



Cost-Benefit Analysis of the Programme for Prevention of Mother to Child Transmission of HIV

with the application
of the routine (universal) and voluntary testing
for HIV of pregnant women by the "OPT-OUT" model



Task Force for prevention
of mother-to-child
transmission of HIV,
Republican AIDS Commission



Research conducted by: G17 Institute, Knez Mihailova Str. 10, 11000 Belgrade

Head of Research: Dr Mirosinka Dinkic, Social Policy Department Director, G17 Institute
Team members: Dr Mirosinka Dinkic, G17 Institute
Iva Jovanovic, G17 Institute
Jelena Momcilovic, G17 Institute
Dr Ljiljana (Petrovic) Stankovic, "GAK Narodni Front" (Clinic for Gynaecology and Obstetrics), member of the PMTCT Task Force
Dr Jelena Zajeganovic-Jakovljevic, UNICEF

Support from: Republican AIDS Commission of Serbia (RAC) and Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)

Published by: UNICEF Belgrade
For publisher: Ann- Lis Svensson, Area Representative

Translation: Marko Vucinic and Ivana Radovic
Editing: Daniel Richer

Photo, Layout & Design: Konstantin Petrovic



Task Force for prevention
of mother-to-child
transmission of HIV,
Republican AIDS Commission



CONTENTS

PREFACE	5
TABLES	6
LIST OF ACRONYMS	10
TERMINOLOGY	11
EXECUTIVE SUMMARY	13
INTRODUCTION	17
Goal	18
Methodology	18
A. CURRENT SITUATION AND SUMMARY OF EXPENDITURES IN THE PAST	
12 YEARS	20
A.1. Current situation in Serbia – HIV + pregnant women and children	20
A.2. Fund allocation in the previous years	21
A.3. Scope of expenditures for treatment of those infected by HIV/AIDS in Serbia	21
B. PROGRAMME IMPLEMENTATION	22
B.1. General principles of implementation of the PMTCT Programme	22
B.2. Cost of the implementation of the PMTCT Programme for women	22
B.2.1. Testing and counselling	23
B.2.2. Antiretroviral treatment of HIV + pregnant women	23
B.2.3. Childbirth of HIV + pregnant women	24
B.2.4. Screening and treatment of identified HIV + women	24
B.2.5. Total expenditures for women	25
B.3. Expenditures linked to children of HIV + mothers during the implementation of the Programme	26
B.3.1. Diagnostic procedures	26
B.3.2. Antiretroviral therapy with Zidovudin	26
B.3.3. Diet of infants of HIV + mothers	27
B.3.4. Screening and treatment of identified HIV + children	27
B.3.5. Total medical expenditures	27
B.3.6. Social care	29
B.4. Total expenditures for the implementation of the Programme according to international prices	29
C. NON-IMPLEMENTATION OF THE PROGRAMME	30
C.1. General Principles of the non-implementation of the Programme	30
C.2. Expenditures for the non-implementation of the Programme for women according to international prices	30
C.2.1. Testing	31
C.2.2. Diagnosis and treatment of HIV + women	31
C.2.3. Total expenditures for women	31
C.3. Expenditures linked to an HIV infected child, in case of the non-implementation of the Programme	33

C.3.1. Expenditures for diagnostics	33
C.3.2. Expenditures for treatment and screening	33
C.3.4. Social care expenditures.....	35
C.3.5. Expenditures per HIV + child.....	35
C.4. Total expenditures for non-implementation of the Programme, international and domestic prices.....	36
D. EVALUATION AND ANALYSIS OF NET BENEFIT BY IMPLEMENTATION OF THE PMTCT PROGRAMME.....	37
D.1. Net effects of the Programme implementation	37
D.2. Net effects on the basis of direct differences in expenditures for the implementation and non-implementation of the Programme.....	38
D.2.1. Implementation of the Programme according to international prices and the non-implementation of the Programme according to domestic prices.....	38
D.2.2. Programme implementation according to international prices and non-implementation according to international prices	39
D.2.3. Implementation and non-implementation of the Programme in case of application of international prices of tests and domestic prices of medicines.....	40
D.3. Total number of healthy newborn babies and net benefit of gained years of life for children born to HIV + mothers during the implementation of the Programme.....	41
D.4. Net benefit from one antenatal diagnose of HIV	42
D.5. Evaluation of effects based on the participation of women and healthy-born children in the labour market.....	44
D.6. Immeasurable effects	45
E. SOURCES OF FUNDS FOR THE IMPLEMENTATION OF THE PROGRAMME	45
F. CONCLUSIONS AND RECOMMENDATIONS	46
ANNEXES	49
Annex 1 – Assessment of the number of HIV + pregnant women in Serbia.....	50
Annex 2 – Assessment of the number of children who become HIV-infected by vertical transmission, as a function of whether or not the Programme is implemented.....	50
Annex 3 – Expected lifespan.....	52
Annex 4 – Calculation of expenditures for the testing of pregnant women	53
Annex 5 – Expenditures for antiretroviral treatment of mothers.....	55
LITERATURE	78

PREFACE

The State Union of Serbia and Montenegro, as a member of the International Community, undertook to implement the goals and recommendations of international documents and declarations related to the prevention of vertical transmissions of HIV infection (PMTCT).

An analysis of the situation in the State and the measures being undertaken for the prevention of mother to child transmissions of HIV infection have shown that an improvement of the existing system was necessary. The recommended strategy that includes the introduction of voluntary testing of pregnant women by the Opt-out model has numerous advantages. Should the state utilise the new PMTCT strategy, the question emerges whether it can endure the economic burden despite the multiple justifications of its implementation from the medical and social perspectives. This study provides the answer to that question.

The study clearly shows that, despite the noticeably increased expenditures in the first years, the implementation of the PMTCT strategy is cost-effective over the ten-year period. The result shows that implementation of the programme of prevention of vertical transmission is justified (feasible and required) in poorer countries, countries with HIV prevalence, and countries in which HIV infections have already taken root.

The study is primarily intended for decision-makers, strategists and planners in ministries and funds, as well as for healthcare practitioners and all others involved in prevention of HIV infections. The study can also serve to educate professionals involved in socio-economics, as well as providing an example for the implementation of such analyses to other healthcare systems.

We take this opportunity to express gratitude to the Centre for Prevention and Control of Infectious Diseases of the Institute for Health Care of Serbia "Dr Milan Jovanovic – Batut", to the HIV/AIDS Centre and the Microbiological Laboratory of the Institute for Infectious and Tropical Diseases and to the Apothecary Institution of the Clinical Centre of Serbia for providing significant support in the collection and interpretation of data indispensable for the production of this study.



Ann-Lis Svensson
UNICEF
Serbia and
Montenegro



Spaso Andjelic
Task Force for Prevention of
Mother to Child Transmission of HIV
Republican AIDS Commission of Serbia



Mirosinka Dinkic
G17 Institute

TABLES

- Table 1.** Increase in expenditures for the deliveries of HIV + pregnant women according to protocol, at the annual level
- Table 2.** Expenditures for ten-year implementation of the Programme for women whose HIV infection is diagnosed during pregnancy, for an average lifespan of HIV + women, according to international prices
- Table 3.** Total medical expenditures for the ten-year implementation of the Programme for children of HIV + mothers whose infection is diagnosed during pregnancy, for an average lifespan of HIV + children, according to international prices
- Table 4.** Expenditures for social care of HIV + children during the implementation of the Programme
- Table 5.** Total expenditures for the ten-year implementation of the Programme for the minimum and maximum assessment of the number of the infected, for an average lifespan and with the application of international prices
- Table 6.** Total expenditures for HIV + women whose infection is not diagnosed during pregnancy due to the non-implementation of the Programme, for an average lifespan, according to international prices
- Table 7.** Total medical expenditures linked to children infected by HIV, if mother's infection is undetected during pregnancy, due to the non-implementation of the Programme, for an average lifespan of HIV + children, according to international prices
- Table 8.** Social care expenditures for HIV + children during the non-implementation of the Programme
- Table 9.** Total expenditures for HIV + women and children during the non-implementation of the Programme for the minimum and maximum assessment of the infected, according to international prices
- Table 9a.** Total expenditures for HIV + women and children during the non-implementation of the Programme for the minimum and maximum assessment of the infected, according to domestic prices
- Table 10.** Net effects for the implementation of the Programme presented as a difference between the expenditures for the implementation of the Programme according to international prices and expenditures of the non-implementation of the Programme according to domestic prices
- Table 11.** Net effects of the implementation of the Programme presented as a difference between expenditures for the implementation and non-implementation of the Programme according to international prices
- Table 12.** Net effects of the Programme implementation presented as a difference between the expenditures for the implementation and non-implementation of the Programme in case of application of the international prices of test and domestic prices of medicines

- Table 13.** Gained years of life during the implementation and non-implementation of the Programme with regard to the average lifespan of HIV + children and the average life cycle in Serbia and Montenegro
- Table 14.** Evaluation of lifelong expenditures and years of life for the minimum number of HIV + women and their children depending on whether the women's infection is detected during pregnancy, according to international prices
- Table 15.** Evaluation of lifelong expenditures and lifespan for the maximum number of HIV + women and their children depending on whether woman's infection is detected during pregnancy, according to international prices
- Table 16.** Net benefit based on the inclusion of HIV + women and healthy-born children in the labour market during the period of Programme implementation
- Table P0.** Testing for HIV and prevalence of HIV infections amongst pregnant women by year
- Table P1.** Assessment of the number of pregnant women infected by HIV in Serbia
- Table P2.** Expected number of newborn infants by HIV + mothers (healthy/who avoided being HIV infected) with the implementation and non-implementation of the Programme
- Table P3.** Expected lifespan of an HIV infected child
- Table P4.** Expected lifespan of an HIV + woman
- Table P5.** Expenditures for routine (universal) and voluntary testing and counselling of pregnant women by "Opt-out" model
- Table P6.** Expenditure for antiretroviral treatment of mothers aimed at preventing vertical transmission of HIV infection, according to international prices, per annum
- Table P7.** Expenditures for antiretroviral treatment of mothers, aimed at preventing vertical transmission of HIV infection, according to domestic prices, per annum
- Table P8.** Childbirth expenditures for an HIV + pregnant woman in case of implementation of the Programme on prevention of mother to child HIV transmission, per annum
- Table P9.** Childbirth expenditures for pregnant women amongst general population when, their HIV status is not detected during pregnancy/non-implementation of the Programme/they are not tested, per annum
- Table P10.** Price of natural delivery with episiotomy
- Table P11.** Price of caesarean section
- Table P12.** Expenditures for analysis of an HIV + mother
- Table P13.** Annual expenditures for therapy per person by domestic and international prices
- Table P14.** Programme implementation expenditures for women whose HIV infection is diagnosed during pregnancy, for average lifespan of HIV + women, by domestic prices

