appropriate for feeding human new-borns.

Based on the knowledge from extensive work on malnutrition, morbidity and mortality in children, breast-feeding began to be an indispensable part of the strategies to improve the health of children, along with the monitoring of growth, oral rehydration salts and immunizations.

Research conducted in the 1970s had demonstrated a clear relation between the replacement of lactation in favor of breast milk substitutes and high infant mortality. In the 1980s, programs such as WELLSTART International were aimed to train physicians, nurses and health programs managers. At the end of the decade as part of the activities of the International Year of the Child, it was convened a meeting on infant feeding. The objective was to promote a Code of Marketing for Breast Milk Substitutes, which establishes the guidelines that should follow the countries and the companies producers of milk in order to promote the health of children and breast-feeding. Finally, UNICEF and WHO, under the leadership of James Grant, prepare and carry out the program of Friendly Hospitals for the child and the mother.

These efforts were capable of giving a turn of 180 degrees in the breast-feeding policies of some countries such as Mexico. The Mexican Social Security Institute, a prestigious institution developed a model adequating its hospitals and personnel to allow intra-hospital breast-feeding soon after birth and in the outpatient clinic.

Which is the situation of the lactation in the Latin American countries? The index of maternal lactation is high (partly due to the

ruralization of the area), although in the 1990s it became very low in urban hospitals due to the modern hospital policies that separate the newborn of the mother and provide him with feeding-bottle.

Exclusive breast-feeding is low and most feeding is complemented with water and tea. It can be seen that there is an inverse relation between the exclusiveness and the urbanity/modernism of the countries; Mexico and Brazil show smaller patterns of exclusive breast-feeding.

The inverse relation between maternal lactation and urbanization and education

UNICEF programs and others on breast-feeding start being successful in the 1990s. Mexico changed hospital environments that did not promote lactation, to one of rooming-in, staff trained to support lactation, and an unmistakable environment concerning the benefits for babies and mothers. Since it is incontrovertible that HIV can be transmitted through breast-feeding, the achievements of the programs of salvage of breast-feeding are once more at risk.

Companies producers of milk have seen that this situation can result in their own benefit, and have begun to pressure strongly in order to break the agreement. In order to illustrate the foregoing, on 30 August 1997 it was published in the South African newspaper *Saturday Star* the following declaration from a staff member of the organization called Freedom of Commercial Speech Trust: "*The prohibition to announce certain legal products, such as the substitutes of the breast milk, prevents the mother holding an informed election on what is most desirable for the health of her child. [...] The errors of the past, such as mothers using very little formula, evil feeding thus their babies and utilizing polluted water, will be avoided upon discarding the belief that substitutes of breast milk are not a healthy alternative.*" The business sector is generating hysteria, disinformation and even disseminating alarming data (not subject to review on the part of the specialists), with the view of attacking and dismiss the achievements of the last twenty years in the promotion of lactation, by means of the rear door that represents AIDS.

In order to counteract this situation, we believe that the suggestions that are reproduced below represent the best of the thinking of

the world experts in health. They coincide also with the Declaration on HIV and Infant Feeding.

- Where there are no tests or counseling, lactation is the best option.
- If the woman knows that she is positive, and also there are care services and substitutes of milk of quality, the best option is to use them.
- In all cases, the woman should be informed fully about her status and her options.
- In no way the progress and commitments achieved by the countries on breast-feeding should be cast aside.

Breast-feeding and transmission of HIV-1: an update

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Breast milk transmission of HIV-1 is an unfortunate reality which needs to be considered carefully as intervention strategies to prevent infant infection are developed. The majority of HIV-infected children have acquired the infection from their mother, and vertical transmission of HIV-1 may occur in utero, at delivery, or postnatally through breast feeding. It has been challenging to determine the frequency of breast milk transmission of HIV because of difficulties in ascertaining the time of infant infection and because feeding practices have been fairly uniform within most vertical transmission cohorts. In vertical transmission cohorts in Africa, breast feeding has been almost universal, while in US and European cohorts breast feeding has been rare and of short duration.

Evidence for breast milk HIV-1 transmission

Evidence for breast milk transmission of HIV-1 has accumulated over the past decade. As vertical transmission rates were determined for cohorts worldwide, it was evident that transmission rates were higher (between 25-43%) in African cohorts than in US/European cohorts (usually less than 20%). There are a variety of explanations for differences in transmission rates, including obstetric practice, maternal clinical status, and viral phenotype. It was also speculated that breast feeding may have contributed to the higher transmission risk seen in African cohorts. There is biologic plausibility for breast milk transmission of HIV-1; HIV-1 can be detected in the breast milk of HIV infected women, and other organisms (i. e., HTLV-1) are transmitted through breast feeding. In cohorts which have included both breast feeding and formula feeding infants, transmission risk is usually higher among infants who breast fed. Since 1985, there

have been several case reports of infant infection through breast feeding following maternal HIV-infection acquired at or after delivery through contaminated blood or sexual transmission. These reports strongly implicated breast feeding transmission, because maternal infection occurred after delivery.

Frequency of HIV-1 transmission through breast milk

In 1992, Dunn and colleagues estimated breast milk transmission rates in a meta analysis of six published studies of cohorts which included both breast feeding and formula feeding infants born of mothers who acquired HIV infection prior to pregnancy. The estimated additional risk of HIV-1 transmission through breast feeding in this analysis was 14% (95 CI-7-22%). The authors also evaluated 4 studies which included a total of 42 mothers who acquired HIV after delivery, and, as would be expected in this setting of primary infection, breast milk transmission risk was substantially higher, at 29%. This study was important in describing the differences in breast milk transmission risk between acutely and chronically infected women and in determining that breast milk transmission, even in the setting of non-acute maternal infection, was appreciable, at 14%. With overall vertical transmission rates of 12 to 43%, this would mean that perhaps 30 to 50% of infant HIV-infections among breast feeding mothers was attributable to breast milk transmission. Dunn's analysis was limited by the paucity of cohorts at the time which included both feeding practices. In the 5 non-African cohorts, a total of only 7% of women overall ever breast fed, while in the single African cohort, only 10 women formula fed.

We conducted an updated meta analysis which included data from the original meta analysis and additional available information on breast milk HIV transmission risk. This analysis included the 6 studies that Dunn evaluated, 2 of which had accrued additional data, and 4 new studies. Pooling the observations from 10 studies which included 3,514 mother-infant pairs, we estimated an additional HIV transmission risk through breast feeding of 17% (95% CI-12-24%). This is a higher estimate with narrower confidence intervals than the reported in 1992, and confirms the observation that breast milk HIV-1 transmission risk is appreciable.

Timing of breast milk HIV-1 transmission

The next important issue to review in breast milk transmission is timing of transmission. When does breast milk transmission of HIV-1 occur? This question is obviously critical as preventive intervention strategies for vertical transmission of HIV-1 are developed.

We separated studies in the meta analysis of breast milk transmission risk on the basis of prevalence of prolonged breast feeding practice in the region and compared estimated breast milk transmission risk in the two groups. The median duration of breast feeding in the Swiss, French, ltalian, and European studies was less than 2 months, most less than one month, while one African cohort described a median duration of 3 months, and two others described "prolonged breast feeding". We observed an almost significantly higher transmission risk in African/South American cohorts (24%) than US/European cohorts (11%).

Two studies have noted a relationship between duration of breast feeding and HIV transmission risk. In the Nairobi MCH cohort, breast feeding for more than 15 months was associated with a 2.5-fold increased risk of infant infection. The ltalian Multicenter Study also noted a relationship between duration of breast feeding and likelihood of infant infection. A study from Uganda did not observe a higher infection rate among surviving infants who breast fed for more than 15 months. In this cohort, however, after adjusting for survival, HIV infected infants had a longer duration of breast feeding than uninfected infants. All three of these studies were limited in their ability to estimate the probability of late postnatal infection, the Nairobi study relied on serologic rather than virologic markers, the ltalian study included retrospectively identified infants, and the Ugandan study may have lacked sufficient power to detect a difference.

Recently, there has been more definitive data on the timing of late postnatal transmission. Four studies have followed infants who had no detectable HIV by PCR testing at 3 to 5 months, to determine the rate of infection over the following 12 or more months. We did a meta analysis of these studies, and the pooled late postnatal transmission rate was 4% (2-5%). These studies confirm the continued risk of breast feeding late postnatally, but are also worrisome for the possibility for significant early breast milk transmission. If the frequency of late postnatal transmission is only 4%, then early breast milk transmission may be as high as 20%.

It is important to remember that meta analysis estimates are imprecise and limited the quality and comparability of individual studies. In addition, observational studies evaluating mothers who chose how they fed their infants may be biased. It is possible, for example, that mothers with clinical disease may be more likely not to breast feed their infants. The most definitive way to determine breast milk transmission risk is a clinical trial.

Correlates of breast milk HIV-1 transmission

There are a variety of potential maternal and infant correlates of transmission, including viral load, breast pathology, infant oral or gut compromise, and vitamin A deficiency, and it is not yet known whether cell-free HIV or HIV-infected cells are transmitted through breast milk. There has been very little study on these factors. There has been one case report of late breast milk transmission in a woman with a breast abscess, and there was a suggestion that mastitis was associated with transmission in a study from the lvory Coast. The relationship between breast feeding duration with transmission suggests a relationship between likelihood of transmission and cumulative exposure, but it is important to realize that duration of breast feeding may not be linearly related to infection risk over time. There may be episodic "high risk" periods in which maternal infectivity or infant susceptibility are increased. The very high breast milk transmission rates among acutely infected women suggests that breast milk viral load was high at this time, although this has not been studied. It also suggests that maternal immune response may be protective for transmission in infants of mothers who acquired HIV prior to pregnancy. In the only published study to evaluate these factors, Van de Perre and colleagues observed that the presence of HIV-infected cells in breast milk was strongly predictive of infant infection, and that women with HIV-specific IgM persistently present in breast milk were less likely to transmit infection.

We are currently conducting a randomized clinical trial of breast and formula feeding in Nairobi which was initiated in 1992. This is a collaborative research effort involving the Universities of Nairobi and Washington, fed by Drs. Joan Kreiss and Ruth Nduati. In Nairobi, where childhood infectious diseases mortality is high and breast milk avoidance may be associated with considerable morbidity and mortality, it was not

clear whether this risk would offset the benefit of averted breast milk transmission of HIV-1. The study is nearing completion and is reviewed twice a year by an independent Data Safety and Monitoring Board chaired by Dr. Tom Fleming, and will stop if there is evidence of significantly different HIV-transmission or mortality in either of the study arms. In 4 City Council antenatal clinics, HIV seroprevalence is 14%. In the interim we have evaluated breast milk in detail for HIV-DNA and cell-free HIV. Breast milk contains 10,000 to 1,000,000 cells per ml, including macrophages, lymphocytes, and epithelial cells. We studied the pattern and quantity of HIV-infected cells in 213 breast milk specimens obtained from 108 women in the study (JID 1995;172:1461-8). Fifty-eight percent contained HIV-1 infected cells, and the prevalence of HIV-infected cells rose to a maximum at 6 to 9 months. HIV-infected cells were quantitated and ranged from 1 in 10,000 to 3,000 per 10,000, over a 3 log difference. Thus, in the woman with the highest concentration, one third of breast milk cells were HIV-infected. Detection of HIV-infected cells was associated with immunosuppression, and among women with immunosuppression, vitamin A deficiency was associated with increased shedding of infected cells. In another study, Paul Lewis, in Dr. Julie Overbaugh's laboratory at the University of Washington, developed techniques to detect HIV-1 RNA in breast milk supernatant samples using QC-RT PCR techniques (JID, in press). Cell-free HIV was detected in 39% of 75 breast milk specimens and tended to be lower in the first week postpartum than at later times. Cell-free HIV did not appear to be associated with immunosuppression, clinical signs or symptoms, or vitamin A deficiency, but there may not have been sufficient numbers to determine these effects. Women with detectable cell-free virus did tend to have higher concentrations of HIV-infected cells in the cellular specimen from the same sample. HIV-RNA levels ranged from 240 to 8,100 copies per ml, which is much lower than is seen in plasma specimens of HIV-infected individuals not on antiretroviral therapy. This is not surprising given the fact that breast milk is a much less cellular fluid which is made in large volumes daily, and is not as directly in contact with the lymphoid system as plasma.

Potential intervention approaches

In the context of what is known about breast milk HIV transmission, a variety of intervention approaches is possible. These include breast milk

avoidance, early weaning, withholding colostrum, vitamin A supplementation of mothers and infants, and antiretroviral therapy while breast feeding. When safe alternatives are available, breast milk avoidance is the recommended option. Early weaning is not as risky or infeasible as breast milk avoidance and would certainly prevent late postnatal transmission. If early postnatal transmission is substantial, however, this approach may need rethinking. Ongoing studies are evaluating the effect of vitamin A supplementation on vertical transmission, and if vitamin A is effective when administered perinatally, continued supplementation during lactation could be considered since it is safe and inexpensive. Continued antiretroviral therapy through lactation is expensive and less practical than breast milk avoidance. It should be noted that breast milk avoidance, with its potential to decrease perhaps 50% of transmission may be of the same order of magnitude as antiretroviral therapy in preventing infant infection.

A variety of peripartum interventions for prevention of perinatal HIV-1 transmission are currently being evaluated, and in light of what is known about breast milk transmission, it will be critical that where these studies involve breast feeding infants, endpoints are evaluated at least as late as 18 months to determine the overall effect of the intervention on vertical transmission. If an intervention is effective in averting peripartum transmission but substantial breast milk transmission occurs, the net benefit may be minimal. Most children who are at risk for HIV come from areas of the world where finding safe and economic alternatives to breast milk is challenging. Unfortunately, it appears that breast milk transmission of HIV-1 contributes to a substantial amount of infant HIV-infection in these settings. Pregnant women should be counseled and tested for HIV and if uninfected advised to breast feed. HIV-infected women should be counseled about the risk of breast milk HIV transmission and the risk and benefits of breast feeding in this context. When women decide not to breast feed, they should be well-counseled on the provision of safe substitutes. As perinatal intervention strategies are developed for resource-poor settings, the area of breast milk HIV transmission will need to remain a high research priority.

Breast-feeding, obstetric and other risk factors associated with mother-to-child transmission of HIV-1 in Sao Paulo State, Brazil

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Institute of Child Health, London, UK
Funding agencies:
Brazilian Ministry of Health
Brazilian Ministry of Science and Technology (CNPq)
Overseas Development Administration, UK

Introduction

Vertical transmission of HIV-1 is a multifactorial process, and prevalence of factors associated with HIV-1 transmission vary across populations. Studies in Europe, North America and Africa have reported vertical transmission rates between 15 and 35% and have identified factors associated with increased risk, such as advanced maternal HIV-1 disease, prolonged ruptured membranes and breast-feeding. The effects of mode of delivery, invasive procedures during pregnancy and presence of other sexually transmitted diseases have been less consistently quantified.

Although initiation of zidovudine during pregnancy and its continuation during labor, delivery and the neonatal period has been proven to reduce vertical transmission of HIV-1, it does not eliminate transmission. A better understanding is needed of the factors that affect transmission to improve the management of HIV-1 infected women during their pregnancies and to develop alternative methods to reduce vertical transmission of HIV-1. We report here the results of the first large study relating to mother-to-child transmission of HIV-1 in Sao Paulo State, Brazil.

Methods

Study population and data collection

The study was a retrospective cohort. Laboratory records of anti-HIV-1 antibody test results were reviewed in seven maternity hospitals in four cities (Ribeirao Preto, Campinas, Santos and Sao Paulo City) in Sao Paulo

State, Brazil. All women who tested positive before or at delivery and who gave birth to live infants between January 1988 and April 1993 were eligible for inclusion.

Data were collected between October 1993 and April 1995. Information on maternal, obstetric, neonatal and postnatal factors was abstracted from medical records and an interview was conducted after informed written consent was obtained. Information on AIDS diagnosis and death was sought from the AIDS Registry for the mothers and children who were not found. Ethical approval was obtained from all participating institutions.