- Table P15. Expenditures for diagnosing HIV infection of a child during Programme implementation**
- Table P16. Expenditures for antiretroviral therapy for children with Zidovudin**
- Table P17. Diet expenditures for children of HIV+ mothers who, according to the PMTCT Protocol and informed choice are not breastfed, per annum**
- Table P18. Diet expenditures for a baby with milk substitute during first six months**
- Table P19. Screening expenditures of an HIV+ child (clinical, immunological and viral screening) during a one-year period**
- Table P20. Expenditures linked to the children of HIV + mothers whose infection is diagnosed during pregnancy owing to Programme implementation, for average lifespan of HIV + children, according to domestic prices**
- Table P21. Expenditures for HIV infection diagnosis of a child in case of non-implementation of the Programme**
- Table P22. Expenditures for treating an HIV+ woman whose infection is not diagnosed during pregnancy due to non-implementation of the Programme, for an average lifespan, by domestic prices**
- Table P23. Expenditures linked to a child infected by HIV if mother's infection is not detected during pregnancy, due to non-implementation of the Programme, for average lifespan of HIV + children, by domestic prices**
- Table P24. Programme implementation expenditures for women whose HIV infection is diagnosed during pregnancy owing to implementation of the Programme, for the minimum and maximum lifespan of HIV + woman, by international prices**
- Table P25. Expenditures linked to children of HIV+ mothers whose infection is diagnosed during pregnancy, owing to Programme implementation, for the minimum and maximum lifespan of HIV + children, by international prices**
- Table P26. Expenditures for treating an HIV+ woman whose infection is not diagnosed during pregnancy, due to non-implementation of the Programme, for minimum and maximum lifespan, by international prices**
- Table P27. Expenditures linked to a child infected by HIV if mother's infection is undetected during pregnancy, due to non-implementation of the Programme, for minimum and maximum lifespan of HIV + children, by international prices**
- Table P28. Programme implementation expenditures for women whose HIV infection is diagnosed during pregnancy owing to implementation of the Programme, for the minimum and maximum lifespan of HIV + woman, by domestic prices**
- Table P29. Expenditures linked to children of HIV+ mothers whose infection is diagnosed during pregnancy, owing to implementation of the Programme, for the minimum and maximum lifespan of HIV + children, by domestic prices**
- Table P30. Expenditures for treating an HIV+ woman whose infection was not diagnosed during pregnancy, due to non-implementation of the Programme, for the minimum and maximum lifespan, by domestic prices**

- Table P31. Expenditures linked to a child infected by HIV if mother's infection is undetected during pregnancy, due to non-implementation of the Programme, for the minimum and maximum lifespan of HIV+ children, by domestic prices**
- Table P32. Net effects of the implementation of the Programme in case of HAART 1 application (difference between implementation expenditures by international prices and non-implementation expenditures by domestic prices)**
- Table P33. Net effects of Programme implementation in case of applying HAART2 (difference between implementation expenditures by international prices and non-implementation expenditures by domestic prices)**
- Table P34. Net effects from Programme implementation in case of applying the therapy of the Clinic for Infectious and Tropical Diseases (difference between implementation expenditures by international prices and non-implementation expenditures by domestic prices)**
- Table P35. Gained years of life during the implementation and non-implementation of the Programme, with regard to the minimum lifespan of HIV+ children and average lifespan in the Republic of Serbia**
- Table P36. Gained years of life during the implementation and non-implementation of the Programme, with regard to maximum lifespan of HIV+ children and average lifespan in the Republic of Serbia**

LIST OF ACRONYMS

Ag – Ab	Antigen – Antibody reaction
AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral therapy
DNK	Deoxyribonucleic Acid (Carrier of genetic information)
ELISA	Technique of detecting antibodies on HIV in the blood of the bearer
GDP	Gross Domestic Product
GAK	Clinic for Gynaecology and Obstetrics
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
PCR	Polymerase Chain Reaction
PCR DNK	Polymerase Chain Reaction (technique of detecting DNK replications)
PCR RNK	Polymerase Chain Reaction (technique of detecting RNK replications)
PMTCT	Prevention of Mother-to-child Transmission of HIV infection
RAC	Republican AIDS Committee
RNK	Ribonucleic Acid (Carrier of the virus genetic information)
WHO	World Health Organisation
UNICEF	United Nations Children’s Fund

TERMINOLOGY

Antenatal diagnosis – diagnosis made prior to the birth of the baby or during pregnancy

Antiretroviral therapy – medicament therapy administered to HIV + persons with the primary goal to destroy the virus or reduce its activity

Birth-rate – number of live newborn babies per 1,000 citizens

Cost-benefit analysis – analysis of the relation of costs and benefits

Discount factor – rate of change of result and expenditure values as they are adjusted to current values over a given period.

Domestic prices of diagnostic and therapy resources– prices of diagnostic and therapy resources in the State currently charged to the Bureau of Health Insurance

Elective Caesarean Section – Caesarean section planned due to medical indications

Economy of scale – a policy of ordering large quantities of articles to reduce the individual prices of each article

Fertility rate - number of live newborn babies per 1,000 women of child-bearing age

Gained years of life – difference between the expected life cycle during the implementation or non-implementation of the Programme

Generative period of a woman – woman of child-bearing age (between 15 and 49 years)

HIV testing of pregnant women by epidemiology indications – considering that epidemiology indications have not been defined by protocol, HIV testing of pregnant women by this model is carried out on the basis of risk assessments made by doctors

Horizontal transmission of HIV – transmission of HIV from one person to the other by sexual intercourse or by infected blood (most frequently through the exchange of needles and other equipment amongst intravenous drug users)

Hospitalisation – treatment administered in hospitals

Informed choice of HIV+ mother not to breastfeed her baby – voluntary decision of an HIV + mother made after counselling and receiving information about the risks of transmission of HIV infection by breastfeeding as well as about the risks for general health of baby fed by infant formula. Each case should be looked at individually, but if consumption of any kind of replacement for breast-milk is an acceptable, feasible, affordable, sustainable and safe option, it should be proposed to the HIV+ mother. Anyhow, completely unacceptable option means combination of breastfeeding and feeding by infant formula (or any other breast-milk substitute).

International prices of diagnostic and therapy resources – prices available on the international market (prices from the brochure “Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS” produced by WHO in June 2003)

Live births – number of live newborn babies per 1,000 newborn babies

Natural increase – difference between the birth-rate and death-rate

Net benefit – positive effects of the implementation of the Programme compared to its non-implementation

Prevalence of HIV infection – number of HIV+ persons per 100.000 people amongst the population in a determined period of time

Prophylactic therapy – therapy that prevents onset of illness

Prophylaxis of opportune infections – prevents the development of infections that more frequently appear amongst persons with immunodeficiency, which is the case with HIV/AIDS

Routine (universal) and voluntary Opt-out HIV testing of pregnant women – testing of pregnant women to HIV as a part of standard antenatal care with the possibility for pregnant women to refuse to undergo the test

Reproductive choice – possibility for making voluntary, informed decisions about having children, their number and time interval between pregnancies

Republic – refers to the Republic of Serbia, excluding Kosovo and Metohija

Serology results – results acquired by blood tests

State - refers to the State Union of Serbia and Montenegro, excluding Kosovo and Metohija

Vertical transmission of HIV – transmission of HIV from mother to child during pregnancy, delivery or breastfeeding

EXECUTIVE SUMMARY

This study (a cost-benefit analysis) is an integral part of the project entitled "Controlling of HIV/AIDS in Serbia: A Comprehensive Country Strategy and an Emergency Action Plan", currently being implemented in the Republic of Serbia with the financial support of the Global Fund to Fight Aids, Tuberculosis and Malaria. The study was initiated by the Republican AIDS Commission Task Force for Prevention of Mother to Child Transmission of HIV. Its goal is to evaluate financial implications of the implementation or non-implementation of the proposed strategy for PMTCT (hereinafter the "Programme") in the Republic of Serbia.

The proposed strategy is a reflection of the situation in the area of vertical transmission as well as of international achievements in this area, and encompasses:

- the introduction of a routine (universal) and voluntary HIV testing of pregnant women by the "Opt-out" model that enables diagnosis of HIV infections among pregnant women in the period of early pregnancy
- allowing a reproductive choice to HIV + pregnant women
- therapy and procedures (a protocol) for HIV + pregnant women who decide to keep their pregnancy and for whom the percentage of vertical transmission is reduced from 40% to 2%, that includes: a) accepting the prophylaxis therapy with Zidovudin and not the combined antiretroviral therapy (HAART) during the period of pregnancy and delivery of HIV + pregnant women, b) childbirth by elective (planned) caesarean section of HIV + pregnant women, c) Informed choice of the HIV + mother not to breastfeed her baby, including the obligation of the state to provide financial support for feeding all children born to HIV + mothers by infant formula up to 6 months of their age, and d) administration of Zidovudin to all infants of HIV + pregnant women after delivery.

The methodology used in this analysis is based on the paper "Cost Effectiveness Analysis of Antenatal HIV Screening in the United Kingdom" (*Editorial by Peckham*). Data and evaluations necessary for the drafting of this analysis were obtained from official institutions or drawn from the Paper (for the data not available in Serbia).

The analysis compares expected expenditures for the implementation and non-implementation of the Programme over a ten-year period and includes, in addition to the expenditures in the foreseen period, expenditures for screening and treatment of HIV + women and HIV + children (which exists as the obligation of the state) until the end of their expected lifespan.

During the work on the analysis, a significant disparity was observed between the prices of current diagnostic and therapy assets billed to the Health Insurance Bureau in our State (so-called "domestic prices") and prices abroad (prices from foreign brochures, so-called "international prices"). Hence, calculation of expenditures was based on both domestic and international prices, with the aim of illustrating the magnitude of loss which the State suffers as a result of the current pricing policy.

The net direct benefit of Programme implementation is presented as a difference between direct expenditures (cost of medical and social care) of the implementation and non-implementation of the Programme, as well as measured in terms of the total number of healthy newborn babies, the net benefit of the increased lifespan of infants born to HIV + mothers during the implementation of the Programme, and the net benefit of one antenatal diagnosis of HIV.

Indirect benefits include the number of children who avoided HIV infection owing to the implementation of the Programme, benefit due to future participation on the labour market of healthy newborn children (upon completion of their education) and treated HIV + women, as well as the effects of general prevention activity and education of the entire population that cannot be evaluated.

The cost-benefit analysis has shown that the current practice of testing of pregnant women triggered by epidemiology indications is ineffective, as only one HIV+ pregnant women was identified in the 12-year period from 1990 to 2002. Another 22 HIV+ women were subsequently identified as having been HIV infected during pregnancy, 14 of them transmitting HIV to their children. In the 12-year period there were a total of 29 HIV+ children who were suspected to have been infected by vertical transmission, while the manner of transmission was confirmed only for the above mentioned 14 children. All of these point to very unreliable epidemiology data on the situation with HIV infections in our State. If estimates on the annual number of HIV+ pregnant women (Annex 1) escaping detection of their HIV+ status under the current system are correct, and assuming a mother-to-child transmission rate of HIV was 40% during the 12 year period, it is reasonable to expect that the actual number of HIV+ pregnant women and HIV+ children in that period may have been 10 to 20 times greater. Hence, the vast majority would have remained undiagnosed, and are either living with HIV or have died in the meantime without being aware of their HIV+ status.

The study estimates that a minimum of 16 and a maximum of 51 HIV+ pregnant women will give birth annually. With the implementation of the Programme, this number of pregnant women would give birth to a minimum of 0.32 and a maximum of 1.02 HIV+ children per annum, while with the non-implementation of the Programme this number would grow enormously, i.e., a minimum of 6.85 and a maximum of 21.85 HIV+ infants would be born annually.

Testing on HIV during the implementation of the Prevention Programme would, we believe, initially cause quite large expenditures – some 1.25 million € per annum, considering its scope of 90% (some 54,000 pregnant women). However, according to international prices, the costs of testing of this number of pregnant women would not exceed 112,716 €. This means that domestic testing prices are 11 times greater than those charged abroad.

Expenditures for the antiretroviral treatment of mothers during pregnancy and delivery and their infants during the first six weeks after birth do not represent significant expenditures in the implementation of the Programme.

Most of the medicines used for antiretroviral therapy of persons infected by HIV/AIDS are imported by the state. Prices on the domestic market are far higher than those listed in the Brochures/international prices, even after being increased by 2 1/2 times, i.e., there is a huge difference between domestic prices of tests and medicines and manufacturer prices. This price difference should be reviewed and future purchases should be reorganised in such a way as to make use of discounts usually offered by placing large-scale orders.

Therefore, with the organising of the purchase of tests directly from the manufacturers, using the benefits of purchasing them through large-scale orders, the prices of testing could be significantly reduced. Thus, we suggest Programme implementation to be based on international prices.

The costs of health care of a child infected by HIV are evaluated at 18,216 € for medical treatment and 28,216 € for social care.

The Implementation of the Programme includes a change in the pricing policy for tests, an introduction of so-called international prices into the domestic market, costs of the 10 year long implementation of the programme and lifelong screening and treatment of newly-diagnosed HIV+ women and children. Direct state funding of medical and social expenditures for women and children would be required, in the amount of 6,219,137 € for the minimum and 17,256,052 € for the maximum assessed number of HIV+ pregnant women.

If the testing by epidemiology indications should continue in Serbia, together with the existing pricing policy for tests and therapy based prices which are several times higher as compared

to international prices, for the same period and conditions, the costs of non-implementation of the Programme would rise to 14,359,335 € for the minimum and 45,189,391 € for the maximum assessed number of HIV+ pregnant women.

Direct costs of Programme implementation would be lower than the costs of non-implementation of the Programme by between 8.14 million € (minimum estimation) and 27.93 million € (maximum estimation), which would be considerable savings for the society.

The society would save even more with the implementation of the Programme if we take into account the benefit of the number of children that avoided HIV infection, namely, a minimum of 65 and a maximum of 210 children for the ten-year period of the Programme's implementation.

Regardless of the chosen antiretroviral therapy, basing the Programme on international prices becomes cost beneficial after six years of implementation for the minimum number, and after five years for the maximum number of the infected. Annual net effects of the Programme implementation are presented in tables in the Annexes (page 32, 33, 34).

By diagnosing a single HIV+ pregnant woman, the state saves on average 34,977 € for the minimum assessed number pregnant women, or 39,881 € for the maximum assessed number of pregnant women, in terms of expenditures for care of these children, and gains additional 25.3 years of children lives (Table 13, 14 and 15).

The second aspect of the Cost-Benefit Analysis in this case is related to the evaluation of the effects based on the inclusion of healthy-born children in the labour market upon completion of their education and the net benefit/gain of women who will be included in the labour market (implementation/non-implementation). We estimate net effects of Programme implementation on that basis to range between 15.34 million € for the minimum number and 53.90 million € for the maximum number of HIV+ women and children (Table 16).

We believe that the implementation of the Programme would create significant indirect and non-measurable effects. These effects are primarily related to the education of the population to undertake preventive measures against HIV transmission and AIDS infections. The so-called horizontal transmission to more than one million women of childbearing age, some 15% of the overall population of the Republic could be prevented only through direct contacts. Indirect Programme benefits would increase significantly as risks and means of HIV infection are effectively conveyed to closer relatives and friends.

It is assessed that the Republic could ensure further funding of the Programme from its own sources, through the health care insurance system, starting from the third year of Programme implementation. The analysis assesses that, due to the lack of a programme on the prevention of vertical transmission, a minimum of 6.85 and a maximum of 21.85 children are infected by HIV every year. The funds allocated by the state for their treatment and social care (which could be saved through the implementation of the Programme) should be directed towards prevention, i.e., testing of pregnant women.

This Programme includes the obligation of doctors to offer testing for HIV to every pregnant woman. It is of extreme importance to establish the screening of pregnant women, both those who accepted and those who rejected to undergo the test, i.e., to establish the prevalence of HIV+ pregnant women in both groups, the degree of transmission, the reasons for rejecting to undergo test, etc. This would ensure the uncovering of any potential mistakes in the implementation of the Programme.

The implementation of the Programme, we believe, would provide the first clear picture of the actual situation regarding HIV+ women in the Republic, paving the way for sustained evaluation of results based on established indicators rather than relying on extrapolated data.

It is very important that all measures are adequately carried out during the implementation of the Programme.

Key conclusions and recommendations:

- Testing of pregnant women according to epidemiological indications is ineffective.
- The health care expenditures during the life of a child infected by HIV are assessed at 18,514 € for medical treatment and 28,216 € for social care.
- Routine (universal) and voluntary testing of pregnant women could prevent these expenditures and enable an increase of the lifespan of HIV+ mothers and children.
- The state would save through the implementation of the Programme in a ten-year period from 8.14 million € to 27.93 million € for the medical treatment and social care for HIV+ mothers and children.
- The state would save, on average, between 1.4 and 4.5 million € in expenditures for the care of HIV+ children by implementing this Programme.
- Between 65 and 210 additional HIV-infected children are born with the non-implementation of the Programme.
- Additional benefits, based on the inclusion of children in the labour market upon the completion of their education and the earnings of treated HIV+ mothers, range from 15.34 million € to 53.90 million €.
- The relatively high costs of testing pregnant women during the implementation of the Programme are offset by the cost of therapy for HIV+ children that would be infected if the programme was not implemented.
- Revision of the prices of tests and medicines in domestic market and organisation of the purchase thereof directly from manufacturers, using the benefits provided by large scale orders (economics of scale).
- Savings due to lower prices of tests and medicines, as well as due to reduced needs for the treatment of HIV+ children (owing to Programme implementation, a smaller number of HIV+ infants are born).
- Funding of the Programme implementation from domestic sources is feasible beginning in the third year of its implementation, becoming cost beneficial from the sixth year for the minimum estimated number of HIV+ pregnant women and from the fifth year according to maximum estimated number.
- The implementation of the Programme will give a clear picture of the actual situation regarding HIV+ women and children in the population of the Republic.

INTRODUCTION

Epidemiological data linked to HIV/AIDS in Serbia is not fully reliable. There were no system studies on the basis of which it could be possible to draw conclusions about trends in the prevalence of HIV/AIDS. Data on prevalence are based on the number of registered HIV+ persons detected during individual and voluntary testing. However, bearing in mind the low level of testing (1.5 persons per 1,000 citizens) in Serbia, these detections represent only the tip of an iceberg.

There were 872 officially registered persons living with HIV/AIDS in the Republic at the end of 2002. According to the assessments of the Health Care Institute of the Republic of Serbia made with the assistance of the WHO software package for the evaluation of prevalence of HIV infections in countries with a small number of the infected, there are six to eleven times more persons with HIV/AIDS in Serbia than currently registered. Considering the estimated number of HIV+ women of childbearing age, as well as their expected fertility, we estimate that a minimum of 20 and a maximum of 64 HIV+ pregnant women in Serbia become infected annually (Annex 1).

The problem of vertical HIV transmission, viewed from the epidemiological perspective, is currently not a priority since children that have been HIV infected that way constitute 1.7% of the total number of registered HIV cases. However, inadequate knowledge, attitudes and practice of the population point to the possibility of an HIV epidemic that represents potential for a steep raise in the number of children that will be infected by vertical transmission in the coming years.

Numerous studies have shown that the application of antiretroviral medicines and planned caesarean section of pregnant women infected by HIV significantly reduce the risk of vertical transmission of the infection (from about 40% to some 2%). According to the data of the American Society of Gynaecologists and Obstetricians and the American Academy of Paediatricians on the degree of HIV transmission among untreated pregnant women, used for the drafting of the analysis (due to the lack of domestic sources), the expected number of HIV+ children per annum was estimated as follows:

- if the Programme is not to be implemented – according to the minimum assessment 6.85, and according to the maximum assessment 21.85 HIV+ children per annum
- if the Programme is to be implemented – that number will be reduced to a minimum of 0.32 and a maximum of 1.02 HIV+ newborn babies per annum (Annex 2, Table P2)

This was the reasoning and clinical explanation for the proposal to introduce measures for timely discovery of the HIV status of pregnant women, i.e., to include into the strategy for HIV/AIDS of the Republic of Serbia (and subsequently into national legislation and health care system) the application of routine (universal) and voluntary “Opt-out” HIV testing of pregnant women instead of the hitherto testing by epidemiology indications. The routine (universal) and voluntary testing would result in multiple gains that together would contribute to the reduction of the number of infected persons among the population.

This study (cost-benefit analysis) is an integral part of the project entitled “Controlling of HIV/AIDS in Serbia: A Comprehensive Country Strategic and an Emergency Action Plan”, implemented in the Republic of Serbia with financial support of the Global Fund to Fight Aids, Malaria and Tuberculosis. The study was initiated by the Task Force for Prevention of Mother to Child Transmission of HIV of the Republican AIDS Commission with the goal of evaluating financial implications of the implementation or non-implementation of the proposed strategy for PMTCT in the Republic of Serbia.

Goal

The goal of the study is to illustrate the costs and –benefits of the Programme for prevention of mother to child transmission of HIV with the application of routine (universal) and voluntary testing for HIV of pregnant women by “Opt-out” model. The evidence suggests that society will achieve multiple gains from the funds invested in such a model of testing.

Questions that the study has to answer:

1. What are the current expenditures of the Republic of Serbia (within the health care system) for the prevention and treatment of HIV infections with special reference to PMTCT?
2. Which expenditures and gains would result from Programme implementation?
3. Which potential expenditures would the Republic of Serbia and the Bureau of Health Insurance incur if the Programme were not fully implemented (status quo)?
4. What can be concluded by comparing these two options and which option would be more cost beneficial at various times during the proposed ten-year implementation period?
5. Which are the most viable options for funding implementation of the Programme

Methodology

Data used in this study for the calculation of expenditures and benefits of implementing the PMTCT Programme that includes routine (universal) and voluntary testing of pregnant women for HIV were obtained from: the Institute for Health of the Republic of Serbia “Dr Milan Jovanovic-Batut”, Institute for Infectious and Tropical Diseases in Belgrade, Clinic for Gynaecology and Obstetrics “Narodni Front” in Belgrade, Pharmacy Institution Belgrade and from the brochure “Sources and Prices of Selected Medicines and Diagnostics for People Living with HIV/AIDS” published by WHO in June 2003 (hereinafter Brochure).