Outcome definition

The child's HIV-1 infection status was determined by IgG anti-HIV-1 antibody tests in serum or oral fluid at 18 months or later, and by clinical criteria. A child was considered HIV-1 infected if anti-HIV-1 antibody positive in serum or saliva at or after 18 months of age or if an AIDS- defining illness was diagnosed or at least two major and two minor HIV-1 related signs were present in the absence of known causes of immunosuppresion at any age. A child was considered not infected if HIV-1 antibody negative in serum or saliva at or after 18 months of age without clinical signs of AIDS. A child was classified as a HIV-1 indeterminate if seropositive when last seen or died from a non-HIV-1 related disease before 18 months of age.

Statistical analyses

Unconditional logistic regression modelling was used to investigate simultaneously the independent effects of each selected risk factor. The individual contribution of each risk factor was assessed by a likelihood ratio test with the criterion for significance set at a $p=0.05$. The final model was obtained by retaining only those factors significantly associated with vertical transmission of HIV-1.

Results

Characteristics of the study population

Four hundred and eighty-five HIV-1 seropositive women delivered 553 live born children in the participating obstetric centres during the study period. For 119 children, HIV-1 infection status could not be determined due to the following reasons: 78 (14%) were lost to follow up (most of them were younger than 2 months of life when last seen at the medical centres); 29 (5%) died before HIV-1 infection status could be determined (most of them were younger than 8 months of age and causes of death were not clearly related to HIV-1 infection); and 12 (2%) were refusals (median age = 3 years old). HIV-1 infection status was established for 434 children (follow up rate = 78%).

Only mother-child pairs for whom the infant's infection status was determined were included in the analysis. Sixty nine of the 434 infants with known infection status were HIV-1 infected (overall vertical transmission risk 16%, 95% CI 13-20%). No significant difference was observed between included and excluded mother-child pairs regarding mode of maternal HIV-1 infection, stage of maternal HIV-1 disease, serological evidence of syphilis during pregnancy, mode of delivery, gestational age at birth and breast-feeding.

Risk factors for HIV-1 vertical transmission

In the multivariate analysis, advanced maternal HIV-1 disease (odds ratio [OR] 4.5, 95% CI 2.1-9.5), ever breast-feeding (OR=2.2, 95% CI 1.2-4.2), child's negative Rh blood group (OR=2.5, 95% CI 1.2-5.5), third trimester amniocentesis (OR=4.1, 95% CI 1.2-13.5) and black racial group (OR=0.3, 95% CI 0.1-0.9) were independently and significantly associated with mother-to-child transmission of HIV-1. Transmission was increased marginally with prematurity and prolonged rupture of membranes. No association was found between child's HIV-1 infection and mode of delivery or serological evidence of syphilis during pregnancy.

Postnatal factors

Children who were breast-fed had a significantly higher risk of being infected than those who were never breast-fed (21% versus 13%, p=0.01). The duration of breast-feeding ranged from 1 day to 2 years, the mean duration was 98 days and the median was 30 days. In the univariate analysis, no clear pattern in risk of transmission by duration of breast-feeding was observed, although a sharp, but no statistically significant rise was found among children who were breast-fed for 91 or more days (p for trend =0.12). A marginally significant trend toward higher transmission risk with increasing duration of breast-feeding was observed after controlling for stage of maternal disease (p for trend=0.06).

In an analysis restricted to breast-fed children, colostrum intake was not significantly associated with infection (OR=0.9, 95% CI 0.3-2.4) and similar results were found after adjustment for stage of maternal HIV-1 disease and duration of breast-feeding was made (OR=0.7, 95% CI 0.2-2.2). Children who were fed with other types of milk while being breast-fed were at 2.1-fold greater risk of HIV-1 infection than those who were exclusively breast-fed, but this association was not statistically significant. Similar results were found when children who were fed with breast milk (with or without other types of milk) and tea or fruit juices were compared with children who were fed with breast milk exclusively. The odds ratios for both types of mixed feeding decreased when adjustment was made for duration of breast-feeding and maternal stage of HIV-1 disease and statistical significance was not reached (OR=1.7, p=0.30 for other milk, OR=1.7, p=0.40 for tea/fruit juice).

No significant association between cracked nipples and transmission of HIV-1 to infants was observed in either univariate or in the multivariate analysis by stage of maternal HIV-1 disease and duration of breast-feeding. Although only 15 children were breast fed by mothers who reported a history of cracked nipples with bleeding, they were almost three times as likely to be infected as children whose mothers did not have cracked nipples, but this association was not statistically significant (OR=2.9, 95% CI 0.9-10.0). Similar results were found after adjustment for stage of maternal HIV-1 infection and duration of breast-feeding (OR=2.6, 95% CI 0.7-9.5).

Conclusions

The overall risk of vertical transmission of HIV-1 in this study population of Sao Paulo State, Brazil, was 16% (95% CI 13-20%) and is likely to reflect the distribution of risk factors in this population, in particular the relatively low proportion of mothers with advanced HIV-1 disease (12%) and breast-feeding (39%). Potential for bias included loss to follow up and the death of children before determination of their HIV-1 infection status. Most children born to women who were lost to follow up or who refused to participate in the study were probably uninfected , otherwise they would have been eventually in contact with the health services for follow up of HIV-1 related diseases. On the other hand, many children who died before their HIV-1 infection status could be ascertained were more likely to be infected. Therefore, overall it appears unlikely that loss to follow up and death of children with unknown HIV-1 infection status have substantially affected the precision of our estimates.

Our findings confirm the concept that mother-to-child transmission of HIV-1 is a multifactorial event, highly influenced by severity of maternal HIV-1 disease, breast-feeding and invasive obstetrical procedures during pregnancy such as amniocentesis. It is biologically plausible that genetic susceptibility to infection plays a role in vertical transmission of HIV-1, and racial group and Rh blood group may be markers for differences in genetic determinants. In our study population, breast-feeding doubled the risk of HIV-1 transmission. Prolonged breast-feeding, bleeding nipples and mixed feeding may exacerbate the risk of HIV-1 transmission through breast-feeding whereas calostrum intake seems not to be associated with transmission. These findings, however should be interpreted with caution until they are repeated in larger studies.

In conclusion, the early identification of HIV-1 infection in pregnant women is crucial for the implementation of strategies to prevent transmission of HIV-1 from mother to child. Recommendations to reduce transmission of HIV-1 to infants should include avoidance of amniocentesis and invasive antenatal procedures that can potentially cause iatrogenic infection of the fetus. Health care providers should help HIV-1 infected mothers to understand and to balance the potential for transmission of HIV-1 through breast milk with the known benefits of breast-feeding. Ultimately, mothers can make an informed decision not only about anti-

retroviral therapy, but also about whether to initiate breast-feeding or not. Support programs for alternatives for breast-milk should be provided for women who opt not to breast feed and who cannot afford artificial feeding.

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The timing of perinatally acquired HIV-1 disease

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Background

The timing of HIV-1 infection in an African setting has not been quantified exactly. Knowledge of the timing of HIV-1 infection will help in interventions being proposed to reduce perinatally acquired HIV disease. Strategies to prevent transmission through breast-feeding will depend on the exact timing of postnatal transmission of HIV-1.

Objectives

1. To quantify the proportion of in-utero, intrapartum and postpartum transmission of HIV-1.

2. To assess the timing of postnatal transmission through breast-feeding.

Methods

Sequential DNA PCR testing were done on infants born to HIV-1 infected women who were part of the birth cohort being followed up to assess the effect of breast-feeding on HIV-1 transmission. PCR testing was done at birth, at six weeks, at three months and three monthly thereafter. Late postnatal transmission was defined as transmission occurring after six months of age.

Results

One third to a half of infection occurred in utero while about 50% of infection appeared to take place at the time of delivery. Postnatal transmission through breast-feeding appeared to represent a continuous risk and accounted for 8% of infection occurring before three months of age.

Period	Breast-feeding (% of total pos)	Formula-feeding (% of total pos)
In utero PCR+	38	45
0-3 months PCR+	51	55
3-6/12 PCR+	5	0
<6/12 PCR+	6	0

Conclusion

The risk of postnatal transmission through breast-feeding appears continuous. Formula feeding from birth or a strategy of early weaning may be an effective strategy to prevent HIV-1 transmission to infants

HIV AND INFANT FEEDING

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Mother-to-child transmission (MTCT) is the major source of HIV infection in children. There are an estimated one million children under 15 living with HIV/AIDS. Over 90% have been infected through mother-to-child transmission. One thousand babies are born infected each day. AIDS has already doubled infant mortality rates in high prevalence communities. Nine million children under 15 have already lost their mother to AIDS and 30 million live with an HIV infected mother who will die before they reach the age of 15. By the year 2010, AIDS may increase mortality of children under the age of 5 by more than 100% in regions most affected by the virus.

The main strategy available today to reduce mother to child HIV transmission is preventing HIV infection for uninfected women. For the infected mothers, all available strategies rely on the fact that the woman has been diagnosed as HIV infected. Therefore, increased access to voluntary testing is a prerequisite for any further interventions. When HIV is diagnosed, a woman can make fully informed choices about her reproductive life. Since 1994, the ACTG076 regimen of AZT has been shown to be able to reduce the risk of MTCT by about two-thirds and is widely offered to HIV infected women in North America and Western Europe.

The virus may be transmitted during pregnancy, labor, delivery, or after the child's birth during breast-feeding. Rates of MTCT range from 15 to 25% in developed countries, and from 25 to 45% in developing countries. One of the main reasons for the difference between developed and developing countries may well be that breast-feeding is much more frequent in developing than in developed countries.

Among infected infants who are not breastfed, approximately two-thirds of MTCT occurs around the time of delivery and the rest during the pregnancy. In populations where breast-feeding is the norm, it may

account for up to one-third of all transmissions. Avoidance of breast-feeding can thus reduce the risk of MTCT by about one third.

Indeed, the additional risk of MTCT of HIV due to breast-feeding has been estimated through a meta-analysis in 1992 at 14%. This can be translated in other usual measures of risk as follows: 1 out of 7 children born to infected breast-feeding mothers is infected through breast-feeding, which also means that 1 out of 3 infections is attributable to breast-feeding; and that the risk of transmission for breastfed children is 1.7 times higher than the risk from non breastfed children. It has been thought that this meta-analysis underestimated the risk of transmission through breast-feeding because data sets coming mainly from developed countries were used, from population breast-feeding for quite short periods (around 1 month in duration).

Most recent studies have reported somewhat higher relative risks, ranging from 2.2 up to 2.8. These data suggest that at least half of the cases of MTCT in the studied populations were attributable to breast-feeding.

A recent meta-analysis using data from Zaire, South-Africa, Brazil, Europe and USA estimated that, in addition to the risk of transmission during pregnancy and delivery estimated at 20-25%, breast-feeding adds a further risk of 11% in countries where breast-feeding is usually short, and 24% in countries where prolonged breast-feeding is the norm.

Other studies have shown that the risk of transmission exists throughout the duration of breast-feeding. Some authors have suggested adopting early weaning (at 6 months) in order to reduce the risk of late transmission. However, others suggested that early weaning may not reduce significantly the risk of MTCT and may, in turn, significantly decrease the benefits of breast-feeding.

Some factors have been found to increase the risk of transmission during breast-feeding: the risk is higher when the mother is infected during the breast-feeding period, and at the later stages of the disease as compared to asymptomatic periods. The risk increases if the mother's nipples are cracked or bleeding. Mothers with Vitamin A deficiency are more likely to transmit the virus.

Given the risk of transmission through breast-feeding, all developed countries recommend that HIV positive women should not breast-feed. In Thailand and Brazil, the government is trying to provide free infant formula to all women known to be HIV infected. Whilst in most African

countries decision-making is complex due to the undebated protective value of breast-feeding against several infectious diseases and overall infant death.

Traditionally, breast-feeding has been heavily promoted as a natural, cheap means of adequate nutrition and protection against many childhood diseases. The cost of infant formula, along with the clean water and fuel needed to prepare it, is often beyond the means of poor families in developing countries. The dilemma is that breast-feeding by HIV positive mother carries a risk of transmitting HIV to the child. Counseling programs along with voluntary testing will be required to help pregnant women make free and informed choices and to support them in whatever decision they take.

One of the big gaps in our knowledge is the size of the protective effect of breast-feeding. Indeed it has been poorly estimated, through studies performed at least 15 years ago, and may vary greatly according to the local environmental conditions (access to safe water, adequate sanitation, etc.). The increase of risk of death before 12 months of age for non breastfed HIV negative infants compared to breastfed HIV negative infants ranges from 1.5 to 5. However, HIV affects mortality not only in the first year of life and decision-making may rely on mortality before age of 5 years rather than solely on infant mortality. Since breast-feeding has a major protective effect during the first year of life, the increase risk of death before 5 years in bottle-fed children is somewhat lower than the increase risk of mortality before the age of 1 year. However, the lowest estimate of 1.3 indicates that in the studied HIV negative population, avoidance of breast-feeding increased 5 years mortality by at least one third.

The table shows the size of protection that breast-feeding should offer against non-AIDS mortality to counterbalance the risk of HIV transmission for children born to HIV infected mothers. For example, if the 5 years mortality in the population is around 50/1000 children, breast-feeding should decrease non-AIDS mortality by 4.5 fold to still be beneficial for children born from HIV positive mothers. For a higher baseline mortality (100/1000 children), breast-feeding should decrease non AIDS mortality by 2.7 to be still beneficial. In other words, until alternative infant feeding methods at least double the under 5 mortality, non breastfed children born from HIV positive mothers will be at lower risk of death than breastfed children in populations with baseline 5 years mortality under 150 per 1000 babies.

Five years mortality in breastfed and non-breastfed children born from HIV positive mothers

Baseline Mortality Rate	Breast-feeding better if RR>
50/1000	4.5
100/1000	2.7
150/1000	2.1
200/1000	1.8

Some examples of baseline (that is non-AIDS) under 5 mortality in selected countries, show that mortality rates are below 100/1000 in almost all countries in Latin America. If women, health care workers, and governments are able to ensure that alternative feeding does not triple the risk of mortality due to malnutrition and infectious diseases, then infants born from HIV infected mothers will be at less risk of death if not breastfed.

In Zimbabwe, seroprevalence surveys among pregnant women have shown prevalence rates of 30% in several sites. This means that 10% of all babies born in these sites will be infected and will die. Thus mortality rates will increase from 60% up to 160%, which is nearly 3 times the baseline rate; 30 to 40% deaths will be attributable to breast-feeding by HIV infected mothers.

Regarding HIV and infant feeding in the general population (and not only for known HIV positive women), it should be remembered that numbers of HIV negative women outweigh by far numbers of HIV infected ones in all countries. In consequence, when HIV status of the mother is not taken into account, benefits of breast-feeding always outweigh the risks of HIV transmission through breast-feeding.

This is clearly stated in the policy statement developed by UNAIDS, WHO and UNICEF: "As a general principle, in all populations, irrespective of HIV infection rates, breast-feeding should continue to be protected, promoted and supported". However, the statement also makes it clear that: "when children born to HIV positive mothers can be ensured access to safe and nutritionally adequate breast-milk substitutes, they are at less risk of illness and death if they are not breastfed."

The United Nations agencies emphasized the right of informed choice of individuals in stating that: "All women and men have the right to determine the course of their reproductive life and health, and to have access to information and services that allow them to protect their own and their family's health."

There are many challenges for ensuring informed choice. The first challenge is to ensure access to testing and counseling. Indeed, the knowledge of her HIV status is a big piece of information for the woman who wants to make choices about infant feeding. Providing information on risks and benefits of breast-feeding and alternative infant feeding methods is difficult since the risks associated with the avoidance of breast-feeding greatly vary according to the country, the geographical area within a given country, and also the individual situation of the woman in a given area. It is therefore important to assess, on an individual basis, the woman's capacity to safely use alternative feeding methods. This not only means to assess the availability of safe water, fuel and adequate hygiene, but also to assess the capacity of women to afford breast milk substitutes. We should be aware that most governments would not be able to provide free infant formula to all HIV infected women.

We should stress the importance of developing counseling and testing services, especially for women. Again, offering Voluntary Counseling and Testing to women is a primary tool in the prevention of the mother to child transmission of HIV. It can help non HIV infected women to remain uninfected but also help HIV infected women in getting adapted family planning services, infant feeding counseling, and access to medical intervention such as anti-retroviral treatments to reduce MTCT. However, it may be difficult for a woman alone to make decisions regarding her sexual and reproductive life and UNAIDS strongly supports programs that try to involve the male partners in the counseling and testing process.

There are important challenges to the wide implementation of counseling and testing services such as the lack of resources and facilities, the risk of stigmatization and abandonment by partner and family, poor access to medical care after diagnosis of HIV for women and children, and poor access to preventive interventions for the reduction of MTCT for HIV positive pregnant women.

We still have to convince people and governments of the benefits of HIV counseling and testing. We should ensure the quality of counseling by increasing training efforts and supporting trained counselors. We

should support the development of community work to increase tolerance and decrease denial and risks of stigmatization, and support the development of referral services for people who are living with HIV/AIDS.

The development of care activities is crucial to increase the acceptability of testing. Expanding access to counseling, testing and family planning services, adapting obstetrical practices, and introducing anti-retroviral regimens will have a heavy impact on clinical settings. However, increasing access to anti-retrovirals and safe means of infant feeding to prevent MTCT is a moral obligation if we want to promote testing of pregnant women.

We still need research for the identification of simpler and more affordable interventions such as short anti-retroviral regimens or infant feeding methods cheaper than infant formula. In conclusion, UNAIDS feels that infant feeding policies for women living with HIV should be only one of the components of a package of interventions to reduce MTCT, and that this package should include at very least, the promotion of voluntary counseling and testing.

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Decision analysis to evaluate policies to prevent HIV-infection through breast-feeding

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Several methodologies have been used to evaluate policies to prevent HIV-infection through breat-feeding from simple decision trees that compare two alternatives, up to the most complex models that combine information on costs with measures of clinical effectiveness such as survival, disability, and quality of life. The first problem which the majority of the analysts face is that of the available information. Analysis of cost-effectiveness and cost-benefit published in the literature refer to models for countries with high fertility and infant mortality and prevalences of very high HIV infection, which probably do not adapt to the majority of the countries of the Latin American region.

Most of these works are out of context when prevalences, from 15 to 20%, of infection in pregnant women are incorporated. Moreover, some models include extreme prevalences up to of 50%. Almost none of these published models include in its analysis prevalences around 1%, that is what is observed in most of the Latin American region. It is also observed that the published models incorporate infant mortality rates and of mortality in children under 5 with very high levels, situation that neither corresponds to many of the countries of the region. In such a way that the first premise for decision-making is that both the information that is incorporated to the analysis and the conclusions that are derived from these models belong to a specific context and as a result to generalize its conclusions has limitations of place and time.

Most of the Latin American region is considerated middle income countries. Many of their budgets for health do not have comparison with the budgets for per capita health that are handled in other countries, for example Africa or Japan. This is very important from the standpoint of the policy recommendations that on AIDS the international agencies issue. Some recommendations for very poor developing countries do not

have application in Latin America. For example, in terms of breast-feeding and HIV infection many physicians utilize the American Academy of Pediatrics recommendations, which avoid lactation in HIV-infected women. Consistent with this position, the recommendations of the CDC are very clear: not to provide breast-feeding when there is evidence of HIV infection. However, this position is opposed totally to the recommendations of international agencies as UNAIDS or the World Health Organization, those which for a long time recommended breast-feeding in poor regions and countries. As a result, these recommendations are paradoxical for the Latin American region that is in a stage of demographic, epidemiological, and economic transition.

First it is necessary to state very clearly the objective of eliminating perinatal transmission of the HIV through breast-feeding. In this regard, what is most important is to have a technical recommendation based on the regional context of each country. This problem faces us with barriers and challenges but also with opportunities. We find ourselves before a formidable opportunity to reduce significantly perinatal transmission, since after the successful experience in most countries with blood banks control.

With respect to the opportunities it is necessary to point out that middle income countries of the region have the ability to pay not only antiretroviral prophylaxis but also to provide with substitute lactation to infected mothers' children. In addition, the levels of prevalence in pregnant women are lower than that observed in other regions of the world. Finally, these programs, if they are instituted, represent an opportunity to provide universal counseling to young women at childbearing age.

With regard to the barriers, we have to recognize that there are logistic barriers, of access. In addition, it is known that any screening test during pregnancy has problems of acceptance not only in the case of HIV. In logistic terms we know that the main limitation that would exist in the region, would concern to the access to health services. We understand that access to health services implies the provision of counseling, testing, antiretroviral prophylaxis, and substitute milk.

With regard to the challenges for reaching our goal of reducing mother-to-child transmission of HIV, we know that traditionally there are difficulties in integrating maternal and child health, and reproductive health programs, with HIV programs.

In the analysis of the actions to prevent vertical transmission in the countries of the region there are interesting points. For example, some countries have been concerned about promoting legislation, important aspect because usually the legislation goes linked to a budget. Other important points are access to counseling and to protocols of antiretroviral prophylaxis, recommendations on breast-feeding to women HIV positive, and the access to substitutes of milk.

Upon reviewing these conditions in the countries of the region it is noteworthy that the majority of them are capable of ensuring the access to artificial lactation and that there is access to antiretroviral prophylaxis. During the meeting only Honduras manifested its decision to promote breast-feeding, even among HIV-infected women.

Access programs to antiretrovirals should be differentiate between preventive and therapeutic. When it is recommended implementing the protocol of antiretroviral prophylaxis we refer to a preventive intervention. It is worthwhile to clarify this because this may or may not include antiretroviral treatment for the mothers after delivery. In terms of budget allocation, it is easier to assign them to preventive interventions.

In terms of policy instruments different criteria have recently been utilized for decision-making. One of them is the analysis of cost-effectiveness that contrasts the costs of a program with its effectiveness. This technique has been strongly criticized because in some way it assigns economic units to aspects as life, and that sometimes causes discomfort a great deal to people. However, it has the advantage that decision-making becomes a transparent process, uses a standard methodology, and can be reproduced. In the analysis of decisions statistical methods and probabilities analysis are used in order to guide the decision-making between alternatives that are competing.

In order to carry out cost-effectiveness analysis epidemiological information is key to define the attributable fraction of breast-feeding as effect of transmission, infant mortality in a region, mortality in children under 5, the progression of disease in children with HIV infection, the mortality during the first year of life, and the natural history of disease. These elements are very important for the development of these models.

An article published in 1996 using this methodology analyzed the impact of the treatment on 100 women, comparing prophylaxis with AZT versus no treatment. The prenatal treatment was calculated in 83,440

dollars, that together with other costs estimated at 15 thousand dollars yielded a total costo of US 104,512 to provide prophylaxis to 100 women. The assumptions were that those receiving AZT there were only 8.3 cases, while among untreated women would be 25 cases. The pediatric treatment amounted to 820 thousand dollars, approximately 8 thousand dollars per each child. However, in the untreated group, in which there were 25 children, the cost was of two and a half million of dollars. The total savings attributable to the prophylaxis were estimated at one and a half million dollars. There are two important factors: one is the acceptance that the screening tests had, and the other one is the prevalence in the population. The savings increases as the prevalence is higher.

The decision-making analyses that involve the cost of the interventions can be of two types: cost-effectiveness and cost-benefit. The fundamental difference is the type of numerators and denominators that are incorporated. In the cost-effectiveness analysis the numerator always is a monetary unit and the denominator are the levels of health expressed as averted cases, deaths, or gains of years of life adjusted by disability. In the cost-benefit analysis monetary units are utilized both in the numerator and in the denominator and the result is the difference among the costs of investment and the savings due to the intervention. For the evaluation of the results some criteria are available. For example, when the cost of the program is high and the effectiveness is high it is necessary to evaluate the feasibility of implementing the intervention; when the cost is high and the effectiveness is low, this intervention is rejected, but when we have a very high effectiveness and the costs are very low, it concerns a dominant alternative and there is usually a tendency to accept it.

Breast-feeding and HIV. Situation in Argentina

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The subject of AIDS cannot be analyzed outside the general context of the country, accordingly I will present some basic data on Argentina. As it is known, the distance from Argentina to Geneva represents more than 15,000 kilometers, which gives us an idea of how far we are from the center of power. The urban population of the country represents 88%. It is perhaps important to mention that our form of government is republican, representative, and federal, which implies that problems should be solved through recommendations of the central government but with the consensus of the provincial states, because there is not a standardization that is imposed from the central government, on the contrary, all the regulations are agreed.

The population is distributed more or less alike between males and women. In this regard the socioeconomic indicators point out that our per capita gross domestic product in the year of 1997 was estimated at more than 8,000 dollars, which makes us a country that is not eligible in order to receive donations from international institutions; but, on the other hand, we can accede to loans. In fact, in these days the negotiation with the World Bank was concluded for a specific program for prevention of AIDS.

The rate of unemployment and underemployment encompasses almost 30% of the population. The schooling rate is high: at primary school it surpasses 95% of the population. The birth rate for the country is of 18.9 per 1,000 and that of total mortality is of 7.7 per 10,000. Life expectancy for the 5-year period 1995-2000 is calculated, for males in almost 70 years, and in women exceeds 75. Infant mortality at this time is of 22.2 per 1,000, neonatal is of 13.6 and postnatal of 8.1; the maternal mortality rate is located in 4.4 per 10,000.

The first case of AIDS in the country appears in 1982. With regard to underreporting and the delay in the reports, we estimate that they can be up to around 30%. If we analyze the cases of AIDS in the pe-

riod that goes from 1982 to 1997, it is observed that the distribution of the risk factor in 47% of the cases is sexual transmission and to the transmission by blood corresponds 43.6%. It is worth clarifying that by transmission by blood we understand the contagion through syringes of addicts to intravenous drugs, blood transfusion and antihemophilic concentrates.

Upon separating this 43.6% we find that more than 90% of it is due to intravenous drugs; the percentage corresponding to hemophilia and transmission by blood is irrelevant since it is found below 10%. With regard to children of HIV positive mothers, 6.6% of the cases, in all the period, are related to the fact of having a mother HIV positive.

The distribution of feminine cases of AIDS in the country is not uniform. More than 97% of the cases of AIDS of the country concentrate on four jurisdictions: the federal capital, the province of Buenos Aires, that is one of the larger provinces of the country, the province of Córdoba and the province of Santa Fe. It is also necessary to point out that 80% of the total population of Argentina concentrates on these four jurisdictions, which means that one thing is related to the other.

With regard to the distribution of pediatric cases of AIDS, we see that these adjust very well to this distribution; thus, in the province of Buenos Aires we find 65%, and on the other hand only 19% concentrates on the federal capital, the provinces of Santa Fe and of Córdoba; in the case of AIDS by vertical transmission this corresponds, respectively, to 4 and 2%.

The greater weight of vertical transmission concentrates on the province of Buenos Aires. Before this fact we should ask which is the relation between vertical transmission and breast-feeding. Since the year of 1995 it became effective in Argentina protocol 076, based on the recommendations that were made on perinatological standards that offered to women, voluntarily, and with counseling, the realization of tests for the detection of antibodies of HIV.

Argentina has a legislation that impedes the realization of examinations that are not voluntary and with informed consent. Accordingly, all studies should be made under this first condition: that they are voluntary, with informed consent and pre and post examinations counseling.

As a result of a study that demonstrated that the risk factors are difficult to identify since many women do not know that they have them, and as a response to the possibility that HIV positive women pre-

vent vertical transmission through the supply of drugs, there have been set new perinatological standards starting in 1997 that establish the compulsory nature to offer all pregnant women the possibility to accede to antibody screening of HIV voluntarily and confidentially; to provide free of charge treatment 076 to pregnant women, and those women who thus desire it can accede to other antiretrovirals, in accordance with her family doctor. Clearly this has relatively high costs, but at any rate the country considers that the voluntary and confidential detection is preferable in pregnant women, as well as the treatment of the same, to the fact to have babies infected by the virus of HIV.

With respect to breast-feeding, the standard establishes that this should be discouraged and the artificial lactation should find support in all those circumstances where a good substitute provision of breast milk can be ensured. Thus, the government, on the other hand, has a program for supplies of artificial lactation in a totally voluntary form, which reflects that much has been worked on this subject in Argentina.

Transmission of HIV by breast-feeding

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Since several years ago, in Argentina it is not recommended breast-feeding in those women infected with HIV. In addition, from March 1995 some hospitals started to propose the protocol ACTG 076 to pregnant women with positive serology for HIV. Since that moment 63% of the children who entered our study had been benefited with the protocol of AZT. We presume that 37% that did not receive it was due to maternal ignorance of her state of infection during pregnancy (Table 1).

TABLE 1

Since March 1995 when some hospitals started to offer the treatment with AZT 139 children under three months of age were admitted for diagnosis:		
With treatment	88	(63%)
Without treatment	51	(37%)

In the National Reference Center for AIDS we work for several years carrying out, among others, the pediatric diagnosis by PCR, culture of virus and detection of AG p24 in children under 12 months stemming from HIV positive mothers. In addition, we also conduct the study of viral load charge for the antiretroviral follow-up of those infected children under treatment.

Of 546 children who have been studied, in 360 it could be obtained information about feeding during the first year of life. Almost 80% of latter did not receive breast-feeding (Table 2). In the 168 children in which the infection state is known there could be observed a significant difference among those who were infected and have been breast-fed (71%), and those that were infected that were fed with feeding-bottle (44%) (p<0,0034, OR =3,23) (Table 3).

Table 2

Total of children studied	546	
Feeding-bottle	289	(79%)
Breast-feeding	71	(21%)
With infection stage	168	
Feeding-bottle	133	(79%)
Breast-feeding	35	(21%)

Table 3

	Infected (n=83)	**Not infected (n=85)**
Breast milk (n=35)	25 (71%)	10 (29%)
Feeding-bottle (n=133)	58 (44%)	75 (56%)

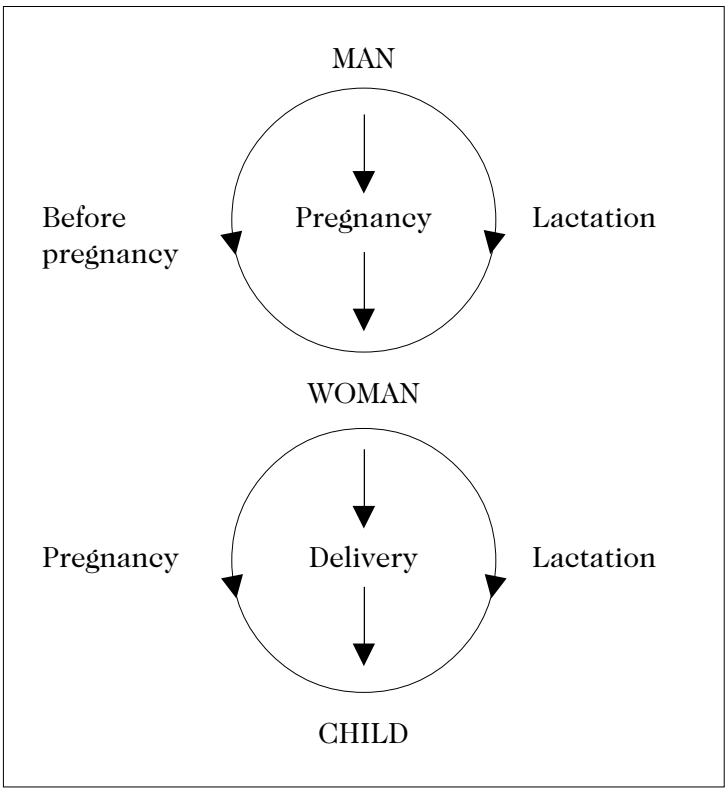
Table 4 describes the case of a pregnant woman, couple of a man HIV+, to whom the serology for HIV in the second month of gestation is done and turns out negative. At birth and at 10 months, both, mother and child, were negative. At 32 months old the child returns to the consultation presenting generalized adenopathies. The serology at that time was positive both in mother and in child. In the questionnaire, the mother reported that although she had been advised not to breast-feed her child, lactation had been up to the child's 24 months. It can be concluded that the mother seroconverted during the lactation of the child.