Elements used in the analysis:

- expenditures linked to the testing of pregnant women (administration of two independent HIV tests and counselling before and after the test),
- expenditures for the antiretroviral treatment of mothers and children,
- difference in expenditures for childbirth of HIV + pregnant women according to the Programme and pregnant women from the general population,
- expenditures for the diet of children who will not be breastfed,
- expenditures for diagnostics and treatment of children who, despite all the measures undertaken, become infected by HIV by vertical transmission,
- expenditures for diagnostics and therapy of mothers, and
- expenditures for social care.

The unit cost that the state is ready to fund for each additional year of life of an HIV + person (woman or child) is determined to amount to 8,500 €¹.

The methodology used for this analysis is based on the study “Cost Effectiveness Analysis of Antenatal HIV Screening in the United Kingdom” (*Editorial by Peckham*). The following data and findings, for which there are no domestic sources, have been taken from the study:

- expected life cycle for HIV + women and HIV + children (Annex 3)
- in case of non-implementation of the Programme, women unaware of their HIV status during pregnancy/childbirth generally learn of their status an average of two years later
- the diagnosis of HIV + children whose mothers were unaware of their HIV status before childbirth will also be two years late

¹ This amount is today's average cost for the screening and treatment of one HIV+ person per annum, or more precisely, it is 8,528€ (for details see paragraph A.3.)

The analysis presumes that the Programme implementation will last ten years and will:

1. ensure the testing of approximately 54,000 pregnant women every year (90% of the total)
2. ensure the screening and treatment of newly diagnosed HIV+ women until the end of their expected lifespan in both options (minimum and maximum number), and
3. ensure the screening and treatment of children born with HIV until the end of their expected lifespan, in both options (minimum and maximum numbers)

A significant difference was observed between the prices of current diagnostic and therapy resources payable by the Health Insurance Bureau in our State (so-called "domestic prices") and prices abroad (prices from foreign brochures, so-called "international prices"). For this reason calculations of expenditures were made using both the domestic and international prices².

This financial study analyses the net effects of the implementation of the Programme on the basis of:

- direct differences in expenditures of implementing and non-implementing the Programme
- total number of healthy newborn babies to determine the number of gained years of life for children born to HIV+ mothers
- net benefit from a single, antenatal diagnosis of HIV infection.

Furthermore, the benefit of implementing the Programme is also evaluated on the basis of gains from:

- participation of women and children in the labour market
- Non-measurable effects of preventing HIV infections.

The brief period of time in which this study had to be carried out did not allow us to analyze the market for medicines and medical material to be used in Programme implementation. Such an analysis would provide exact screening of prices and other indicators that have had effect on the pricing policy to date and would serve as a basis to project trends thereof in the years of the Programme implementation. Therefore, we have based the cost-benefit analysis on the so-called permanent prices. Namely, projected expenditures for the implementation or non-implementation of the Programme are expressed in current prices. For this reason, there was no need to determine the discount factor that brings to a levelling of the expenditures for implementing the Programme, which in this case are viewed as benefits, and expenditures for non-implementing the Programme, which are viewed in the analysis as expenditures.

² See tables P14, P20, P22 and P23

A.

CURRENT SITUATION AND SUMMARY OF EXPENDITURES IN THE PAST 12 YEARS

A.1. Current situation in Serbia – HIV + pregnant women and children

According to the existing legislation in Serbia, HIV testing of pregnant women is carried out according to the epidemiological indications. The doctor, based on his/her personal evaluation of risk, decides whether to send a pregnant woman to undergo the test. Analyses carried out in numerous countries, including our own³, have shown deficiencies of such practices.

Only a small number of pregnant women have undergone HIV testing in Serbia (table P0), 1,400 each year on average (ranging from 25 in 1990 to 5,820 in 1994). In the period from 1990 to 2002 (data for 1996 are not available) 17,663 pregnant women were tested and only one turned out to be HIV+. The number of tested pregnant women, in relation to the number of registered pregnancies, has lingered around 1% in several previous years, and with regard to the number of women who decided to maintain their pregnancy (the number of registered pregnancies reduced by the number of intentional abortions) around 1.7%. With such limited scope of testing, it is highly likely that a large number of HIV+ pregnant women remain unregistered. As a result, these women discover that they are infected only after they give birth. Additional testing measures, as prescribed by the Programme, would thus significantly reduce the probability of vertical transmission of the virus to the infant.

For example, in the above mentioned period, only one pregnant woman infected by HIV was identified. Only after having given birth were 22 HIV+ women identified as having been HIV infected during pregnancy, 14 of which transmitted HIV to their children. In the 12-year period there were a total of 29 HIV+ children who were suspected of having been infected by vertical transmission⁴, while the manner of transmission was confirmed only for the above mentioned 14 children. All this points to very unreliable data on the situation with HIV infections in the State.

Given the estimates that the annual number of HIV+ pregnant women range from a minimum of 20 to a maximum of 64 (Annex 1, Table P1) and applying the mother-to-child transmission rate of 40% over the entire period of 12 years, it is reasonable to expect that the cumulative number of HIV+ pregnant women and HIV+ children during that period is 10 to 20 times greater, the vast majority of whom remained undiagnosed. They are either living with HIV or have died in the meantime without ever having been made aware of their HIV status.

This indicates that the policy of selective testing of pregnant women for HIV brings about the danger that HIV+ pregnant women will remain unidentified and without adequate treatment both before and after pregnancy.

³ Data taken from UNICEF's analysis "Rapid Assessment of Situation and Services for Children and Women on PMTCT in Serbia"

⁴ Institute for Health Care "Dr. Milan Jovanovic Batut" of the Republic of Serbia

A.2. Fund allocation in the previous years

According to data from the Institute for Infectious and Tropical Diseases there are no precise data in Serbia on the expenditures for the testing of pregnant women in the period from 1990 to 2002, during which time 17,663 pregnant women were tested. and Given the prices of operating supplies from the Pharmacy Institution Belgrade, expenditures were in the neighbourhood of 404,500 € for the 12 year period, i.e., some 33,700 € per annum for the average number of pregnant women tested each year (some 1,400).

According to data provided by the Institute for Infectious and Tropical Diseases, out-patient examinations and HAART treatment expenditures amount to 700 € per month for one person infected by HIV, i.e. living with AIDS (excluding costs of hospitalisation and monitoring), which comes to 8,400 € per annum. Taking into consideration the total expenditures of the Bureau of Health Insurance that include hospitalisation, the expenditures per patient are some 8,500 €.

While there is no precise information on how and when the 23 HIV+ mothers diagnosed in the State learned about their infection and the infection of their children, it is safe to assume their treatment did not commence until 2 or more years after childbirth⁵. Assuming that HAART treatment lasted an average of five years for both mothers and children, these treatment costs can be estimated at some € 1.55 million.

With an additional 119,000 € presumably spent on monitoring, a total of 1.67 million € was likely spent for the 37 persons during the 12-year period. Thus, it is presumed that the state allocated some 10,900 € per each year of life of one infected person during this period⁶.

It must be underscored that a portion of expenditures for treatment and screening was not covered by the Bureau of Health Insurance, but met through donations. For example, expenditures for reagents in 2003 were covered from donations amounting to 240,000 €⁷. Furthermore, according to available information⁸, a number of patients purchase medicines abroad, and some medicines and tests for monitoring the illness are not on the positive list⁹. Therefore, the cost of acquisition of such tests are covered by the patients themselves and it can be concluded that the total expenditures for the treatment and screening of the HIV + status of mothers and children are greater than the amounts cited above.

A.3. Scope of expenditures for treatment of those infected by HIV/AIDS in Serbia

At the end of 2002, there were 872 officially registered persons with HIV/AIDS living in Serbia. According to data from the Institute for Infectious and Tropical Diseases in Belgrade, 400 persons are undergoing treatment today. Expenditures for out-patient examinations and medicines for these 400 persons amounted to 3,360,000 € in 2003. Expenditures for hospitalisation, including intensive, semi-intensive and regular care, amounted to 45,594 €, and out-patient examinations to 5,700 €. Total expenditures for the treatment of persons infected by HIV/AIDS in 2003, covered by the Health Insurance Fund, amounted to 3,411,294 €. Therefore, in 2003 each treated person cost the state 8,528 €.

⁵ On the basis of the study "Cost Effectiveness Analysis of Antenatal HIV Screening in the United Kingdom" (Editorial by Peckham)

⁶ This calculation did not take into account hospitalisation costs, or the expenditures covered by donations, as such data is unavailable for the 23 mothers and their children, nor could an assessment be made regarding such expenditures.

⁷ Dr Djordje Jevtovic, Institute for Infectious and Tropic Diseases, Belgrade

⁸ Interviews with health care practitioners employed in health institutions

⁹ PCR DNK for HIV, PCR RNK for KIV, Kaletra

B.

PROGRAMME IMPLEMENTATION

B.1. General principles of implementation of the PMTCT Programme

The proposed strategy for the Prevention of Parent/Mother-to-child Transmission of HIV foresees a number of preventive measures and procedures amongst which the most significant one is the introduction of routine (universal) and voluntary testing for HIV of pregnant women with the "Opt-out" model that enables the diagnosis of HIV infections during early pregnancy among the majority of pregnant women. Thus, a pregnant woman has the option of reproductive choice and if she opts to remain pregnant, she is offered therapy and procedures that reduce the degree of vertical transmission from 40% to 2%. This includes:

- acceptance of prophylaxis therapy with Zidovudin and not the combined antiretroviral therapy (HAART) during pregnancy and childbirth of HIV+ pregnant women
- childbirth with selective caesarean section of HIV+ pregnant women
- informed choice of the HIV+ mother not to breastfeed her baby including obligation of the state to provide financial support for feeding all children born to HIV+ mothers by infant formula up to 6 months of their age, and
- application of Zidovudin to all infants of HIV+ women after childbirth.

The evaluation of expenditures for the implementation of the Programme was based on the presumption that its implementation would last at least ten years, starting in 2004, and that it was the obligation of the state to screen and treat all diagnosed HIV+ women and children until the end of their lives.

The expenditures of the Programme implementation and its success are based on:

- high degree of acceptance of testing for HIV amongst pregnant women (90%)
- high degree of acceptance of all measures in the Programme for prevention of vertical transmission (see above)
- low price of diagnostic tests and medicines used in the therapy of HIV infections (international prices)

B.2. Cost of the implementation of the PMTCT Programme for women

According to the WHO software package for the evaluation of prevalence of HIV infections in countries with small numbers of the infected, there are 6 to 11 times more people with HIV/AIDS in Serbia than officially registered. Considering the number of registered patients, 84.3% of whom are of childbearing age, (15 to 49 years), it is thus estimated that the total number of women of childbearing age infected by HIV/AIDS ranges from 539 to 1,685. Considering the expected level of fertility of these women, the assessed annual number of HIV+ pregnant women unaware of their HIV+ status at the moment of becoming pregnant, ranges from a minimum of 20, to a maximum of 64. Of this number, it is expected that a minimum of 16 and a maximum of 51 of women will opt to continue with their pregnancy and give birth to their babies (Annex 1, Table P1). The average expected lifespan of HIV+ pregnant women is 18.25 years (Annex 3, Table P4)

During the implementation of the Programme, the diagnosing of the new HIV+ pregnant women (from 16 to 51) will incur additional costs to the state. These costs include initial testing all pregnant women (expected coverage of 90% or some 54,000), final diagnosis of HIV+ ones, their therapy during pregnancy and childbirth, and lifelong screening and treatment. The major expenditure in the first two years of Programme implementation refers to the cost of testing all the pregnant women.