Table 4

Date	Child			Mother	
	Age	EIA	WB	EIA	WB
20-06-91	2nd month pregnancy	-	-	Neg	-
15-01-92	Birth	Neg	Neg	Neg	Neg
15-10-92	10 m	Neg	-	Neg	Neg
04-08-94	32 m	Pos	Pos	Pos	Pos
12-09-94	33 m	Pos	Pos	-	-

It is hence that, in view of the fact that the virus can be transmitted from man to woman previously, during or after pregnancy, and woman can transmit it to the child during pregnancy, childbirth or in lactation (Figure 1), it is important to act with greater effectiveness at all time to prevent that the infection occurs and is transmitted to the child.

Figure 1


MAN
Before pregnancy
Pregnancy
Lactation
WOMAN
Pregnancy
Delivery
Lactation
CHILD

Breast-feeding and the infection of HIV/AIDS in Brazil

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AIDS was identified for the first time in Brazil in 1982. The first reported cases occurred in Sao Paulo and Rio de Janeiro. Until August 1997 a total of 116,389 cases had been reported to the Ministry of Health, of which 20.7% presented in women and 3.3% in infants. However, in all the states of the Federation cases of the disease have already been reported to the Ministry of Health. This year they were distributed homogeneously, being more concentrated in the southeastern region.

In recent years the HIV/AIDS epidemic in Brazil presented important changes in its profile, being characterized by its penetration in the women's, juvenile and in extreme poverty population. In 1984 the man/woman ratio was 23:1, and since 1996 came to be 3:1. The growth of AIDS cases in the female population, especially among women at childbearing age, has resulted in an increase in the cases of AIDS in infants who acquire it through vertical transmission.

The first case of vertical transmission was reported in 1985, in the state of Sao Paulo, and since then the number of cases associated with this category has increased year with year. In the period 1984-1987, vertical transmission represented 22% of the pediatric AIDS cases, increasing to 87.5% for 1996-1997. A multicenter study in the state of Sao Paulo that included infants been born in the period of January 1988 to April 1993, showed a rate of vertical transmission of 16%, in which infants breast-fed had a greater risk of infection (21%), as compared with those not breast-fed (13%).

Due to the growth of the epidemic in the female population at childbearing age and to the results of protocol 076 of ACTG showing the effectiveness of zidovudine in the reduction of approximately 70% of vertical transmission, the Ministry of Health established as one of its principal objectives the reduction in the vertical transmission of HIV/

AIDS, with respect to the control of the epidemic of AIDS. In order to achieve the foregoing, several strategies are utilized.

Offering of the HIV/AIDS test to all pregnant women

Despite the fact that the prevalence of the HIV infection among pregnant women does not exceed 3%[1], the recommendation of the Ministry of Health is that anti-HIV test is offered to all of them, regardless of the identification of any risk factor, since there are not criteria capable of identifying the risk of infection of HIV/AIDS in the majority of the infected women.

Considering that the best way of preventing vertical transmission is to prevent the infection in the population of women at childbearing age, it is fundamental that these receive information on the STD/AIDS prevention. In this way, it is expected that the universal offering of anti-HIV test would help to reduce vertical transmission, not only identifying HIV-infected pregnant women, candidates for zidovudine, but also to reduce the vulnerability of women toward the infection of HIV. This is especially important if we consider that many women utilize the health system during pregnancy, and that the information received of these services has high credibility in the Brazilian population.

The policy to practice anti-HIV tests for the population is not restricted to pregnant women. The Ministry of Health currently has 100 centers, distributed throughout the country, in which the test is carried out anonymously. These centers offer the service free of charge, and provide counseling and HIV screening. It is important to point out that in Brazil anti-HIV test cannot be practiced compulsorily, and should be preceded by pre and post test counseling and follow-up.

Availability of zidovudine in capsules, injection and oral solution

The Ministry of Health has made available zidovudine in capsules, injections, and oral solution, guaranteeing thus to all the HIV-infected pregnant

[1] Preliminary data.

women and her children the access to the treatment plan utilized in protocol 076.

In regard to the Brazilian governmental policy for the antiretroviral treatment, it is important to point out that since 1991 the Ministry of Health made available to patients at no cost some antiretroviral therapy. Over time the number of patients served has increased progressively, as well as the number of antiretrovirals provided. Currently, the Ministry of Health has the following ARVs drugs: zidovudine (AZT), didanosine (DDI), zalcitabine (dd C), lamivudine (3 TC), estavudine (d4 T), saquinavir, ritonavir, and indinavir. For the year of 1998 this program includes nelfinavir.

The ARVs are distributed to patients in accordance with the technical criteria determined by an Advisory Committee created in 1996. The definition of clear technical criteria, and the follow-up of the same, has been fundamental for the rational use of these very expensive drugs.

In regard to antiretroviral therapy for pregnant women, it is recommended that an antiretroviral scheme *in consideration* is selected, as for any other adult, a clinical assessment, the count of lymphocytes CD4 and the levels of viral load. The patients that do not present indications of treatment should receive zidovudine during pregnancy and in delivery, being suspended the drug after delivery. Women with CD4 < 500 cells/mm^3 or viral load 10,000 copies/ml should receive combined antiretroviral therapy, which should always include zidovudine.

Substitution of breast milk

With respect to lactation, the Ministry of Health recommends the substitution of breast milk for artificial milk or for pasteurized breast milk from the milk banks. Unlike other countries, in Brazil milk banks are available as an alternative for children whose mothers cannot breast-feed them, including HIV/AIDS infected mothers. The milk bank network currently has 84 units distributed along the entire country, always located in the maternities. It is important to clarify that the Brazilian policy is focused to protect the infants against the infection of HIV through breast milk, maintaining the policy to stimulate lactation in children of mothers HIV-negative or still untested.

To improve the services during pregnancy (prenatal) and assistance in delivery

Perhaps the mayor challenge to implement actions to reduce vertical transmission is the poor medical assistance during pregnancy and delivery. The high index of maternal mortality, is still a public health problem in Brazil. In this way, the priority that the Ministry of Health has given to the health of women, and the joint effort with the CN-STD/AIDS, in coordination with the Health Program for Women, has resulted in a better structure for action in order to reduce vertical transmission of HIV.

Training of human resources

In order to implement all the strategies for reducing vertical transmission it is necessary to train human resources. One of the principal needs is to train health professionals working in the maternal and child area in order to give counseling before and after the test. The majority of these people are not still trained to perform this function. Another great need is to train laboratory professionals so that the implementation of tests is more expeditious. For the training of laboratory professionals the Ministry of Health developed a program for remote teaching, in which videotapes, and a doubt clarification system are utilized through the fax. It has been made a great effort also in order to train the health professionals in the proper management of pregnant women infected by HIV and of her children. This training is carried out by the STD/AIDS Coordination, that has formed repliers in all the states of the Federation, and has stimulated the multiplication of training strengthening it with the delivery of teaching material and financial resources to the STD/AIDS state and municipal coordinators, and to several universities.

Finally, it is important to emphasize that the objective of reducing vertical transmission of HIV is one of the policies that the Brazilian government offers to the general population together with prevention actions of STD and AIDS, and to the HIV-infected individuals a worthy assistance, that always seeks the improvement of the quality of life.

Women and AIDS in Chile

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In Chile, life expectancy of women at birth reaches 78.26 years, revealing that some of the basic public health problems are solved. However, the country faces a stage of epidemiological transition characterized by health problems of developed countries and of underdeveloped countries. This has produced a change in the health systems, which should solve problems of a great variety and complexity.

An important change has occurred in the total fertility rate that has turned from 3.2 in 1975 to 2.5 in 1995; 14.6% of the live births in this last year are teenage mother children. In our country the existing social and cultural model determines serious difficulties in the different prevention aspects: "machismo", power relationships within the couple, gender discrimination and differences in the perception of sexuality. All these situations contribute to a great extent to the vulnerability of women with regard to HIV infection.

Preliminary data of a study of sexual behavior carried out in Chile during 1996 showed important differences between both sexes with regard to the motivations of the first sexual relation. Women declared that love for a man was the main reason, while more than a half of men reported greater importance in sexual pleasure. Some aspects of sexual negotiation evaluated in this study show an absence of power in woman; for example, they do not make efforts to convince their partners of using a condom when they do not agree with it.

The reasons why HIV tests are practiced in men and women are different. In women there exists a clear predominance of medical indication (17.6%), while in the men this only reaches 6.4%, revealing the decision-making power that the woman has in this regard.

The beginning of the AIDS epidemic in our country was in 1984, with the report of the first affected man. The first case of AIDS in a

woman was notified a year later. Since that date up to 30 September 1997 183 women have been reported, with an annual incidence rate that has increased from of 0.02 per 100,000 population in 1985 to 0.57 per 100,000 in 1996. In men the rate of AIDS changed from 0.15 to 4.32 per 100,000 in the same period. The global trend of HIV infection in our country has been evaluated as moderate. Today the epidemic is in a middle level, in comparison with the rest of the continent and the one found in large cities. Thus, the metropolitan region (where there is located the national capital) presents the highest rate: 28.4 per 100,000 inhabitants followed by region 5, place of great port activity, with a rate of 21.9 per 100,000. In the third place is region 2 of great mining development, with a rate of 12.3 per 100,000. The cumulative national rate reaches to 15.8 per 100,000 inhabitants.

Upon analyzing the epidemic according to sex, 91.2% are men and 8.8% women. The male:female ratio has changed from 12:1 in the period 1988-1992, to 9:1 in the period 1993-1997. This indicates an increase in the figure of sick women, which is proportionately greater than the growth observed in men.

The information according to age groups reveals that 85% of the AIDS cases concentrates between 20 and 49 years, the age group most affected in men is that from 30 to 34 years, unlike women that concentrate more on the group from 25 to 29 years. The foregoing coincides with world estimates of UNAIDS that reveal that women acquire the infection at earlier ages than men.

The principal mechanism of transmission is sexual, with predominance of men that have sex with men (76%), but with an important increase in the number of cases in women who declare heterosexual transmission as mode of exposure. The homo/bisexual: heterosexual reason has varied to 6.7:1 in the 1985-1990 period, to 3:1 in 1991-1997. 75% of women with AIDS acquired the infection because of unprotected heterosexual relations.

The transmission by blood reaches 7% of the total of the affected population. Such category of exposure is controlled at present, through the decree that established the compulsory nature of the screening for HIV to all the donations, from the year 1987. In recent years a slow but progressive increase is observed in the transmission by practices associated with intravenous drug addiction. 5.7% of the women notified of AIDS acquired HIV through blood transfusions, indicated in the majority

for causes related to delivery and puerperium. 7.4% of them were infected through intravenous drug abuse.

Vertical transmission currently comes to 27%; there has not still been evaluated the impact of the application of the protocol AGTC 076, established two years ago, by difficulties in the implementation. 12.1% of the women with AIDS are daughters stemming from seropositive mothers.

AIDS epidemic affects each day more to the most vulnerable population, being observed as a trend over time the increase in people with an educational and occupational low level, without distinction between men and women.

Upon analyzing some socioeconomic parameters collected in the report of cases, throughout all the period, in the case of men, and with respect to schooling there are important differences between the affected population and the total male population of the country. The HIV/AIDS group with upper schooling practically duplicates what is informed for the general man population. In women, on the other hand, are very insignificant differences with regard to this variable between both populations, being the HIV/AIDS women representative in the educational level of the total population of women of the country.

With regard to the occupation declared by HIV/AIDS men, the information is consistent with what is reported concerning the schooling, pointing out an important over representation of HIV/AIDS professionals *versus* the total population of men of the country (14% and 3%, respectively). However, the group of HIV/AIDS men that carry out works classified as basic or workers (57% *vs.* 35%) also appears over represented. In women a significant difference at the level of workers is observed among HIV/AIDS women and the total population of women that work of the country (32% *versus* 3%).

The information obtained of the case reports is complemented with the information from the seroprevalence studies with sentinel center methodology carried out in the country starting in 1992. The female population studied corresponds to pregnant women who attend prenatal checkup in the regions of greater prevalence of the country. The observed prevalence has turned from 0% in 1992 to 0.1% in 1994. The evaluation of this methodology determined that given the low prevalences obtained by this study, it would be conducted biennizally, being found that the study corresponding to the year 1996 is in the stage of analysis.

Situation of vertical transmission by breast-feeding

In Chile, at present vertical transmission reaches 27%. Until September 1997 there had been made the diagnosis of HIV infection in 67 children, of healthy in 135 children, remaining under study a total of 45 minors. The first case of vertical transmission by breast-feeding was a born child in June 1987 whose mother received blood transfusion for hemorrhage in the immediate puerperium. The background of the positivity of the donor was known in October of that year. The later study conducted in the mother demonstrates seroconversion (in equal date) and rules out other factors from exposure to HIV on the part of her; the spouse turns out seronegative and does not refer other sexual partners. The child was breast-fed until October 1987. The diagnosis of the child was made in May 1988, at the age of 8 months, with HIV and study of positive antigen. Subsequently, in 1988, two twin minors were infected by this way, in conditions similar to the ones described above.

Recommendations

Chile, shows infant mortality rates that are among the lowest in Latin America (11.1 per 1,000 live births in 1995). With adequate levels of basic sanitation, and low mortality from diarrhea in infants (0.1 per 1,000 live births in 1995), Chile is among the countries in which breast-feeding should be avoided in the presence of HIV.

HIV and breast-feeding in Costa Rica

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Introduction

In Costa Rica, 100% of the population is covered by the social security system through the Costa Rican Social Security Fund. From that standpoint we will review the actions that have been taken with regard to breast-feeding and the HIV infection.

Every child has the right to be breast-fed by his mother, since the breast milk is regarded as the best food. In the last decade, breast-feeding has been progressively displaced by artificial feeding. Among many causes, one of the more troubling is the HIV transmission by breast milk.

The establishment of breast milk banks to provide with milk the high risk newborn unable to breast-fed, is one of the fundamental objectives of these banks, since the anti infectious and nutritional properties of the maternal milk make it the ideal food.

The breast milk bank is also of great help for mothers that for any reason cannot breast-feed their children.

Breast milk, in addition to providing essential nutrients for the optimal growth and development of the infant, has proved indispensable to ensure the survival of children living in poor environments. Rooming-in, natural delivery, and the practice to initiate breast-feeding in the immediate postpartum have proved to be a strategy of great impact, on the habit of breast-feeding. Decision-makers in the field of health care are promoting actions on behalf of the health as a right of every human being.

As the HIV/AIDS pandemic moves forward breast-feeding by HIV infected mothers is questioned. The breast-feeding policy in the context of the HIV-epidemic is presented below.

Historical background

The first Breast Milk Bank started in the country in 1974; it was created at the National Children's Hospital. Its principal beneficiaries were the high-risk and low birthweight newborn hospitalized in the Neonatal Intensive Care Unit.

This bank had a great reception. Thanks to the negotiations of volunteers it succeeded in obtaining a vehicle in order to transport milk donated by mothers from their homes. All these milks were *pooled* and mixed, both from donations and hospitalized mothers.

In 1978 the modality of care changed and the rooming-in was adopted, by which the mother could breast-feed her child directly. Healthy mothers were initially only included; subsequently mothers with childbirth by cesarean and those that had had high-risk pregnancy or childbirth were added. That same year the INISA (Research Institute in Health) and the Lions Club donated an automatic milk extractor pump.

In 1979 a second milk bank was created in the San Juan de Dios hospital which turned out a success, to the degree that it was necessary its regulation since: a) the donations of breast milk increased; b) diarrheal diseases in the newborn diminished; c) the early beginning of the feeding of the newborn; d) the clear reduction of the incidence of neonatal hypoglycemia.

That same year the donation of other breast milk extraction pumps was obtained and consequently more breast milk banks opened in the rest of the country. All these measures improved the incidence and prolonged the duration of breast-feeding.

In 1983 a National Commission of Breast-Feeding was installed legally, under Executive Decree No. 17273 of 31 October 1983. Within the functions of this Commission, formed by an interdisciplinary team, in 1986 the first official breast milk bank standards were published in the country. Before the publication of these standards and previously to the staff training, it was carried out a workshop in order to identify the relationship between breast milk and the transmission of HIV. Thanks to the results of this workshop conducted in 1988 the breast-feeding standards were updated.

The main objectives of these standards were:

1. To favor children as the major beneficiaries of the immunological advantages of breast milk.

2. To cover the nutritional needs of hospitalized children with the ideal and most complete food that can be offered to them: breast milk.