Calculation of these costs includes the following elements:

- B.2.1. The costs of testing with the ELIZA test and counselling of 54,000 pregnant women per annum (the expected coverage is 90%) and confirmatory Western Blot test for those for whom the ELIZA test was positive
- B.2.2. The costs of applying the antiretroviral therapy on identified HIV+ pregnant women during their pregnancy with the aim to prevent mother-to-child HIV transmission
- B.2.3. Difference in expenditures of the delivery of pregnant women whose HIV status is known at the time of childbirth (the case of Programme implementation) in relation to the general population of pregnant women (Table 1)
- B.2.4. Expenditures for lifelong screening and treatment of identified HIV+ women after childbirth

The expenditures for abortions opted for by pregnant women after having become aware of their HIV+ status are not included in this analysis¹⁰.

B.2.1. Testing and counselling

The programme of routine (universal) and voluntary testing for HIV of pregnant women using the "Opt-out" model anticipates a coverage of 90%, i.e., that 54,000 women in Serbia will agree to undergo testing during early pregnancy. The expenditures include the price of counselling in accordance with the "Opt-out" model, the price of the ELIZA test for all pregnant women and confirmatory Western Blot test for those pregnant women for whom the ELIZA test show a positive HIV status.

Annex 4 elaborates in detail the expenditures linked to counselling and testing, which annually amount to between 112,100 € for the minimum and 112,716 € for the maximum number of HIV+ pregnant women according to international prices.

In order to show the size of loss on the part of the state because of high prices of diagnostic tests and medicines used in the therapy for HIV infections, we also calculated Programme implementation expenditures according to current prices in the Serbian market (domestic prices). Counselling and testing expenditures according to domestic prices, for the same turnout of pregnant women, would range from 1,245,637 € for the minimum and 1,254,185 € for the maximum number of HIV+ pregnant women (Annex 4, Table P5).

B.2.2. Antiretroviral treatment of HIV+ pregnant women

It is presumed that 75% of HIV+ pregnant women will agree to the antiretroviral treatment during pregnancy and that the treatment will last 5 months¹¹. It is also presumed that all HIV+ pregnant women will agree to be treated with Zidovudin during delivery. Explanation of advantages of applying Zidovudin instead of HAART therapy, as well as a comparison with the application of domestic medicine Zidosan is given in Annex 5, Tables P6 and P7.

In view of the proposed protocol, the expenditures for the treatment of HIV+ pregnant women during five months of a year range from 3,112 € for the minimum to 9,920 € for the maximum assessed number of pregnant women, and the expenditures of treatment with Zidovudin during delivery range from 573 € to 1,827 €, i.e., the total expenditures for the antiretroviral treatment of HIV+ pregnant women during pregnancy and delivery at an annual level range from 3,685 € for the minimum to 11,747 € for the maximum assessed number of HIV+ pregnant women.

¹⁰ These expenditures are not taken into account by the study "Universal HIV Screening of Pregnant Women in England: Cost Effectiveness Analysis", either.

¹¹ On the basis of the study "Cost Effectiveness Analysis of Antenatal HIV Screening in the United Kingdom" (*Editorial by Peckham*)

B.2.3. Childbirth of HIV + pregnant women

The PMTCT Programme foresees that 90% of childbirths will be carried out by caesarean section and the remaining 10% by natural delivery. The expenditures for the delivery of pregnant women during the Programme implementation are calculated as a difference between actual costs (table P8) reduced for the costs of delivery which the same number of pregnant women would have without awareness of their status (Table P9). The increase in the delivery expenditures (Table 1) amounts to 906 € for the minimum and 2,888 € for the maximum number of assessed HIV + pregnant women per annum.

Table 1.

Increase in expenditures for the deliveries of HIV + pregnant women according to protocol, at the annual level

	Min No. HIV + women (n = 16/year)	Max No. HIV + women (n = 51/year)
Actual delivery expenditures of HIV + pregnant women according to the protocol, in €*	2,729	8,699
Expenditures for delivery of the same number of women from the general population, in € **	1,823	5,811
Increased expenditures for childbirth, in € (difference)	906	2,888

*Table P8

**Table P9

B.2.4. Screening and treatment of identified HIV + women

Expenditures for laboratory analyses (monitoring of clinical, immunological and viral status) of identified HIV + women are presented in Table P12 and amount to 942 € per annum per person according to domestic prices¹².

Expenditures for lifelong treatment of identified HIV + pregnant women after childbirth are based on the application of the three most frequent types of combined antiretroviral therapy: HAART1, HAART2 and the therapy applied in the Institute for Infectious and Tropical Diseases in Belgrade (Table P13). It is presumed that one of the three therapies is applied during the last five years of life. At the annual level, expenditures for HAART1 amount to 3,172 €, for HAART2 to 3,193 € and for the therapy applied in the Institute for Infectious and Tropical Diseases in Belgrade to 1,873 € per person according to international prices.

¹² International prices were not available

B.2.5. Total expenditures for women

According to the data on the funds allocated in Serbia for the treatment of HIV infected persons and the assessment on the likelihood of complications emerging in relation to HIV infection, the average total expenditures for the Programme implementation have been increased by 5% in order to cover the costs of hospitalisation, therapy and prophylaxis of opportune infections, the treatment of various infectious and non-infectious complications and tumour therapy.

Table 2.

Expenditures for ten-year implementation of the Programme for women whose HIV infection is diagnosed during pregnancy, for an average lifespan of HIV+ women, according to international prices*

	WOMEN WHOSE HIV INFECTION IS DIAGNOSED DURING PREGNANCY	
	Average expected lifespan of an HIV + woman in years (18.25)	
	Min No. HIV+ women (n = 16/year)	Max No. HIV+ women (n = 51/ year)
ELIZA test for HIV for 54,000 pregnant women per annum, including counselling of pregnant women by doctors	1,117,800	1,117,800
Western Blot test for HIV	2,814	8,971
PCR RNK carried out 2 times during pregnancy	31,706	101,064
Retroviral (therapy during pregnancy)	31,122	99,201
Zidovudin (therapy at childbirth)	5,731	18,268
Expenditures for delivery according to protocol, increased in relation to general population	9,060	28,879
Lifelong expenditures for analyses for HIV+ women whose infection is discovered during pregnancy (screening of the viral, immunity and clinical status: PCR RNK, CD4 + lymphocytes, biochemical blood analysis, complete blood picture)	2,141,347	6,825,543
Expenditures HAART 1	2,537,600	8,088,600
Expenditures HAART 2	2,554,400	8,142,150
Expenditures for therapy most frequently applied in the Institute for Infectious and Tropical Diseases in Belgrade	1,498,400	4,776,150
TOTAL EXPENDITURES in €		
VERSION 1 (Expenditures HAART 1)	5,877,181	16,288,326
VERSION 2 (Expenditures HAART 2)	5,893,981	16,341,876
VERSION 3 (Expenditures for therapy most frequently applied in the Institute for Infectious and Tropical Diseases in Belgrade)	4,837,981	12,975,876
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES	5,536,381	15,202,026
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES INCREASED BY 5% for: the cost of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	5,813,200	15,962,127

* Expenditures are based on the Programme lasting 10 years and screening and treatment of discovered HIV+ women until the end of their lives

For an average lifespan, which is 18.25 years for women, the total average Programme implementation expenditures for the minimum number of identified HIV+ pregnant women (16) according to international prices amounts to some 5.8 million € and for the maximum number of identified HIV+ pregnant women (51) to some 15.96 million € (Table 2).

In order to illustrate the magnitude of unnecessary state expenditures resulting from high prices of diagnostic tests and medicines used in the therapy for HIV infections, we also calculated Programme implementation expenditures according to current prices in the Serbian market (domestic prices). The average total Programme implementation expenditures amount to 25,127,600 € for the minimum number of identified HIV+ pregnant women and to 51,567,039 € for the maximum number of identified HIV+ pregnant women (Table P14).

Expenditures calculated for the minimum and maximum lifespan of women according to international and domestic prices can also be found in the Annexes (Tables P24 and P28).

B.3. Expenditures linked to children of HIV+ mothers during the implementation of the Programme

The number of HIV+ children will be significantly reduced through the implementation of all the foreseen components of the Programme (see above). As the percentage of vertical transmission is reduced from 40% to 2%, in the first year, HIV+ pregnant women will deliver 0.32 children according to the minimum assessment and 1.02 children according to the maximum (Annex 2). The average expected lifespan of HIV+ children is 11.66 years (Annex 3, Table P3).

Direct lifelong expenditures for an HIV+ child include two components: medical and social.

The calculation of medical expenditures includes the following elements:

- B.3.1. Costs of diagnostic procedures for each infant born to an HIV+ mother up to the verification of the HIV status.
- B.3.2. Costs of antiretroviral therapy with Zidovudin for each infant born to an HIV+ mother in the first 1.5 months of its life.
- B.3.3. Costs of artificial diet for each infant born to an HIV+ mother which, according to the PMTCT protocol and informed decision of the mother are not to be breastfed
- B.3.4. Costs of lifelong treatment and screening of identified HIV+ children.

B.3.1. Diagnostic procedures

It is difficult to work out the serological results of children born to HIV+ mothers in the first 15 to 18 months of their lives because they have (passively acquired) antibodies of their mothers. An early diagnosis of HIV infections of newborn babies is possible by detection of nucleic acids of the virus in the peripheral mononuclear cells of newborn babies (PCR DNK). The percentages of likelihood of detecting HIV infections of newborn babies differ when the test is done at childbirth, at the end of the first week and during the first month of its life. Almost 100% accuracy in discovering HIV infections of newborn babies by the PRC DNK method is achieved when the infant is four months old. That is why during the implementation of the Programme all children of HIV+ mothers pass through a number diagnostic procedures in the first 18 months of their lives when the definitive diagnosis is made on the HIV status. These procedures cost 410 € per child according to international prices (Table P15).

B.3.2. Antiretroviral therapy with Zidovudin

The costs, per annum, of the 45-day antiretroviral treatment of newborn babies with Zidovudin (one of the principles of success of the Programme implementation) are 69 € for the minimum and 220 € for the maximum assessed number of HIV+ children (Table P16).

B.3.3. Diet of infants of HIV + mothers

Because of the high risk of HIV infection (percentage of transmission is some 30%), the Programme foresees obligation of the state to fund the diet of infants of HIV+ mothers with milk substitute for the first six months of their lives.

The Programme foresees that once newly diagnosed HIV+ mothers are fully informed on the risks of HIV transmission through breastfeeding and risk for general health of the baby when fed with breast milk substitutes, 95% opt for a diet for their infants with breast milk substitute in the first six months of infants' lives. According to the prices of milk substitutes and the diet protocol for infants provided by the Clinic for Gynaecology and Obstetrics "Narodni Front" in Belgrade, food expenditures for the first six months of infant's lives amount to 6,886 € per annum for the estimated minimum and to 21,968 € for the maximum number of HIV + women/infants (Table P17).