3. To stimulate the donation of breast milk through an educational process on:

- Advantages of breast milk.
- Incentives for the donors.
- Dissemination of the purposes of the milk bank.

4. To motivate mothers in postpartum period in order to continue exclusively breast-feeding over a period of four months.

5. To have enough breast milk in order to offer it to the children that need it and whose mothers cannot provide it to them.

6. To serve as model for the creation of new milk banks in other hospital establishments.

The recommendation to prevent the transmission of infectious agents were:

1. Verification of good hygienic habits on the part of the donors at home.

2. Exclude HIV or hepatitis infected women, active tuberculosis, active typhoid or healthy carrier, mastitis, cancer, venereal diseases, herpes, and excretion of cytomegalovirus by breast milk (a special questionnaire for the collection of these data was prepared; in addition laboratory tests in order to carry out these examinations are available).

3. To enjoy good health (a questionnaire was designed for this purpose).

4. To have refrigerator and telephone at home.

5. Mothers whose children presented congenital infection were excluded.

6. Not to smoke more than 10 cigarettes per day.

7. Not to take more than two ounces of liquor per day.

8. Not to ingest beverages with gas, coffee, or tea in excess.

9. Not to be receiving medication that counterindicates breast-feeding.

In order to promote breast milk donations some incentives were designed:

1. Daily snack after donating milk (a fruit, a sandwich and a refreshment, milk).
2. A certificate of gratitude to the mothers after five days of donations.
3. Delivery of a card similar to that of the blood donors.

Milk's quality control:

1. Before become a donor, quality control tests are carried out to samples of every mother.
2. Ten samples of breast milk are collected at random within the first 20 days of every month.
3. Fungi and bacteria cultures.
4. Milk from HIV-infected mothers is rejected.
5. Whether milk does not meet the above mentioned requirements should be pasteurized or else not to be utilized, according to the case.

In the cases of mothers HIV carriers, according to the 1983 standards the mother can feed her own child exclusively, taking the necessary steps of asepsis.

Law No. 7430. The Legislative Assembly of the Republic of Costa Rica decrees the promotion of breast-feeding

The Law Promoting Breast-feeding was promulgated in October 1994 by the Congress of the Republic. The fundamental objectives are based on promoting safe and sufficient nutrition for infants, through education of the family and the protection of breast-feeding.

Thus there is given specific support to the programs and activities that promote it and the publicity and distribution of breast milk substitutes, of food supplements, when they are marketed as such, and of the related utensils, is regulated.

Within the more outstanding point of this law, it is worth to mention:

Article 3. The National Commission of Breast-feeding is created to be in charge of dictating the policies and standards that on breast-feeding should be promulgated. In addition, it will coordinate and foster activities aimed at promoting breast-feeding.

The Commission is made up by a member of the:

- Ministry of Health
- the Ministry of Public Education
- the Ministry of Economy, Industry, and Trade
- the Costa Rican Social Security Fund
- the Costa Rican Research Institute and Teaching in Nutrition and Health
- the School of Nutrition of the University of Costa Rica, and
- the Costa Rican Union of Associations and Chambers of the Private Enterprise.

The fundamental objectives of the Commission are:

1. Assistance practices of support for breast-feeding.
2. Promotion of breast-feeding through educational activities.
3. Legislation that protects the working mother.
4. Research projects that put into practice activities of promotion and protection of breast-feeding

Article 10. It is mandatory to individual or legal entities that market substitute milk products, to obtain a previous authorization of the text from the product in question to the Department of Food Protection to the Ministry of Health.

Article 11. Unauthorize publications deceitful or ambiguous when:

- To make comparisons with the breast milk in order to discourage it.
- Contain images, paints, drawings of infants or texts that can idealize the utilization of the preparations for infants, the formulas of follow-up and other modified milks that are administered through feeding-bottle.

• The use of names that associate the products with breast-feeding, such as *maternized* or *humanized milk*.

Article 12. It is prohibited to the manufacturers and distributors to facilitate for the pregnant women and for the nursing mothers, directly or indirectly, and free of charge, products or utensils that promote the utilization of breast milk substitutes (except in the event of national disaster).

Article 13. The promotion and distribution of substitutes of breast milk, as well as of related utensils are prohibited in health services settings.

Articles 14 - 20. The container or label of the breast milk substitutes should contain in Spanish the following information:

1 The phrase *Important notification*.

2. The slogan *Breast milk is the best food for the infant*.

3. The need for requesting advice of a physician, nurse, or nutritionist before utilizing the product.

4. The instructions to prepare adequately the product, with the indication of the possible risks of an inadequate preparation.

5. The name and the complete address of the manufacturer.

6. The expiration date of the product.

7. The mention of the origin of the product (animal or vegetable) and the chemical elements utilized.

The labels of food supplements marketed as breast milk substitutes should contain the following:

1. Warning that the supplementary feeding should not start before the child is six months old.

2. The slogan *Breast milk is the best food for the infant*.

3. List of the ingredients utilized in the product.

4. The need for requesting medical advice before utilizing the product.

5. The conditions required for its storage.

6. The expiration date of the product.

Other milk labels:

1. For condensed milks or sugarcoated the warning *This product should not be used for the feeding of the infants*.

2. For whole milks skim or modified, fluid or in powder, the slogan *Breast milk is the best food for the infant*.

The labels of the related utensils should present the following phrase *Feeding with cup and spoon is safer.*

The modified milk containers should not include specific indications on their benefits in order to combat diseases.

Finally, the names of the products should not suggest associations with breast-feeding.

Articles 25 - 27. It mandates to the Costa Rican Social Security Fund:

1. To prepare and to deliver educational material to all pregnant women in order to stimulate breast-feeding.
2. To the training of the pregnant women to be prepared adequately for breast-feeding.
3. To give support for the pregnant woman.
4. To stimulate breast-feeding in the immediate postpartum.
5. To train health agents.
6. To give facilities so that the mother breast-feeds her child when they are hospitalized.
7. To promote and to protect breast-feeding.
8. To reject presents or benefits from the manufacturers or distributors of breast milk substitutes or other products marketed as such and of the related utensils. This determination is also valid for the health agents.

Rights of the working women during pegnancy and lactation in Costa Rica

Article 94 of the Working Code. It is prohibited to discharge a woman who is pregnant or breast-feeding her child; if this occurred she legally can negotiate with the work judge her immediate reinstatement.

Article 94 and 94 bis of the Working Code. Every pregnant woman has the right to receive free medical care, both in the prenatal period and during delivery.

Article 95 of the Working Code. Every pregnant worker has right to a rest paid of a month before delivery and three after delivery; in case of adopting a child she has right to three months of permission paid, from the following day in which she receives the child.

Article 97 of the Working Code. Every mother at time of lactation can have in the working place 15 minutes every three hours, or if she prefers it, twice a day half an hour during her tasks to be able to breast-feed her child, throughout the time that lactation lasts.

HIV/AIDS and breast-feeding

Until 1988, in the breast milk banks the *pools* (mixtures) of milks were carried out. That same year was dictated a regulation that disappeared that measure, which meant that the banks continued to function as it had been established, but without mixing milks. In 1990, considering the percentage of children who acquired the HIV infection through breast milk and the growing number of cases reported in women in Costa Rica, the decision to disappear all banks of breast milk in the country was taken, and donations of breast milk were prohibited.

Also in that same year the standard was set and it was counterindicated that under any circumstance mothers HIV carriers breast-fed their children. At the same time, the Costa Rican Social Security Fund provides artificial formulas substitutes of breast milk free of charge to all children of HIV infected mothers, until they turn one year old.

The program of Breast-feeding Clinics was created in 1994, as a strategy where all health agents who integrate it are total and really interested parties in promoting breast-feeding, and are capable of facilitating the population that thus requests it with appropriate information and practical knowledge in order to maintain breast-feeding, contributing to the solution of problems.

These clinics do not contradict, on the contrary, are based also on the measures of biosafety already presented by the country regarding infectious and contagious diseases.

For the year of 1997, the current regulation recommends:

1. Not to create breast milk banks.
2. To counterindicate breast-feeding in HIV/AIDS mothers (substitutes free of charge are offered during a year).
3. To support the lactation clinics and its biosafety measures.
4. Feeding the child exclusively with breast milk during the first six months of life, weaning from this moment on.
5. Breast milk plus other food until the two years of life.
6. By regulation, every newborn is also vaccinated against hepatitis B.
7. A newborn from an HIV-infected mother enters the protocol of HIV control at the National Children's Hospital.

Plans for 1998

1. HIV testing to every pregnant woman (confirmed).
2. Free viral load determinations in the necessary cases (confirmed).
3. Free antiretroviral triple therapy to all pregnant woman (confirmed).
4. Acquirement of pasteurizers to be distributed in the Lactation Clinics (confirmation pending).

Prevention and control of HIV/AIDS program. The Cuban experience

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Introduction

When in 1981 the first cases of what later was called Acquired Immunodeficiency Syndrome (AIDS) were reported, we did not know that we were facing one of the most serious problems, not only in health, but also socially, known until now. An example of what is previously expressed is that the estimate of people in the world who lived infected by the Human Immunodeficiency Virus (HIV), or patients of AIDS, to December 1996, was of 22.6 million; that on that same date there was a cumulative of 8.4 million cases of AIDS, of which 6.4 million had died. In 1996 it was estimated that 8,500 new people were infected daily. The social implications, together with the destabilization of the family affected by the disease and the death of one or more of its members and the abandonment of others, frequently children or elderly people and the economic consequences for several countries upon losing an important part of its work force.

In Cuba, although a prevention program was not structured as such until 1985, already since 1983 the Ministry of Public Health (MINSAP) created an interdisciplinary commission that dictated as first measures the prohibition of importation of blood derivatives of countries that had reported cases, and the establishment of a surveillance system for notification of cases with sarcoma of Kaposi or suffering recurrent pneumonia in all units of the MINSAP assistance network.

Development of the Cuban program

The Prevention and Control of HIV/AIDS Program in Cuba has been based on the following basic premises.

1. It is feasible to avoid the transmission through blood.
2. It is possible to limit to the minimum perinatal transmission.
3. Drug addiction does not constitute a problem in the country, which means that this way of transmission does not represent risk.
4. Sexual transmission constitutes the principal risk element.

The components of the program are made up by:

1. Epidemiological surveillance.
2. The educational component.
3. Medical care.
4. Laboratory.
5. Research projects.

Within epidemiological surveillance the investigation of all the blood donated is carried out so that this does not become an element of transmission of HIV; the examination is also prescribed for search for anti-HIV antibodies in pregnant women at the time they are reached by the family doctor. Those that are confirmed as HIV-infected an epidemiological survey is applied as well as a follow-up of their sexual contacts, associates and suspects; in addition an active investigation is carried out for the detection of HIV in other groups as: people who suffer some sexually transmitted disease and their declared sexual contacts, to the tuberculous ones, to prisoners, to people who request it, among others.

The educational component has an Intersectorial Plan in which in addition to the MINSAP participate the Ministry of Education, the Ministry of Higher Education, the Cuban Institute of Radio and Television, the Ministry of Culture, the Cuban Federation of Women, the Young Communists Union, the Students of the Intermediate Education Federation, the University Students Federation, the Revolution Defense Committees, among other organizations and organisms, which join their efforts in the confrontation of AIDS and contribute, in different forms, to its prevention.

Other important aspect of the educational component are the communication campaigns directed to the general population and to vulnerable groups. A responsible sexuality is also promoted through multiple, interpersonal, and group educational strategies, as well as through a methodology of participatory action.

The medical care component involves outpatient care to seropositives or patients and prevention activities, and hospital care, that should be planned increasingly toward the community through the action of the AIDS Prevention Groups (GPSIDA), and the multidisciplinary control that serves as carver of risky behaviors and counseling. Another aspect of medical care is the strengthening of hospitals and the enhancement of the third level care for the attention of HIV/AIDS cases.

The laboratory and research components have been complementary to all the work that has been developed during these years.

Results

As a result of the broad active investigation that has been developed from the beginning of the year of 1986 to date (19,894,186 determinations) 1,770 people have been detected as seropositives to HIV, of which 637 have developed AIDS and 471 have died. 73.7% of the seropositives detected are males.

Of 1,985,961 determinations of anti-HIV antibodies done in pregnant women only 30 have been positive and of them 18 decided to interrupt pregnancy.

Forty seven children were born from seropositive mothers to HIV, of which 17 were discharged as uninfected, 5 were born infected and in none there is evidence of being infected by breast-feeding; 25 of them are under study.

Twelve people have been infected by blood transfusion or its derivatives, 9 of them before 1986, date when the investigation began .

Conclusions

In Cuba, the HIV/AIDS epidemic has grown slowly. Transmission by blood or blood derivatives has been minimums and is controlled.

- Perinatal transmission has been minimum.
- There is no evidence of HIV infections attributable to breast-feeding transmission.

Epidemiological situation of HIV infection in Honduras. The case of perinatal transmission

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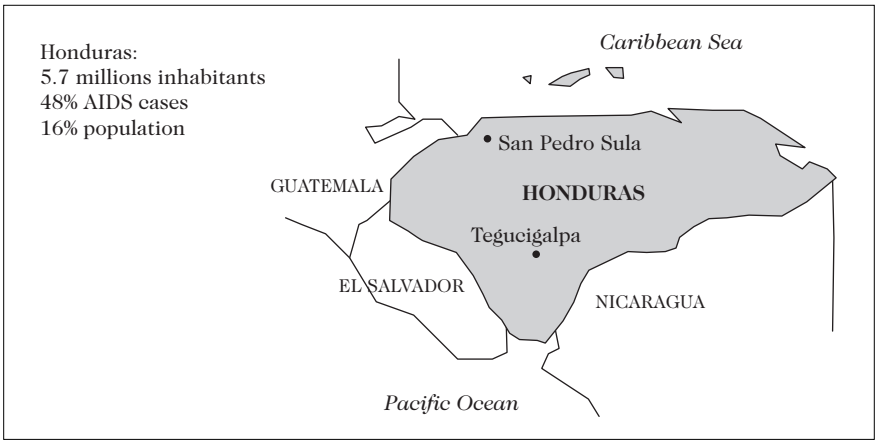
The Republic of Honduras is located in the Central American Isthmus, surrounded by the republics of Guatemala, El Salvador, and Nicaragua. Up to June 1997 its estimated population was of 5.7 million inhabitants, equivalent to 16% of the Central American population. However, its report of cumulative cases of AIDS to the Pan American Health Organization represented 48% of the total of cases reported in the entire isthmus.

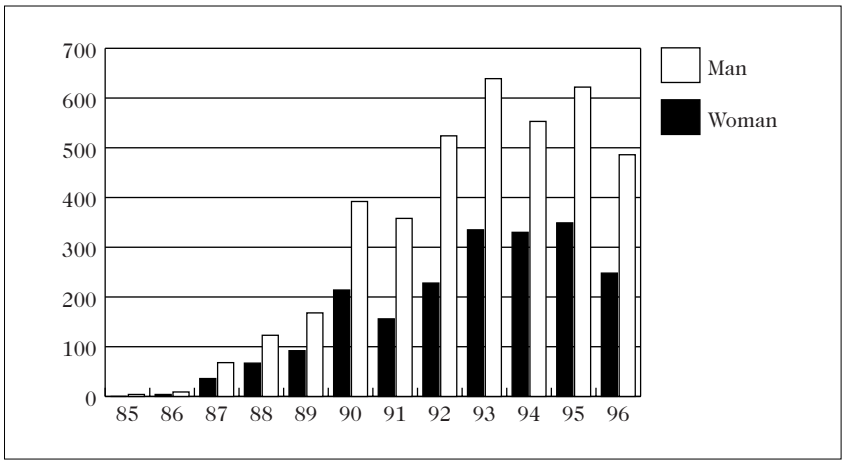


From the report of the index case in 1984 up to 30 June of the present year the Division of STD/AIDS of the Ministry of Health of Honduras has recorded a total of 7,635 cases of AIDS reported by the health services network. The annual incidence of cases in the country has seen an increase of 50 cases per million in the 1980s to 134.6 per

million in 1995. This amounts to an approximate average of 800 annual cases of AIDS.

Originally HIV/AIDS epidemic showed a pattern of eminently homosexual transmission, having reported proportions male:female of 10:1. As the epidemic advanced in time, a shift has been observed toward heterosexuality, with a proportion male:female of 1.8:1. The increase of infected women at childbearing years began to make clear the presence of cases of AIDS in the pediatric population of the country. However, the proportion male:female has maintained thus for the last four years, which has obliged the STD/AIDS Division to explain that "excess of men" through the poor classification in some of its cases of AIDS in men that were self-identified as heterosexual, being really homo or bisexual.

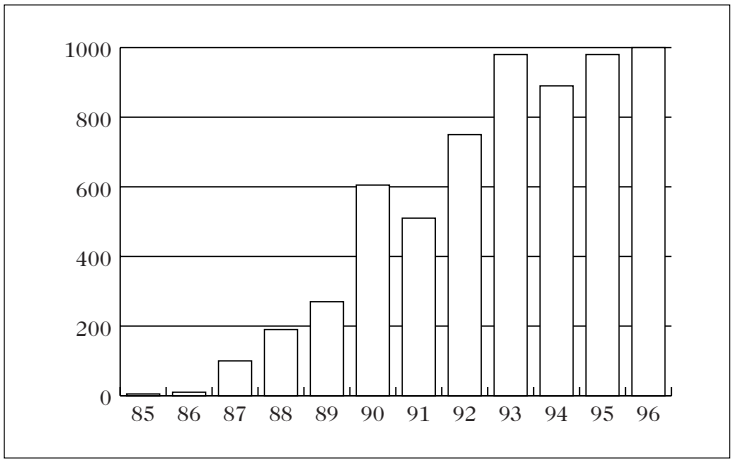
Figure 1



Sixty percent of the AIDS cases were reported in the northwest sector of the country, particularly in the city of San Pedro Sula. This sector is the industrial center of the country, which favors the migration from other regions, particularly of young people of both sexes that come

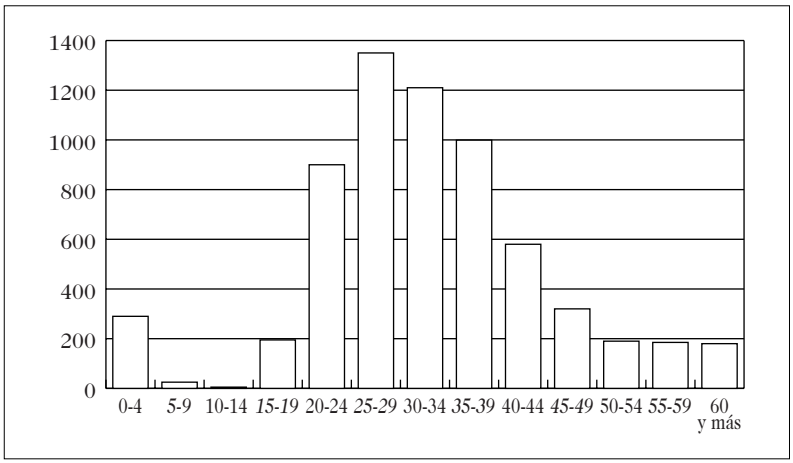
to join the economically active population of the country. Other cities within this geographical belt of high incidence are Puerto Cortés, La Lima, El Progreso, Tela, La Ceiba, and Trujillo.

Figure 2
Cases of AIDS per year



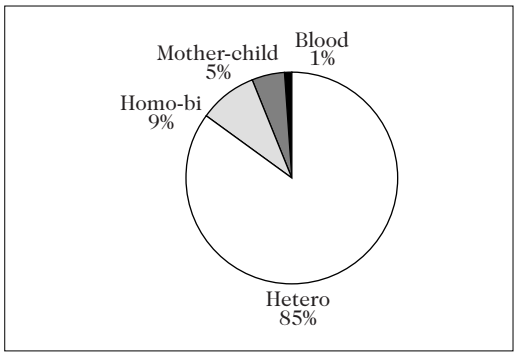
It is in this economically active population, that exactly agrees with the population with more marked sexual activity, where AIDS epidemic has manifested with greater emphasis. The most affected age group is the one than is between 20-39 years, representing approximately 70% of all the cases from the beginning of the epidemic. Nearly 20% of the cases have been reported in the group between 15-24 years. To children under 5 it corresponds 5% of the report.

FIGURE 3
Cases of AIDS by age groups



Of the AIDS cases reported through June 1997, the proportions in accordance with the way it was acquired are: 85% in heterosexual population, 3.0% in homosexuals, 6.0% in bisexuals, 4.9% by perinatal transmission, 0.8% by blood transfusion, and 0.1% by intravenous drug addiction.

FIGURE 4
Cases of AIDS according to way of transmission

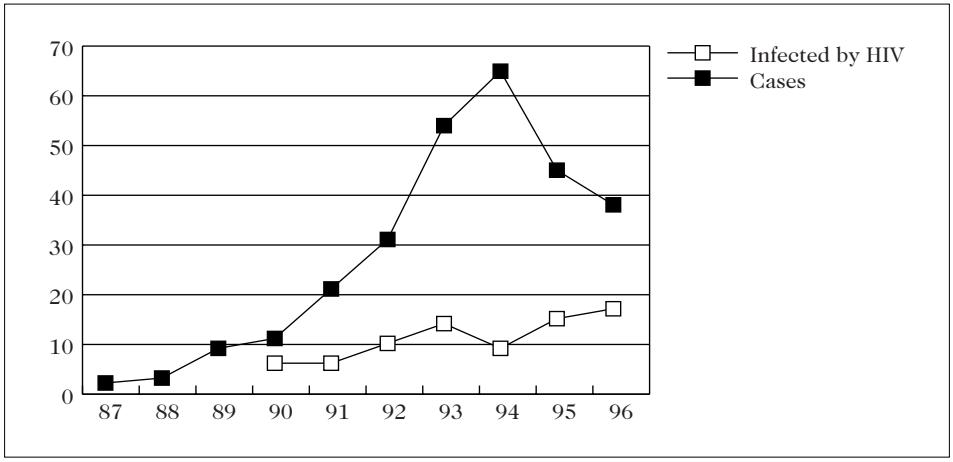


The perinatal transmission

The STD/AIDS Department of the Ministry of Health of Honduras is aware of the magnitude of the problem of children who are born of women infected with the human immunodeficiency virus. There is a recognition of its impact on family and on society, which should be faced decidedly. Despite the fact that the prevalence of HIV estimated for the country is 1%, in the northwest sector (the most populated) levels have been detected between 2% and 4% through studies of sentinel monitoring in clinics of prenatal care during the last six years.

Despite the problems of underdiagnosis of pediatric AIDS with regard to the similarity of its clinical manifestations with the characteristic morbidity processes of our environment (diarrheal diseases, respiratory infections, malnutrition), to date there are 400 AIDS cases notified in children under 5.

Figure 5



To date the magnitude of the epidemic, with a predominance of heterosexual transmission, has impeded the implementation of strategies of prevention of the transmission of the infection of HIV, as protocol 076. Although it is certain that this intervention could have started par-

tially, the non-ethical aspect of this alternative together with the lack of guarantee of sustainability has stopped the initiative.

In addition, with regard to the suspension of breast-feeding in women infected with HIV that become pregnant, the official position up to date has been that, in view of the fact of not being able to meet the needs for milk substitutes of the children that would cease to be breast-fed, and considering the recommendation of WHO based on the benefits of breast-feeding still in infected mothers by HIV, not to suspend maternal lactation.

The strategies utilized to address this problem have consisted in:

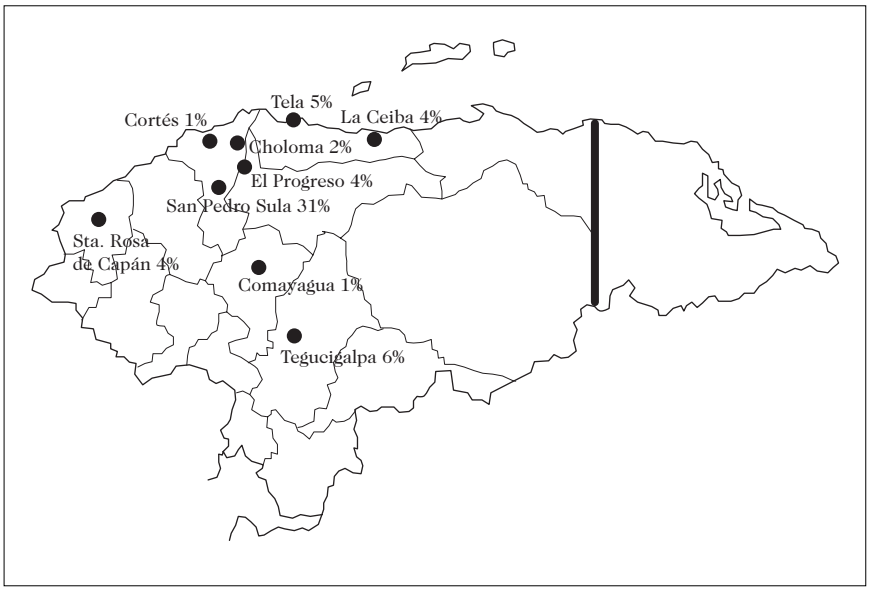
- Counseling services on reproduction in clinics of woman care.
- Counseling services on STD/AIDS in the clinics of the network of services of the Ministry.
- IEC directed to adolescents of both sexes, within the framework of interventions of the formal sector (in collaboration with the Ministry of Education) and of the informal sector.
- IEC in prenatal clinics.

The future

The draft legislation in discussion in the National Congress currently contains provisions in order to guarantee milk substitutes to children of HIV-infected women, among other rights. This law comes to fill a gap felt by Hondurans living with HIV.

It will remain pending still, and depending on the results of the studies of short AZT therapy that are currently carried out in Africa under the responsibility of UNAIDS, to implement this other strategy and to prevent even more cases of children with AIDS. In that way, Honduras will succeed in being consonant with the lines of prevention already in practice in other developing countries.

Geographical distribution of perinatal AIDS cases in Honduras 1985-1996



Source: STD/AIDS Department

Recommendations for the management of pregnant women with HIV infection

*Griselda Hernández**

* National Council of AIDS Control and Prevention, Mexico

In Mexico 32,216 cases of AIDS have been reported up to October 1997. However, considering delays and underreporting 51,000 cases are estimated; of these 16% corresponds to women. The trends that have been observed in recent years are the progressive reduction of the cases of AIDS by blood transfusion and the increase of the proportion of cases in rural areas, being observed two polar patterns of transmission of AIDS: one urban that is presented in the large cities and on the northern border, with predominance in men and a greater percentage of homosexual transmission, with a small proportion of transfusion cases and duplication periods greater than 18 months. The second pattern is rural, it is presented in the center of the country, and in the south with predominance in women, a greater heterosexual transmission, high frequency of post-transfusion cases and with shorter duplication periods.

Due to the important decline of cases in women due to to blood transmission, at present despite the gradual increase of secondary cases to heterosexual transmission it still does not have an impact on the cumulative case curve. In the analysis of the cumulative cases in children under 15 up to October 1997 it is observed that 61% is secondary to perinatal transmission, and that 78% of the mothers declared to have had sexual relations with an ill person of AIDS or HIV-infected, which shows the increase of sexual transmission in women and its consequences.

It has been calculated that in Mexico there exist approximately 4,200,000 pregnancies yearly, of which only 60% arrives at the end of gestation —that is, that 1,700,000 pregnancies are lost in their early stages. In 1990 2,735,312 live births were reported throughout the country. In various sentinel surveys conducted in pregnant women of 12 entities of the Mexican Republic there has been found a cumulative average prevalence of 0.001% and in recent years of 0.04%, which means that to date we

have the possibility that up to 4 of each 10,000 pregnant women who have children are HIV-infected, and taking into account the current fertility rate we expect annually 1,094 infected pregnant women.

In Mexico, in accordance with the prevalence found in pregnant women and the rate of perinatal transmission it is expected that annually there are born 330 HIV-infected children, of which the infection could be prevented in 220 children administering AZT during pregnancy and to the newborn in accordance with the reduction in 67% reported from protocol ACTG 076. It is for this reason that starting in 1995 CONASIDA in Mexico recommended offering the screening for HIV to pregnant women voluntarily and confidentially and free of charge the treatment with AZT for the mother during pregnancy, the day of childbirth and to the newborn during 6 weeks. However, so far there have been given only 22 treatments and despite having trained previously the personnel responsible for the obstetric attention we continue to face problems of denial of care.

With regard to the prevention of the transmission through breast-feeding it is recommended:

• The criteria that have been considered to date in order to determine the local policy of lactation or feeding for the infected mother children are: seroprevalence to HIV in the women of urban and rural areas, local neonatal feeding practices, duration of lactation, beliefs associated with lactation, ability to provide and sustain an adequate artificial feeding, costs of the artificial feeding, local mortality associated with artificial lactation, levels of schooling of infected women, quality of the existing services for women, stigmatization and discrimination potential existing in the area and availability of screening for HIV with adequate counseling conditions.

• In localities where infectious diseases and malnutrition are the leading causes of mortality, if an adequate diet with artificial lactation cannot be ensured, maternal lactation should be recommended systematically, including from those HIV-infected.

• In regions or in groups of people in which infectious diseases and malnutrition are the leading causes of infant mortality, but there can be ensured an adequate artificial feeding with all the conditions necessary for its preparation, storage, cleaning and maintenance, artificial lactation should be recommended.

• In localities or in cases in which infectious diseases and malnutrition are not the leading causes of infant mortality and the necessary resources are available, breast-feeding will not be recommended.

Since Mexico has a mosaic of social, economic, and cultural situations, any general or local policy should be flexible and individualized. All the viable alternatives to replace breast-feeding in infected women and diminish the risk of transmission of HIV through the use of substitutes from breast milk, should be sought.

However, in all cases of pregnant women HIV positive detected on a timely basis and that receive prophylactic treatment with zidovudine should be discouraged breast-feeding, since otherwise the effectiveness of the prophylactic treatment diminishes.

The AIDS epidemic in Paraguay

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*Gertrudis Teme**

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Once analyzed the number of cases recorded of the Acquired lmmunodeficiency Syndrome (AIDS) in Paraguay up to October 1996, it can be observed that its impact on the population is sustained and regularly rising. During the first four years from the appearance of the disease, the annual median number of cases did not reach 10; during the following 5-year period 20 cases have occurred per year, and in the last four years 46 were diagnosed, 25, 24 and 46 cases, respectively, each year (Table 1).

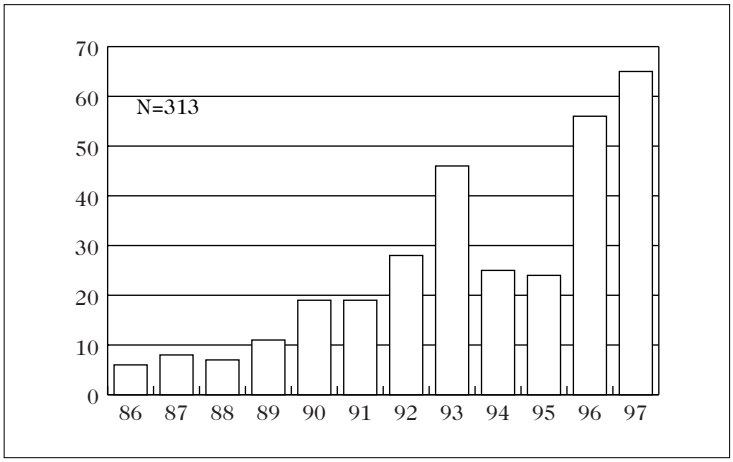
TABLE 1
*AIDS cases according to diagnosis and cumulative cases per year Paraguay, 1986-1996**

Year	No. of cases	
	In the year	Cumulative
1986	6	6
1987	8	14
1988	7	21
1989	11	32
1990	19	51
1991	19	70
1992	28	98
1993	46	144
1994	25	169
1995	24	193
1996	46	239
Total		239

Source: National Program Against AIDS
*Preliminary data up to 31 October 1996

The first case of AIDS was reported in 1986, since then a total of 313 cases (Figure 1) have been registered in the National Program Against AIDS. In 1986 it was registered the lower number of cases (6), and to October 1996, the greatest one (46); the reduction observed in 1994 and 1995 could be due to limitations in the capacity for search and diagnosis and not to a real reduction in the incidence.