B.3.4. Screening and treatment of identified HIV + children

Children whose HIV+ infection is confirmed are subject to screening and treatment until the end of their lives. Monitoring of the clinical, immunological and viral status of children born with HIV+ amounts to 744 € per annum per child according to domestic prices¹³ (Table P19).

The lifelong treatment of identified HIV+ children includes one of the three most frequently applied antiretroviral therapies: HAART1, HAART2 or the therapy applied in the Clinic for Infectious and Tropical Diseases in Belgrade. It is presumed that one of the chosen therapies is applied during the last five years of children's lives. At an annual level, expenditures per person according to international prices amount to 3,172 € for HAART1, 3,193 € for HAART2 and 1,873 € for the therapy applied in the Clinic for Infectious and Tropical Diseases in Belgrade.

B.3.5. Total medical expenditures

The average total expenditures of the implementation of the Programme are increased by 5% in order to cover the costs of hospitalisation, therapy and prophylaxis of opportune infections, the treatment of various infectious and non-infectious complications and therapies of tumours.

¹³ International prices were unavailable

Table 3.

Total medical expenditures for the ten-year implementation of the Programme for children of HIV+ mothers whose infection is diagnosed during pregnancy, for an average lifespan of HIV+ children, according to international prices

	CHILDREN BORN TO HIV+ MOTHERS DURING THE IMPLEMENTATION OF THE PROGRAMME	
	Min No. HIV+ women (n = 16/year)	Max No. HIV+ women (n = 51/year)
	Min No. HIV+ children (n = 0.32/year)	Max No. HIV+ children (n = 1.02/year)
	Average expected lifespan of HIV+ child (11.66)	
Cost of diagnostic analyses for all children born to HIV+ mothers (PCR DNK, ELIZA, Western-Blot) min n = 16/years, max n = 51/years	65,600	209,100
Costs of antiretroviral treatment for all newborn babies of HIV+ mothers	689	2,196
Incremental costs of diet of infants according to protocol.	48,924	155,832
Costs of analyses of HIV+ child (Screening of viral, immunity and clinical status: PCR RNK, CD4 + lymphocytes, biochemical blood analysis, complete blood picture) min n = 0.32 year, max n = 1.02 years	145,136	462,620
Costs HAART 1	50,752	161,772
Costs HAART 2	51,088	162,843
Costs for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	29,968	95,523
TOTAL COSTS in €		
Version 1 (Costs HAART 1)	263,136	838,747
Version 2 (Costs HAART 2)	263,472	839,818
Version 3 (Costs for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	242,352	772,498
AVERAGE TOTAL COSTS FOR THE IMPLEMENTATION OF THE PROGRAMME	256,320	817,021
AVERAGE TOTAL COSTS FOR THE IMPLEMENTATION OF THE PROGRAMME INCREASED BY 5% for: costs of hospitalization, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	269,136	857,872

* Expenditures based on the Programme lasting 10 years and the screening and treatment of identified HIV+ children until the end of their lives

For an average lifespan, which is 11,66 years for children during the implementation of the Programme, the average total medical expenditures for the implementation of the Programme, according to international prices, amount to some 270,000 € for the minimum number of identified HIV+ children (0.32 years) and to 860,000 € for the maximum number of identified HIV+ children (Table 3).

In order to illustrate the size of loss on the part of the state resulting from high prices of diagnostic tests and medicines administered in the therapy for HIV infections, we also calculated Programme implementation expenditures according to current prices in the Serbian

market (domestic prices). The average total Programme implementation expenditures amount to 475,600 € for the minimum number of identified HIV+ children and to 1,515,900 € for the maximum number of identified HIV+ children (Table P20).

The Annex contains the calculation of expenditures for the minimum and maximum lifespan of children according to both international and domestic prices (Tables P25 and P29).

B.3.6. Social care

In addition to medical expenditures for the screening and treatment of HIV+ infections, the society also bears the costs of social care of HIV+ children. The calculation of expenditures was made on the basis of an average gross annual discounted wage expressed in Euros (Table 4).

Table 4.

Expenditures for social care of HIV+ children during the implementation of the Programme

No. of HIV+ children on annual level	Programme Implementation	
	min n = 0.32/year	max n = 1.02/year
Total amount for lifelong social care in €*	136,801	436,053

* The amount is related to lifelong expenditures for social care for all HIV+ children discovered during 10 years of Programme implementation

The total expenditures for social care during the implementation of the Programme for an average lifespan of HIV+ children (11.66/year) amount to some 137,000 € for the minimum (0.32/year) and to some 436,000 € for the maximum number of identified HIV+ children (1.02/year). (See Table 4).

B.4. Total expenditures for the implementation of the Programme according to international prices

The total expenditures of the Programme implementation are a sum of expenditures for the implementation of the Programme for women, medical costs for children and expenditures for social care of HIV+ children who were infected despite the programme of prevention of vertical transmission (Tables 2,3,4 and 5).

Table 5.

Total expenditures for the ten-year implementation of the Programme for the minimum and maximum assessment of the number of the infected, for an average lifespan and with the application of international prices

	Minimum assessment of HIV + women min n = 16/year children min n = 0.32/year	Maximum assessment of HIV + women max n = 51/year children max n = 21.85/year
Programme implementation costs for women	5,813,200	15,962,127
Programme implementation costs for children (medical)	269,136	857,872
Costs for social care for HIV+ children	136,801	436,053
TOTAL in €	6,219,137	17,256,052

C.

NON-IMPLEMENTATION OF THE PROGRAMME

C.1. General Principles of the non-implementation of the Programme

The non-implementation of the PMTCT Programme foresees a continuation of the current system (status quo). The testing of pregnant women for HIV would continue according to the epidemiological indications, i.e., upon the proposal of the doctor who establishes some form of high-risk behaviours of the pregnant woman (history of intravenous drug use, work in sex industry, etc). Such testing achieved the coverage of only 1% in the past, and only one HIV + pregnant woman was diagnosed. During this period several scores of HIV + pregnant women remained undetected (failure to undergo the test) and were prevented from enjoying adequate therapy and procedures that would reduce the risk of HIV transmission to their children. Furthermore, numerous analyses have established that this type of risk evaluation among pregnant women is based on the subjective opinion of health care practitioner due to the lack of adequate protocols, therefore being unsuitable, while the indications themselves come under question especially today when the sexual type of HIV transmission is becoming predominant¹⁴.

The evaluation of expenditures for the non-implementation of the Programme are based on a ten-year period, beginning in 2004, and includes, the same as for the implementation of the Programme, expenditures for the screening and treatment of all diagnosed HIV + women and children until the end of their lives.

The calculation of expenditures for the non-implementation of the Programme includes both the costs according to international and domestic prices of diagnostic tests and medicines in the therapy of HIV infections. This was done because it is presumed that efforts to reduce prices would not be undertaken to the same extent, or at all, in the case of the non-implementation of the Programme. Most of the calculations of expenditures according to domestic prices are presented in the annex.

C.2. Expenditures for the non-implementation of the Programme for women according to international prices

Equal number of HIV+ women appears both in case of implementation and non-implementation of the Programme, which, according to the evaluation of the WHO software package on the number of HIV + women of childbearing age in Serbia and the rate of fertility amounts to a minimum of 16 and a maximum of 51 HIV+ pregnant women. They are not aware of being HIV+ during pregnancy (as they failed to undergo HIV testing) which is why they do not apply measures for the reduction of vertical transmission (Annex 1).

The expected lifespan of HIV + pregnant women is 17.63 years (Annex 3, Table P4).

The HIV + diagnosis is made on the basis of clinical symptoms. For this analysis, data have been taken from the study "Cost Effectiveness Analysis of Antenatal HIV Screening in the United Kingdom" (*Editorial by Peckham*), i.e., diagnosis runs two years late on average following the childbirth.

The calculation of these expenditures includes the following elements:

C.2.1. Cost of testing with the ELIZA test and counselling of 1,400 pregnant women per annum (expected average number of tests of pregnant women according to the epidemiology indications)

C.2.2. Cost of diagnostics and lifelong treatment and screening of identified HIV +

¹⁴ Data taken from UNICEF's analysis "Rapid Assessment of Situation and Services for Children and Women on PMTCT in Serbia"

women after childbirth

The expenditures for the non-implementation of the Programme do not include the costs of antiretroviral treatment and of the delivery of HIV+ pregnant women whose status is discovered by testing according to indications. These expenditures were neglected as it was presumed that one or even no pregnant women would be discovered during the ten-year period, as only one HIV + pregnant woman was discovered by this procedure in the past 12-year period.

C.2.1. Testing

During the non-implementation of the Programme it is presumed that the scope and costs of testing of pregnant women that would be carried out according to epidemiological indications would be equal to the average testing in Serbia for the last 12 years. This average is some 1,400 tested pregnant women per annum, or 2,318.40 € according to international prices and 25,760 € according to domestic prices.

C.2.2. Diagnosis and treatment of HIV + women

The diagnosis includes ELIZA and confirmatory Western Blot test for HIV for a minimum of 16 (22.52 € according to international prices and 311.42 € according to domestic prices) and a maximum of 51 HIV+ pregnant women (71.77 € according to international and 992.26 € according to domestic prices) who would discover their HIV + status only after delivery.

Following the diagnosis, annual expenditures for screening, amounting to 942 €, (Table P12), and treatment (Table P13) are the same as with the implementation of the Programme (HAART1 - 3,172 €, HAART2 - 3,193 € and the therapy applied in the Clinic for Infectious and Tropical Diseases in Belgrade - 1,873 € per annum per person according to international prices).

According to the current market prices in Serbia (domestic prices) the expenditures are several times higher, amounting to 11,945 € for HAART1, 11,456 € for HAART2 and 10,891 € for the therapy applied in the Clinic for Infectious and Tropical Diseases in Belgrade (per annum per person).

C.2.3. Total expenditures for women

The treatment expenditures are increased by 5% for the costs of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications and tumours.

Table 6.

Total expenditures for HIV + women whose infection is not diagnosed during pregnancy due to the non-implementation of the Programme, for an average lifespan, according to international prices

	WOMEN WHOSE INFECTION IS NOT DIAGNOSED DURING PREGNANCY	
	Average expected lifespan of an HIV + woman (17.63)	
	Min No. HIV + women (n = 16/year)	Max No. HIV + women (n = 51/year)
ELIZA test for HIV For 1400 pregnant women that are currently being tested annually in the Republic.	23,184	23,184
ELIZA and Western Blot test for HIV (confirmatory test for HIV infection)	2,252	7,177
Costs for lifelong analyses for HIV + mothers (Screening of the viral, immunological and clinical status: PCR RNK, CD4 + lymphocytes, biochemical blood analysis, complete blood picture)	1,522,736	4,853,720
Cost HAART 1	2,030,080	6,470,880
Cost HAART 2	2,043,520	6,513,720
Cost for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	1,198,720	3,820,920
TOTAL EXPENDITURE in €		
VERSION 1 (Cost HAART 1)	3,578,251	11,354,960
VERSION 2 (Cost HAART 2)	3,591,691	11,397,800
VERSION 3 (Cost for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	2,746,891	8,705,000
AVERAGE TOTAL EXPENDITURES FOR THE NON-IMPLEMENTATION OF THE PROGRAMME	3,305,611	10,485,920
AVERAGE TOTAL EXPENDITURES FOR THE NON-IMPLEMENTATION OF THE PROGRAMME INCREASED BY 5% for: cost of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	3,470,891	10,695,638

*Costs are based on the Programme implementation period of 10 years and the screening and treatment of discovered HIV + women until the end of their lives. Because of the non-implementation of the Programme the HIV infection diagnosis is two years late on average.

For an average lifespan, which is 17.63 years for women during the non-implementation of the Programme, total average expenditures for the non-implementation of the Programme amount to some 3.47 million € (international prices) for the minimum number of identified HIV + mothers (16) and some 10.69 million € for the maximum number identified HIV + mothers (51). (see Table 6 above)

In order to illustrate the size of loss on the part of the state resulting from high prices of diagnostic tests and medicines administered in the therapy for HIV infections, we also calculated Programme non-implementation expenditures according to current prices in the Serbian market (domestic prices). The average total expenditures for the non-implementation of the Programme amount to 9,585,730 € for the minimum number of identified HIV + mothers, and to 29,962,839 € for the maximum number of identified HIV + mothers (Table P22).

The annex (Tables P26 and P30) contains the calculations of expenditures based on the minimum and maximum lifespan of women, according to international and domestic prices.

C.3. Expenditures linked to an HIV infected child, in case of the non-implementation of the Programme

If the Programme is not implemented, it is unlikely that vertical transmission rates will decrease. . According to minimum assessments some 7 HIV+ children are born every year, and according to maximum assessments, some 22 HIV+ children are born every year (min = 6.85 children/per year; max = 21.85 children/per year – Annex 2).

The average lifespan of an HIV+ child is 10.09 years when the Programme is not implemented, and it is lower than for HIV+ children whose mothers are aware of their HIV status during early pregnancy (implementation of the Programme). (Annex 3)

The diagnosis of HIV infections of HIV+ children are two years late¹⁵.

We have assessed that the direct lifelong expenditures for a child infected by HIV consist of two components: medical and social.

The calculation of medical expenditures includes the following elements:

- C.3.1. Cost of ELIZA and confirmatory Western Blot test for diagnosing HIV+ children after showing symptoms
- C.3.2. Cost of lifelong treatment and screening of identified HIV+ children

When mother's HIV status is not known, children are not subject to analyses and antiretroviral treatment.

C.3.1. Expenditures for diagnostics

The cost per child of confirming HIV+ status for those who show clinical symptoms (testing HIV+ children with the ELIZA and administering the confirmatory Western Blot test) amount to 14 € according to international prices and 266 € according to domestic prices (Table P21)

C.3.2. Expenditures for treatment and screening

Per person expenditures for screening and therapy after the discovery of the status amount to 744 € for the screening according to domestic prices and 3,172 € for HAART1, 3,193 € for HAART2 and 1,873€ for the therapy applied in the Clinic for Infectious and Tropical Diseases in Belgrade according to international prices (Tables P19 and P13).

According to current market prices in Serbia (domestic prices) the expenditures are several times greater, amounting to 11,945 € for HAART1, 11,465 € for HAART2 and 10,891 € for the therapy applied in the Clinic for Infectious and Tropical Diseases in Belgrade, annually per person.

¹⁵ Based on the study "Cost Effectiveness Analysis of Antenatal HIV Screening in the United Kingdom" (Editorial by Peckham)

C.3.3. Total medical expenditures

Treatment expenditures are increased by 5% for the costs of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications and tumours.

Table 7.

Total medical expenditures linked to children infected by HIV, if the mother's infection is undetected during pregnancy, due to the non-implementation of the Programme, for an average lifespan of HIV + children, according to international prices

	CHILDREN INFECTED BY HIV Mother's infection undetected during pregnancy	
	Min No. children (n = 6.85)	Max No. children (n = 21.85)
Average expected lifespan of HIV + child (10.09)		
Costs of diagnostic analyses (ELIZA, Western-Blot) for children who were sent for testing because of clinical symptoms	767	2,447
Costs of analyses for clinical, immunological and viral evaluation of HIV + child (PCR RNK, CD4 + lymphocytes, biochemical blood analyses, complete blood picture)	325,961	1,039,743
Cost HAART 1	7,8,759	2,356,479
Cost HAART 2	743,650	2,372,080
Cost of therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	436,222	1,391,452
TOTAL EXPENDITURES in €		
Version 1 (Cost HAART 1)	1,065,487	3,398,669
Version 2 (Cost HAART 2)	1,070,377	3,414,270
Version 3 (Cost of therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	762,949	2,433,642
AVERAGE TOTAL EXPENDITURES FOR NON-IMPLEMENTATION OF PROGRAMME	966,271	3,082,193
AVERAGE TOTAL EXPENDITURES FOR NON-IMPLEMENTATION OF PROGRAMME INCREASED BY 5% for: costs of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications and tumours	1,014,585	3,236,303

* Expenditures based on the Programme lasting 10 years and the screening and treatment of discovered HIV + children until the end of their lives.

For an average lifespan (10.09 years) for children during the non-implementation of the Programme, the total average expenditures of the non-implementation of the Programme for children amount to some 1.014 million € for the minimum number and 3.236 million € for the maximum number of identified HIV + children according to international prices (Table 7).

The average total expenditures of Programme non-implementation according to current market prices in Serbia (domestic prices) amount to 3,227,370 € for the minimum number of HIV + children and 10,294,400 € for the maximum number of HIV + children (Table P23).

The calculations of expenditures based on the minimum and maximum lifespan of women, according to domestic and international prices, can be found in the annex (Tables P27 and P31).

C.3.4. Social care expenditures

The State's social expenditures are inversely proportionate to its investment in prevention of HIV vertical transmission. The HIV+ mother of an HIV+ child stays on sick leave until the end of child's life to care of it, during which period she receives sick leave compensation paid out by the health insurance system. If the HIV+ mother dies before her HIV+ child, the child will be put under guardianship and the guardian will continue receiving compensation on the same basis. We have presumed that the amount of compensation for the second person/guardian is at the level of the mother's sick leave compensation. The average gross annual wage, discounted and expressed, in Euros was used for the calculation of expenditures (Table 8).

Table 8.

Social care expenditures for HIV+ children during the non-implementation of the Programme

	Non-implementation of the Programme	
Number of HIV+ children on annual level	min n = 6.85/year	max n = 21.85/year
Amount of lifelong care expenditures * in €	1,546,235	4,932,152

* This amount relates to lifelong expenditures for social care for all children identified during the 10 years planned for Programme's implementation

For an average lifespan of HIV+ children during the non-implementation of the Programme (10.09 years), the total expenditures for social care for the minimum number of diagnosed HIV+ children (6.85/year) amount to 1.55 million € and for the maximum number of diagnosed HIV+ children (21.85/year) amount to 4.9 million € (Table 8).

C.3.5. Expenditures per HIV+ child

According to our calculations, in case of non-implementation of the Programme -, the expenditures for an HIV+ child for an average lifespan amount to:

- Expenditures for medical care 18,514 € per HIV+ child (according to international prices)
- Social expenditures (expenditures for caring of the child) 28,216 € per an HIV+ child

C.4. Total expenditures for non-implementation of the Programme, international and domestic prices

The total expenditures for the non-implementation of the Programme comprise expenditures for mothers, medical expenditures and expenditures for social care for the HIV + children who are infected because of the non-implementation of vertical transmission prevention (Tables 9 and 9a), according to international (Tables 6,7 and 8) and domestic prices (Tables P22, P23 and 8).

Table 9.

Total expenditures for HIV + women and children during the non-implementation of the Programme for the minimum and maximum assessment of those infected, according to international prices

	Minimum assessment of HIV +	Maximum assessment of HIV +
Expenditures for the non-implementation of the Programme for women	3,470,891	10,695,638
Expenditures for the non-implementation of the Programme for children (medical)	1,014,584	3,236,302
Expenditures for social care for HIV + children	1,546,235	4,932,152
TOTAL in €	6,031,710	18,864,092

Table 9a.

Total expenditures for HIV + women and children during the non-implementation of the Programme for the minimum and maximum assessment of the infected, according to domestic prices

	Minimum assessment of HIV +	Maximum assessment of HIV +
Expenditures for non-implementation of the Programme for women	9,585,730	29,962,839
Expenditures for the non-implementation of the Programme for children (medical)	3,227,370	10,294,400
Expenditures for social care for HIV + children	1,546,235	4,932,152
TOTAL in €	14,359,335	45,189,391

D.

EVALUATION AND ANALYSIS OF NET BENEFIT BY IMPLEMENTATION OF THE PMTCT PROGRAMME

D.1. Net effects of the Programme implementation

Surveys carried out in other countries¹⁶ have shown that the efficiency of the application of certain programmes as prevention in identifying HIV + persons can be evaluated on the basis of the quantified difference between expenditures for the implementation and non-implementation of such a programme.

The net effects in this financial analysis are examined on the basis of:

- direct difference between the expenditures for the implementation and non-implementation of the Programme
- total number of healthy newborn babies, i.e., gained years of life for children born to HIV + mothers
- net benefit of one antenatal diagnosis of HIV infection

Furthermore, the benefit of the implementation of the Programme is also evaluated on the basis of gains from:

- inclusion of women and children in the labour market
- immeasurable supplementary effects of the prevention of HIV infections

Owing to the implementation of the Programme, HIV + women are diagnosed some two years earlier and live, on average, some six months longer as compared to the non-implementation of the Programme.

The difference in medical expenditures between the implementation and non-implementation of the Programme is a result of longer-period screening and treatment of women whose HIV infection was detected during pregnancy (an average 2 ½ years). Furthermore, the implementation of the Programme also includes expenditures for therapy during pregnancy and delivery and the cost of childbirth for each newly discovered HIV + pregnant woman. In the first two years of the Programme implementation, the major portion of expenditures still relates to the cost of testing all the pregnant women.

It is the fact that the mentioned supplementary expenditures of the Programme implementation are payable by the health insurance system, but they also increase the quality and expected increase of the lifespan of the women. Also, Programme implementation would result in a far greater number of healthy newborn babies and a significantly increased average lifespan for them (Tables 13, P35 and P36).

The situation is quite opposite with children. The total expenditures are significantly higher in the case of the non-implementation of the Programme as compared with Programme implementation expenditures. When pregnant women are unaware of being HIV + and, consequently, do not receive adequate treatment, there is a significant rise of vertical transmission of the infection to the infants. When the Programme is non-implemented, a greater number of HIV + babies are born, but the infection is discovered on the basis of clinical symptoms some two years later. Furthermore, the lifespan of HIV + children whose mothers are not aware of being HIV + during pregnancy is shorter by 1.6 years and additionally reduces the number of years during which the HIV + child is screened and treated (which would significantly improve their life status). For those whose status is detected,

¹⁶ Cost Effectiveness Analysis of Antenatal HIV Screening in the United Kingdom (*Editorial by Peckham*); Universal HIV Screening of Pregnant Women in England: Cost Effectiveness Analysis

however, (minimum 6.85 and maximum 21.85) the costs of screening, treating and caring for them, as compared with HIV + born children when the Programme is implemented (minimum 0.32 and maximum 1.02), is significantly higher.