Figure 1
AIDS cases by year
Paraguay, 1986 to October 1997



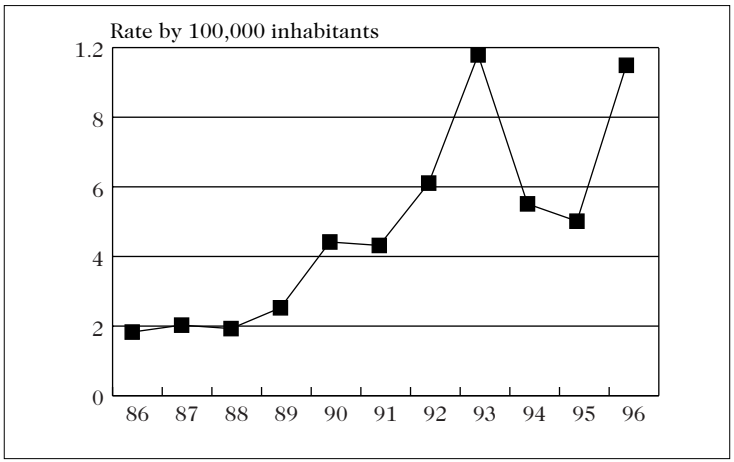
Source: MSP and BS/PNLS

The evolution of cases shows a gradual accumulation and the acceleration of the transmission in some particular period is not identified.

In recent years the annual incidence rate has approached 1 case of AIDS per 100,000 inhabitants, with the exception of Bolivia this is the lowest rate in the American Southern Cone countries (Figure 2).

The most affected age groups are those related to sexual transmission, where the group from 30 to 34 years present the highest rate (16,01%), considering the accumulation of 239 cases from the beginning of the epidemic in Paraguay until October 1996 (Table 2). Analyzing the

FIGURE 2
AIDS incidence rate
Paraguay, 1986 to 31.10.96



Source: National Program Against AIDS.

TABLE 2
AIDS incidence rate according to age
*Paraguay, 1986 to 1996**

Age Group	N° of Cases	Inhabitants Inhab. middle period=1991	Rate x 100,000 inhab.
< 15	8	1,770,123	0.45
15-19	3	447,846	0.67
20-24	48	405,805	11.83
25-29	42	367,236	11.44
30-34	52	324,830	16.01
35-39	36	288,278	12.49
40-44	27	195,035	13.84
45-49	10	145,896	6.85
50 y +	12	452,258	2.65
Desc	1		

Source: National Program Against AIDS.
* Preliminary data up to 31 October 1996

age distribution over the years it seems that there exists a displacement toward older groups, trend that would probably be explained by the time that elapses from the moment of the infection to the diagnosis of AIDS. It is known that the best diagnostic opportunity is given in the period of infection, and reality shows that a good proportion of detection is occurring actually in the stage of case of AIDS, when not already of dead by AIDS.

The available information on HIV infection in Paraguay corroborates the previous hypothesis being observed that the medium infection age every time is actually smaller. The AIDS epidemic in Paraguay is increasingly young.

The distribution of cases and its respective incidence rates by sex show that the epidemic in Paraguay affects steadily and increasingly males, emphasizing notably that every time is more feminine. In 1990 for the first time cases of AIDS were registered in women, five years after the initiation of the problem, occurring from then on a number of cases of AIDS in women of some 10 per year (Table 3).

Table 3
AIDS incidence rate according to sex
*Paraguay, 1986-1996**

	No. of Cases		Inhabitants		Rate x 100,000	
Year	Males	Women	Males	Women	Males	Women
1986	6	0	1,927,052	1,879,977	0.31	0
1987	8	0	1,985,776	1,936,597	0.40	0
1988	7	0	2,045,117	1,994,043	0.34	0
1989	11	0	2,105,054	2,052,231	0.52	0
1990	15	4	2,165,568	2,111,080	0.69	0.19
1991	19	0	2,226,667	2,170,630	0.85	0
1992	27	1	2,288,392	2,230,935	1.18	0.04
1993	35	11	2,350,688	2,291,936	1.49	0.48
1994	19	6	2,413,548	2,353,569	0.79	0.25
1995	17	7	2,476,914	2,415,773	0.69	0.29
1996	35	10	2,497,196	2,458,041	1.40	0.41

Source: National Program Against AIDS
* Preliminary data up to 31 October 1996

Sexual transmission represents 66% of the 239 recorded cases to date. At the beginning the pattern of transmission was directly related to homosexuals, being observed with the course of the years that at present heterosexual transmission has more importance than homosexual transmission (Table 4).

TABLE 4
Cases of AIDS according to category of transmission
*Paraguay, 1986 to 1996**

Category	No. of Cases	%
* Sexual Transmission:	158	66.11
- Heterosexual		
- Homosexual	70	29.29
- Bisexual	69	28.87
	19	7.95
* I.V. drug addiction		
* Perinatal	28	11.72
* Blood Transf.	7	2.93
* Unknown	9	3.77
	37	15.48
Total	239	100.00

Source: National Program Against AIDS
* Preliminary data up to 31 October 1996

Almost 12% of the cases recognize the intravenous drug addiction as transmission mechanism, being 3.77% of cases related to blood transfusions, and 2.93% to perinatal transmission. Is important to point out that AIDS in Paraguay is increasingly related to intravenous drug addiction and that proportionately cases related to sexual transmission are fewer each year (Table 4).

Prevention of vertical transmission of HIV in Peru

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* National AIDS Program Coordinator, Ministry of Health, Perú

This chapter presents epidemiological information, data on legal standardization, and data on the implementation of the program for prevention of vertical transmission of HIV in Peru.

In Peru the epidemic was introduced in 1983 and until 1997 there were reported more than 6,000 cases of people with AIDS. We know that this number has been increasing and that after 1995 there are more than 1,000 cases of AIDS per year. As it occurs in other countries of the region, the male-to-female ratio declines with the course of the years. For the year of 1990 the male-to-female ratio was of approximately 10:1, declining to nearly 3:1 in 1996. We recognize that approximately 20% of cases of AIDS in Peru occur in women and only near 2% of the cases are due to vertical transmission.

With regard to prevalence surveys, in pregnant women in Lima it is of 0.3%, according to a study conducted in the year of 1996 among 3,546 pregnant women tested in 10 hospitals of Lima. This seroprevalence survey was anonymous unrelated, utilizing the surveillance system of congenital syphilis, that is free and compulsory in the country. It does not exist a census of women who stopped participating in the study. In the ten hospitals in which the study was conducted a period of ten consecutive weeks was utilized. It was practiced the test of syphilis and subsequently the anonymous linked to the test of HIV to all women who arrived at the time of delivery.

The test was carried out at the time of delivery and not in the first prenatal checkup since at least 50% of women with institutionalized delivery in Peru do not have prenatal checkup. As a result, it was decided to utilize a survey at the time of delivery. There are sentinel posts in eight cities of the country, outside Lima; however, these positions do not make it possible to estimate accurately the HIV-prevalence; only one of them

reports that the prevalence of HIV in other cities of the country is at least of 0.05%.

In tandem the legal standardization has been developed on HIV in Peru. Although the program for prevention of vertical transmission utilizing protocol 0076 is enforced since February 1996, the standardization barely was instituted until June 1997, same month in which appears the regulation to law 26626. The article number 10 of said law establishes that the Ministry of Health will arrange the provision of the budgetary resources so that:

a) HIV-infected pregnant women receive antiviral treatment, provided free of charge, in the scheme and by the time recommended by PROCETSS; and

b) every child stemming from HIV-infected mother receive antiviral treatment and be provided with artificial lactation free of charge.

Despite the fact that the program was launched in February 1996, it is until June 1997 when a standardization is established that permits or guarantees the program's sustainability. In addition article 11 mentions that diagnostic tests of HIV infection can only be carried out after counseling and written authorization from the person involved.

Here we have mentioned only these two articles, but the 30 articles that constitute the cited law guarantee the rights with regard to autonomy, confidentiality, health, and work for people with HIV.

In a study conducted in the year of 1996 in the Maternity of Lima (it is worth pointing out that of 20,000 annual deliveries this hospital attends 15% of them, which converts it into the hospital that more deliveries serves of the country) by Dr. Jorge Alarcón in collaboration with the University of Washington, in which 12,500 pregnant women participated, risk factors were evaluated for HIV infection in pregnant women to diminish the screening costs in this population.

The multivariate analysis of the study of Dr. Alarcón demonstrated that the factors related to seropositivity of pregnant women were the following: to have had the first sexual relation before 18 years and to have more than one sexual partner. The time of union with the current couple would be a protective factor: this means that per every year the union increases a 40% of reduction in the possibility of being infected is available.

The belief that the husband was a woman chaser had an odds ratio of 2.0; that the husband used drugs was of 3.3 (it concerns non-in-

travenous drugs, since in the country the intravenous drugs do not represent a serious problem); knowledge that the couple was HIV infected had an odds ratio of 26.8.

The last three variables refer to the medical history of the patient. To have had a sexually transmitted disease had an OR of 2.8; to have had tuberculosis, 4.6; have had an abortion was of 2.4. These OR's are adjusted by all other variables in the same model.

Dr. Alarcón evaluated the risk utilizing significant variables in the multivariate study and found that the number of women who have at least two of the four following variables: stable couple, a union of less than two years, preceding of STD, preceding of tuberculosis, amounts to 67% of the population and to 90% of the seropositives.

Screening utilizing history variables would make it possible to rationalize the tests of HIV and diminish the costs, maintaining a great sensibility of around 90%.

Based on the previous data, in Peru counseling services are being currently implemented, taking into consideration that 80% of the cases of AIDS of the country are in Lima, the capital of 7,000 inhabitants, and 95% of the cases of vertical transmission also are found in Lima. Our initial objective was to launch the program in Lima. At present all Lima hospitals have counseling services. Screening is voluntary, although still the aforementioned risk assessment is not implemented. The next step is to initiate this risk assessment and to introduce it prior to the screening of HIV, which would facilitate or would decline the costs of screening. In addition, there are antiretroviral treatments available in the aforementioned hospitals in Lima, as well as in three centers outside the capital. Outside Lima a network of distribution of drugs has been organized. So far there exist three networks in the north, the south and the east, taking as basis department capitals.

In conclusion, drugs are available in ten hospitals of Lima and in three cities of the interior.

With regard to artificial lactation, although the program envisaged it since the year of 1996, there was not budget for it. The law approved in June 1997 allocated budget for free artificial lactation, which will be carried out starting in 1998, once approved the corresponding budget.

Promoting breast-feeding in a world with AIDS

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* National Program of Control of STD/AIDS Diseases (PROCETSS), Dominican Republic

In 1992 the World Health Organization and the United Nations Children's Fund published the recommendation that has guided most countries in the preparation of national standards with regard to breast-feeding in case of HIV-infected mothers.

The slogan of the celebration of the World Day of AIDS in 1997 was *Children living in a world with AIDS* and the efforts should be directed to mobilize and sensitize the population about the situation that boys and girls will face as a consequence of the AIDS epidemic.

Those living in the so-called developing countries understand, suffer and live daily the effects of childhood in a world with AIDS. For this reason we have to discuss the ethical and practical consequences of the application of this recommendation and standards of breast-feeding and the HIV-infected mothers in places where the leading causes of death in children are infectious diseases.

Some basic data about the situation of the Dominican republic are first presented.

• The Dominican Republic is a country of over 8 million inhabitants and we occupy 48,734 square kilometers of the eastern part of the island La Española. In the ethnic composition it prevails the racial mixture. Women represent 50% of the total of the population, and those which are in their childbearing years represent 24% of the total population. Sixty one percent of the population lives in the urban area.

• The crude death rate between 1991 and 1996 was 6.8 per 1,000. The fertility is of 3.2 children by woman at childbearing age. In the first year of life 43 children die per 1,000 live births and of those of 1-4 years 57 per 1,000 die. It is estimated a maternal mortality of 229 per 100,000. The life expectancy is 67 years.

• Acute diarrheal disease continues to be the leading cause of infant mortality being the second cause of morbidity with an annual incidence of 7 episodes per child and with an approximate duration of 5 days by diarrheal episode.

• Acute respiratory infection is the leading cause of child morbidity with an average of 10 episodes by child per year and with an approximate duration of 7 days by episode.

• Chronic malnutrition is found in 11% and overall 6% among the population under 5 years of age.

• The conditions of the dwellings and the limitations to the access to the basic services are the determining causes of which our country occupies the sixth place among the Latin American countries with smaller index of human development.

In the Dominican Republic we have always recognized that breast-feeding promotion should be a priority as a great impact strategy in the reduction of child morbidity and mortality, poor nutrition and birth rate.

Breast-feeding represents the cornerstone of all programs for survival and child development, it contributes to the spacing of pregnancies and as a result, in the majority of cases, to a safer motherhood. Everyone acknowledge breast milk as ideal food, is matchless and superior than any other type of animal milk or formula, despite the fact that science and technology have made an effort in imitating it. Its uniqueness lies in its biochemical, immunological, and emotional properties, to which should be added its economic value and even the mechanism whereby it arrives usually to the boy/girl, this is, by breast-feeding.

The relation that is established between the mother and the boy/girl is of such reciprocity that determines an optimal growth, and development, the survival of the boy/girl and the mother's physical, and emotional well-being.

The progress of the country in the promotion of breast-feeding has been impressive. I will only mention some of the most important:

• The Ministry of Work carried out a Modification to the Working Code favoring breast-feeding

• The Ministry of Education included in the programs for elementary and basic school the importance of breast-feeding.

• The Ministry of Public Health and Social Welfare, with the National Commission of Breast-feeding, have certified nine Hospitals Friends of Childhood, achieving important changes in the standards and procedures of public hospitals; they have formed community support groups; launched educational campaigns; worked with medical and nursing staff, and community and with lawmakers.

• In 1994 it was approved the law that declares as national priority the promotion, education, and encouragement of the practice of breast-feeding.

Supported by these efforts we have succeeded in increasing exclusive breast-feeding in the last five years (1991-1996) from15% to 39% in the first month of life; from 4.5% to 25% between two and three months, and from 0.3% to 6% in boys/girls of 4-5 months. The medium duration of lactation increased from 9 to 10 months. However, we lack a great deal to achieve since the levels of exclusive breast-feeding are low and 80% receives feeding-bottle in the first month.

Despite all these efforts and achievements now we face a new dilemma: to decide what we should make with this marvelous product in those mothers that are HIV-infected and confront the risks of these babies to acquire the infection through breast milk or die of another disease due to hygiene conditions and to poverty.

With sadness I report that in the Dominican Republic the growing acceptance of exclusive lactation until 6 months is facing the growing HIV/AIDS reality. As of August 1997 4,047 cases of AIDS were reported with an estimated under reporting of 50-70%. It is estimated that there are more than 200,000 HIV-infected adults. Each day more women are being infected with HIV, which makes it possible to foresee that the perinatal transmission will begin to increase. The prevalence of HIV in pregnant women ranges between 0.3% and 7.9%.

We have had to think profoundly about the national standards with respect to breast-feeding and HIV. We believe tha each woman and her partner should take informed decision.

Based on the evidence scientifically demonstrated, as general standard breast-feeding should not be recommended to HIV-infected women. But we should take into account at all times the feelings of infected women and respect their decision and their emotional needs. It should also be taken into account the situation of the developing countries, in which it is necessary to make understand the family that lives

in very adverse environmental conditions, that in this case the option of breast-feeding can surpass the risk of dying as a consequence of the feeding-bottle.

Now then, in the face of the terror and the rejection that remains in the population with regard to AIDS, is a mother with little educational level capable of understanding this message, and are the health workers, with their own barriers, capable of orienting her objectively so that she makes her own decision?

The positive effect of breast-feeding on the reduction of the infant mortality rate is well documented. According to 1990 data of the Center of Maternal and Child Health Research, the infant mortality rate of boys/girls who breast-fed was of 18.7 per 1,000 live births and in the not breast-fed it amounted to 560 per 1,000 live births.

In other countries it has been estimated that deaths due to HIV through breast-feeding are between 1,000 and 19,000, depending on the estimate used with regard to the transmission rate (1%, 5%, 10%, 20%). The calculations of additional deaths due to child diseases associated with the elimination of breast milk fluctuate between 10,000 and 75,000.

We should recognize that we face a dilemma and a crisis in which ethics and moral are involved, since we recognize that exclusive lactation until 6 months is optimal for a child feeding, it is not less certain that of every 100 boys/girls born of HIV+ mothers, 33 potentially suffer from the disease. We should also safeguard the other 67% that is potentially HIV–. The measures that we take will determine their survival.

We are breast-feeding promoters but should recognize that it is not ethical nor moral to continue insisting that babies should be breast-fed, when serious and convincing studies indicate that with this practice babies born HIV negative might be infected as the studies of Brazil and Tanzania have demonstrated.

The recommendation to a HIV+ mother, living in poverty, that she should breast-feed is still more difficult regarding recent studies that indicate that, possibly, the duration of lactation should be limited depending on the nutritional and health status of women.

These are the main arguments on discussion. What to do? First, every woman, every family, has the right to obtain all the information necessary for making a decision and has the right to health services that can give them comprehensive care, emotional support, timely and appropriate information.

We do not have the right to deprive any human being of the right to live, but we should offer what is safe. In these circumstances it is possible that breast-feeding is no longer safe.

Thus we urge the international community that supports us in the search for a solution of this dilemma and in the way of giving the information and attention that is a right. There are not doubts that breast-feeding is the healthiest choice for the baby, and in the developing countries is the preferred practice, most desirable, and economic for the family. However, we do not have adequate responses for the population and it is necessary to continue investigating, particularly in our countries, the effects of breast-feeding for the baby of an HIV-infected mother, the effects of breast-feeding in the health of the HIV+ mother and up to when she should continue breast-feeding her baby. We should continue investigating and expanding the access to treatments for pregnant women infected, in order to reduce the perinatal transmission of the virus.

We hope to benefit from this debate on breast-feeding and HIV/AIDS and from the experiences of other countries in the search for solutions to this dilemma, in order to strength our health systems and, especially, for the well-being and health of our peoples.

HIV and breast-feeding in Venezuela

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Epidemiological data

Venezuela is a country that belongs to the Andean area as well as the Caribbean region. It has a population of 21 million inhabitants. Its population is young and is distributed in 23 states, the majority in urban areas.

The first case of AIDS was notified in 1982. Since then and up to September 1997 we have 7,024 cases recorded with 4,081 deaths (Table 1). The incidence rates were increasing from 0.01 per 100,000 inhabitants in 1982, to 3.24 in 1990 and 5.17 in 1994; then a decline was observed due to under reporting and the reporting delay, even though it is a compulsory reportable disease.

The epidemic predominated among males (90%). The male-to-female ratio is 9:1, currently varying the same in some states up to 4:1. The most affected ages are the group from 20 to 44 years, with greater impact on that of 30-39 years. It is the third cause of death in the group of 25-30 years in the country (Table 2).

The main category of transmission is sexual (90%), occupying in recent years the heterosexual transmission the second place (33%) and the homosexual the first place (48%). The perinatal transmission is of 3%, which reflects the increase of heterosexual cases and the reduction of the male-to-female ratio. The transmission by blood and by drugs has not increased and is of 4% (Table 3).

Table 1
Acquired Immuno Deficiency Syndrome.
Cases and deaths by year and rates by 100,000 inhabitants
Venezuela 1982 September 1997

Years	Cases	Rates	Deaths	Rate
1982	1	0.01	1	0
1983	4	0.03	4	0.02
1984	18	0.11	17	0.10
1985	32	0.19	25	0.14
1986	76	0.43	65	0.36
1987	172	0.95	124	0.67
1988	362	1.93	232	1.23
1989	458	2.38	298	1.55
1990	625	3.24	461	2.39
1991	731	3.70	521	2.64
1992	884	4.37	554	2.74
1993	973	4.70	596	2.88
1994	1090	5.17	648	3.07
1995	799	3.70	319	1.48
1996	650	2.92	177	0.80
1997	149	0.66	39	0.18
Total	7024	30.84	4081	17.92

Source: Epidemiological Surveillance. STD/AIDS-MSAS Division

Table 2
Acquired Immuno Deficiency Syndrome.
Deaths according to age and sex
Venezuela 1982 September 1997

Age	Male	%	Deaths	Fem.	%	Deaths
-2	59	0.94	24	38	5.41	23
2-4	21	0.34	11	18	2.56	10
5-9	20	0.32	11	5	0.72	1
10-14	18	0.28	14	5	0.72	2
15-19	107	1.70	46	21	2.98	4
20-24	596	9.43	330	79	11.24	40
25-29	1320	20.88	744	132	18.77	68
30-34	1479	23.40	874	130	18.50	78
35-39	1106	17.50	663	105	14.94	50
40-44	705	11.15	431	64	9.11	39
45-49	362	5.73	225	45	6.41	26
50-54	204	3.23	145	19	2.70	14
55-59	110	1.74	76	9	1.27	5
60-64	61	0.96	46	8	1.13	6
65-69	36	0.56	19	6	0.86	2
70-+	20	0.32	11	1	0.14	1
Desc.	97	1.54	36	18	2.56	6
Total	6321	100	3706	703	100	375

Source: Epidemiological Surveillance. STD/AIDS-MSAS Division

Table 3
Acquired Immuno Deficiency Syndrome.
Cases and deaths according to category of transmission
Venezuela 1982 September 1997

Category of trans.	Cases	%	Cases				Deaths			
			Masc.	%	Fem.	%	Masc.	%	Fem.	%
Sexual	4148	89.99	-	-	-	-	-	-	-	-
Homosex	1977	47.66	1977	48.08	-	-	1054	48.66	-	-
Heterosex	1362	32.84	963	23.42	399	80.28	432	19.95	205	79.46
Bisexual	809	19.50	800	19.67	-	-	478	22.07	-	-
Blood	117	2.54	91	2.21	26	5.23	56	2.59	16	6.20
Trans. accs.	50	1.09	24	0.58	26	-	15	0.69	16	-
Hemoph.	67	1.45	67	1.63	-	-	41	1.89	-	-
Drugs	99	2.15	85	2.07	14	2.82	41	1.89	6	2.32
Perinatal	134	2.91	76	1.85	58	11.67	35	1.61	31	12.02
Mixed/hbd	111	2.41	111	2.70	-	-	70	3.23	-	-
Known	4609	65.62	4112	65.05	497	70.70	2166	58.45	258	68.80
Unknown	2415	34.38	2209	34.95	206	29.30	1540	41.55	117	31.20
Total	7024	100	6321	100	703	100	3706	100	375	100

Source: Epidemiological Surveillance. STD/AIDS-MSAS Division

Perinatal transmission

The increase in perinatal transmission is of great concern for the OPL/AIDS. Sentinel surveys were conducted for four years in several states (5) and in several hospital centers. The last one conducted in 1996 and that included 5,000 samples from the outpatient and prenatal clinics found ten people positive to HIV antibodies.

With the arrival of the antiretroviral treatments arrangements were carried out for their acquisition, since only the INSS (Social Securities National Institute) administers them to its patients; what was done is that the assigned mothers and their children received treatment controlled by the Children's Hospital.

Regarding hospital and private clinics, we know that the pregnant woman is requested for the HIV test in her controls and if she is positive and have economic possibilities she receives treatment. The health personnel has been informed of the necessary and compulsory nature of pre and post test counseling. In Venezuela medical insurances did not cover HIV/AIDS infection until the year of 1996, when a single allocation accepted it.

The OPL/AIDS maintains intrainstitutional relations with other programs as those of TBC, mental health, oncology and others. In addition, it has interministerial relations with the Ministry of Education, the parenteral-family, of Justice and others, as well as with international organizations and NGO's for the internal and external strengthening in all these areas.

An important entity is the Maternal and Child Direction, which is basic for the subject that compete us; it is responsible for the breast-feeding and prenatal checkup programs. In addition, it has the (Programa de Atención Materno-Infantil (PAMI) that provides milk to pregnant women and to children until 6 years, except for the newborn whom are provided with breast milk only according to its recommendation.

ADDENDUM I

Prevention of HIV Transmission from Mother-to-Child: Meeting on Planning for Program Implementation

Geneva, 23-24 March 1998

Meeting Statement

Background

Transmission of HIV from mother to child can occur during pregnancy and delivery, as well as through breast-feeding. 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 breast-feed. An integrated prevention program which combines the use of this regimen and the use of safe alternatives to breast-feeding would be effective in reducing mother to child transmission of HIV among breast-feeding 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 breast-feeding; 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 minimize 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 utilized. 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 postpartum 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 labor 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 (nongovernmental and community-based organizations, 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 mobilizing 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 breast-feeding.

•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 breast-feeds is currently not known. Zidovudine may provide some degree of protection, although probably less than the protection it provides to infants who are not breast-fed. Since the majority of HIV positive women facing transmission from mother to child are women who breast-feed, it is critical to resolve this issue. It is also necessary to learn more about the effect on the morbidity and mor-

tality of infants born to HIV positive women of introducing alternatives to breast-feeding.

Nevertheless, the greatest reduction in mother to child transmission of HIV is likely to occur when an integrated prevention program is implemented which combines the provision of zidovudine and safe alternatives to breast-feeding. In some countries, it may prove to be impractical to implement simultaneously access to zidovudine and access to safe alternatives to breast-feeding. 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 breast-feeding, 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. Recognizing the urgency of the situation and at the same time the fact that it will take time to mobilize 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 utilize 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, mobilize 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.

ADDENDUM II

Subregional workshop
Prevention of the vertical transmission of HIV
Argentina, Bolivia, Brazil, Chile, Paraguay, and Uruguay
Buenos Aires, Argentina

29-31 of July 1998

Conclusions and technical recommendations of the Encounter

Executive Summary

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Introduction

The prevention of vertical transmission of HIV is at present a priority determined for ethical reasons, of cost efficiency that is accompanied by very effective results. The countries integrating the subregion have different levels of vertical transmission of HIV and Argentina has begun the implementation of the pertinent interventions in order to achieve a significant reduction of the perinatal cases in the country.

The Ministry of Health and Social Action, through the National Program against the Human Retroviruses and the Project against AIDS (LUSIDA), jointly with the theme group of UNAIDS in Argentina decided the realization of the subregional Workshop: *Prevention of the vertical transmission of HIV*. This workshop was planned as a joint meeting of the representatives of the provinces and municipalities of the STD/AIDS, maternal and child, and primary health care programs, medical and scientific societies, and of civil organizations of Argentina and representatives of its neighboring countries.

The organization and the development of this meeting was support by international agencies as UNAIDS, OPS/WHO, UNICEF. In addition, it counted with involvement of the presidents of the theme groups on AIDS of the United Nations system, of the participating countries, and of the Regional Initiative on AIDS for Latin America and the Caribbean (SIDALAC), that the World Bank and ONUSIDA develop in this region.

The thematic content of the meeting was covered through the presentation in conferences and round tables and sessions of discussion in working groups of the most relevant subjects in this area. In this report the most relevant conclusions of the subjects addressed will be pre-

sented first, and at the end the technical recommendations and the aspects of policies and the implementation of the same.

Background

Availability of effective interventions for the reduction of vertical transmission of HIV

HIV infection in pregnant woman, although is present in all the provinces and municipalities of Argentina, at different levels, has a rising trend, basically derived from heterosexual transmission, and in intravenous drug users, also growing in the subregion.

The vertical transmission of HIV can occur during pregnancy, childbirth and through breast-feeding. In general, the level of transmission can change in accordance with different variables, however, it is estimated that 35% of the children of seropositive women can acquire HIV: 10% in pregnancy, 10% during childbirth and 15% by lactation. In addition, it has been reported that the prophylaxis with zidovudine previously, during and after delivery reduce significantly (between 50% and 66%) the transmission. The protocol of treatment ACTG 076 was described in 1994 and achieved the reduction in the transmission to 8% (reduction in 66%), an alternative shorter treatment and of greater facility of application (oral route exclusively) achieved a reduction in the transmission of 50% when breast-feeding was excluded to a level of 9%.

Economic implications of the prevention of vertical transmission of HIV

The justification of the preventive interventions have in addition to an ethical component, support in the cost-effectiveness analysis of the same still in situations of low prevalence. Basically, these interventions are cost-effective in view of the fact that in the majority of the participating countries antiretroviral treatments in multiple combination are provided to AIDS cases in adults and to pediatric cases.

Breast-feeding and its substitutes

Child nutrition in this context is of particular importance in the strategy of reduction of the vertical transmission of HIV. It is accepted without discussion that breast-feeding is most desirable for the maternal and child health of the countries. However, it is recognized that HIV is transmitted through breast milk, and therefore, seropositive women should be informed and advised adequately concerning this hazard for their children, and upon ensuring a nutritional, adequate, hygienic and sustained source, can take an informed decision in order to reduce the hazard of transmission by this way through replacement feeding.

Screening and counseling

The process of diagnosis of infection by HIV in women constitutes the greater challenge for the current health systems. For example, the coverage of institutionalized delivery in the participating countries ranges from 40% to 90%, as well as the prenatal checkup due to a low percentage of women that attend early the consultation, and to a low number of controls by woman.

The psychosocial and ethical aspects of the diagnosis of HIV infection in pregnant woman were dealt with special emphasis by the participants. It was proposed the need of confidentiality and of informed consent for all the components of the strategy of reduction of the vertical transmission. Despite the controversy concerning the rights of women and of the child to be born, it is considered that the diagnosis of HIV in the woman should be voluntary, as well as the later interventions that arise as a result of the same (for example, dietary substitution for the newborn, ARV treatment for the woman and the baby).

Technical recommendations of the Encounter

The prevention of mother to child HIV transmission is a priority

To offer universal, voluntarily, confidential, and free counseling and diagnostic test of HIV infection to pregnant women. A particular emphasis should be given to pre and post screening of HIV counseling following strict ethical standards. The active search of pregnant women should be promoted, with particular emphasis on those with risk increased to HIV and that are not covered by adequate prenatal care. Seropositive women should be informed and advised adequately concerning the risk of transmission of HIV to their children. In those infected an adequate nutritional source, hygienic and sustained, should be ensured as an alternative to breast milk through the informed decision process in order to reduce the transmission risk by lactation.

The interventions with antiretroviral prophylaxis for the prevention of the vertical transmission of HIV, although were based originally on the protocol ACTG 076, follow various protocols in accordance with the situation of prenatal care. For example, in Brazil shortened protocols due to this situation are carried out. In view of the fact that in Argentina the use of the protocol ACTG 076 has started, it was considered that this would be the protocol to follow while is implemented completely and the use of other protocols is evaluated carefully, for example, the shortened treatments and with other antiretrovirals, particularly given the late entrance of women to prenatal care.

It is required continuous training for the health workers at the different levels of action (of primary health care, reference centers, general practitioners, gynecologists and of other specialties, psychologists, social workers, obstetric or midwives, etcetera). The treatment with antiretrovirals for women should be considered not only as a prevention strategy for vertical transmission, but as an adequate care for the woman. These antiretroviral treatment policies, however should follow policies and patterns defined by each country. During the Encounter, the need for the integration of the programs for Primary Health Care, Reproductive Health, Maternal and Child AIDS/ STD, and of Health Education, was identified as a priority.

It is desirable the development of operational research and the monitoring of the strategy adopted in regard to child nutrition to avoid

damaging the breast-feeding program in the general population. In the countries in which it is viable, the evaluation of the operation of breast milk banks is recommended including the process of HIV screening. This strategy developed by Argentina could be restarted by other countries, both within and outside the region.

The role should be considered, in continuous change and adaptation, of the various governmental sections, of regional structures, of the agencies, organizations and international programs, and of community participation. Finally, the areas in which it is necessary to do greater consideration in order to issue recommendations and decision-making were identified. For example, the effectiveness of other interventions as the use of elective cesarean, washing of the vaginal channel, shortened treatments and use of different ARV from AZT should be studied. In addition, a consultation of experts should be made for the adequate utilization of Fast Tests of Diagnosis, protocols to follow in case of late attention to the prenatal checkup of pregnant women (even in labor without previous control). The coordinated involvement of multiple governmental and international managers could serve as model of the future work in AIDS prevention.

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