In the total amount of all expenditures for the implementation of the Programme for children born to HIV + mothers, according to international and domestic prices, the largest part goes to the expenditure of screening the children during the first 1 ½ years of their lives. The highest expenditure is associated with making final diagnoses of HIV infection, , with a unit cost of some 20,500 € (total expenditures of diagnostic testing of all the children of HIV + mothers divided by the number of identified HIV infections of children). Implementation of the Programme (HIV testing of mothers in their early pregnancy and application of protocols to reduce the risk of vertical transmission) minimizes the number of HIV infected children requiring lifelong care, while increasing the lifespan of those requiring it (minimum 67 and maximum 210 healthy newborn babies). While not all vertical transmissions can be prevented, the most important factor in achieving this result is the efficient identification of HIV + mothers during pregnancy.

D.2. Net effects on the basis of direct differences in expenditures for the implementation and non-implementation of the Programme

Direct expenditures for the implementation and non-implementation of the Programme assume, as in the previous paragraphs, that the Programme will be implemented or non-implemented in a ten-year period and that it is the obligation of the society to ensure lifelong screening and treatment of all newly diagnosed HIV + persons (both mothers and children).

Taking into consideration the uncertainty of possible efforts by the state to resolve the problem of existing prices of tests and medicines in our State (domestic prices), which are at least overpriced, as well as to ensure the procurement thereof at international prices (that are on average some 10 times lower than domestic prices), the analysis of direct expenditures includes three different concepts.

D.2.1. Implementation of the Programme according to international prices and the non-implementation of the Programme according to domestic prices

The most realistic concept presents expenditures for the implementation of the Programme according to international prices and the non-implementation of the Programme according to domestic prices. That is, if the testing should continue in Serbia in accordance with the epidemiological indications and the existing pricing policy of tests and therapies remained, the direct expenditures for the implementation of the Programme for the minimum number of the HIV infected would be lower than for the non-implementation of the Programme by some 8.14 million €. If calculating the maximum number of HIV + pregnant women, the difference in expenditures is even greater and amounts to 27.93 million €, which is not an insignificant saving for the society (Table 10).

Table 10.

Net effects for the implementation of the Programme presented as a difference between the expenditures for the implementation of the Programme according to international prices and expenditures of the non-implementation of the Programme according to domestic prices

	PROGRAMME IMPLEMENTATION (international prices)		PROGRAMME NON-IMPLEMENTATION (domestic prices)		* DIFFERENCE	
	Min. No.	Max. No.	Min No.	Max No.	Min No.	Max No.
Expenditures for women	5,813,200	15,962,127	9,585,730	29,962,839	-3,772,530	-14,000,712
Expenditures for children (med.)	269,136	857,872	3,227,370	10,294,400	-2,958,234	-9,436,528
Expenditures for social care for children	136,801	436,053	1,546,235	4,932,152	-1,409,434	-4,496,099
TOTAL in €	6,219,137	17,256,052	14,359,335	45,189,391	-8,140,198	-27,933,339

*The table only presents the difference between direct expenditures to be borne by the society in case of Programme implementation or non-implementation. The table does not present the benefit from the birth of healthy babies and gained years of life

The annual level of net effects of the Programme is presented in the tables in Annex (P32, P33 and P34). Regardless of selected antiretroviral therapy, the Programme becomes cost beneficial from the sixth year of implementation for the minimum number of the infected, and from the fifth year of implementation for the maximum number of the infected.

D.2.2. Programme implementation according to international prices and non-implementation according to international prices

The second concept presents direct expenditures of the implementation or non-implementation of the Programme according to international prices and the difference between specific elements in the Programme. If the procurement of tests and therapies in Serbia were to be made according to international prices, direct expenditures for the implementation of the Programme for the minimum number of HIV+ pregnant women would be higher by 187,400 € relative to the non-implementation of the Programme. For the maximum number of HIV+ pregnant women, total expenditures for the implementation of the Programme would be lower by 1.61 million € relative to its non-implementation, representing considerable savings for the society (Table 11).

Table 11.

Net effects of the implementation of the Programme presented as a difference between expenditures for the implementation and non-implementation of the Programme according to international prices

	PROGRAMME IMPLEMENTATION (international prices)		PROGRAMME NON-IMPLEMENTATION (international prices)		* DIFFERENCE	
	Min No.	Max No.	Min No.	Max No.	Min No.	Max No.
Expenditures for women	5,813,200	15,962,127	3,470,891	10,695,638	2,342,309	5,266,489
Expenditures for children (medical)	269,136	857,872	1,014,584	3,236,302	-745,448	-2,378,430
Expenditures for social care for children	136,801	436,053	1,546,235	4,932,152	-1,409,434	-4,496,099
TOTAL in €	6,219,137	17,256,052	6,031,710	18,864,092	187,427	-1,608,040

*Table only shows the difference between direct expenditures to be borne by the society in cases of the implementation or non-implementation of the Programme. The Table does not present the benefit from the birth of healthy babies and gained years of life.

D.2.3. Implementation and non-implementation of the Programme in case of application of international prices of tests and domestic prices of medicines

The third concept reflects the variety of prices of tests in various institutions in our State and presumes that it will be much easier to ensure the international prices of tests (as some health centres in the State have already been procuring tests at lower prices) than for the therapy, i.e., medicines. The total direct expenditures of the Programme implementation would in that case be lower both with regard to minimum and maximum number of HIV + pregnant women than in case of its non-implementation. For the minimum number of HIV + pregnant women, the society would save 202,000€, and for the maximum number of HIV + pregnant women 3.17 million € (Table 12).

Table 12.

Net effects of the Programme implementation presented as a difference between the expenditures for the implementation and non-implementation of the Programme in case of application of the international prices of test and domestic prices of medicines

	PROGRAMME IMPLEMENTATION International prices of tests and domestic prices of medicines		PROGRAMME NON-IMPLEMENTATION International prices of tests and domestic prices of medicines		* DIFFERENCE	
	Min No.	Max No.	Min No.	Max No.	Min No.	Max No.
Expenditures for women	13,222,371	39,578,861	9,309,258	29,620,008	3,913,113	9,958,853
Expenditures for children (medical)	433,220	1,380,932	3,139,203	10,013,369	-2,705,983	-8,632,437
Expenditures for social care for children	136,801	436,053	1,546,235	4,932,152	-1,409,434	-4,496,099
TOTAL in €	13,792,392	41,395,846	13,994,696	44,565,529	-202,304	-3,169,683

*The table only shows the difference between direct expenditures to be borne by the society in cases of Programme implementation or non-implementation. The table does not present the benefit from the birth of healthy babies and the gained years of life.

D.3. Total number of healthy newborn babies and net benefit of gained years of life for children born to HIV + mothers during the implementation of the Programme

With the exception of the second concept for the minimum number of HIV + pregnant women (where there is an expenditure of 187,400 Euros), the savings to society are in the thousands, perhaps millions, of Euros. The impact of Programme implementation is even greater when we consider that, over the ten-year period, a minimum of 65 and a maximum of 210 children will avoid HIV infection (Annex 2). If the Programme were to be implemented 98% of HIV pregnant women would give birth to healthy infants.

Over the ten-year period and according to minimum assessment, 157 healthy infants would be born to these women while only 3 would be HIV infected. (According to the maximum assessment, 500 would be born healthy while only 10 would be HIV infected.) On the other hand, non-implementation over the same period would lead to 91 healthy and 69 HIV + children according to minimum assessment, and 291 healthy and 2000 HIV + according to the maximum assessment. Over a ten-year period, this represents between 157 and 500 healthy births to these HIV + mothers (as compared to between 91 and 290 if the Programme were not implemented), or an additional 66 to 210 non-infected children. (Tables 13 and Annex 2).

For this reason, it may be concluded that the most valuable effect of the implementation of the Programme refer to the gain in the years of life of the healthy newborn infants. In terms of an average lifespan of children, for the minimum number of identified HIV + pregnant women a total of 1,129 years of life of the children are gained, i.e. 3,599 years for the maximum number of children. In case of Programme implementation, the average life cycle of some 70 years is ensured for every child, as compared to 45.5 years in case of the Programme non-implementation the (Tables 13, P35 and P36).

It has been established that with the implementation of the Programme the average lifespan of HIV + children is 12 years and it is two years longer than the lifespan of children of HIV + mothers whose infection was not diagnosed during pregnancy (Annex 3).

Table 13.

Gained years of life during the implementation and non-implementation of the Programme with regard to the average lifespan of HIV+ children and the average life cycle in the Republic

	Programme implementation				Programme non-implementation			
	Min No. HIV+ women (n = 16/year)		Max No. HIV+ women (n = 51/year)		Min No. HIV+ women (n = 16/year)		Max No. HIV+ women (n = 51/year)	
	No. of HIV+ children	No. of healthy children	No. of HIV+ children	No. of healthy children	No. of HIV+ children	No. of healthy children	No. of HIV+ children	No. of healthy children
Average lifespan of children	11.66	72 ¹⁷	11.66	72	10.09	72	10.09	72
No. of gained years of life of children	3.73	1,128.96	11.89	3,598.56	69.12	658.80	220.47	2,098.80
Total gained years of life of children	1,132.69		3,610.45		727.92		2,319.27	
Gained years of life per child	70.79		70.79		45.49		45.48	

D.4. Net benefit from one antenatal diagnose of HIV

The net benefit *from one antenatal diagnosis of HIV* is defined as a difference between the expenditures for HIV infections per one HIV+ woman or child during the Programme's implementation or non-implementation and as a benefit from the gained years of life due to the implementation of the Programme.

During the implementation of the Programme, diagnosing an additional 15 to 51 HIV+ women during their pregnancy incurs additional costs to the state in terms of testing of all pregnant women (some 54,000). To this must be added expenditures for definitive diagnosis, therapy during pregnancy and at childbirth, delivery and lifelong screening and therapy of the newly discovered 16 to 51 HIV+ women. In the first two years of Programme implementation the major expenditure is the testing of all pregnant women. In case of the non-implementation of the Programme, no expenditures are incurred for testing of all pregnant women, nor for therapy and procedures prior to and during childbirth, and because of the late diagnosis (two years in relation to the Programme implementation). Consequent to reduced life expectancy of the HIV+ women (some six months), the expenditures for screening and treatment are lower. For the minimum assessment of HIV+ pregnant women during the Programme implementation, the diagnosis of HIV in early pregnancy results in additional expenditures (if the average value of all three antiretroviral therapies considered) of 9,216 € per each HIV+ pregnant women than in the case of non-implementation of the Programme and 4,312 € per person for the maximum assessment of HIV+ pregnant women (Tables 14 and 15).

For the prevention of one paediatric infection it is necessary to diagnose an average of three infected women. Recall that it has been determined that 20 HIV+ pregnant women give birth to 6.85 children infected by HIV. During Programme implementation all infants of HIV+ mothers pass through a number of diagnostic procedures until HIV infection is diagnosed. Treatment and screening continue beyond 18 months for only a small number of children who

¹⁷ The average life cycle in Serbia, excluding Kosovo and Metohija. See: Statistical Almanac of Serbia 2003, pages 43,44,62

are infected by HIV despite the implementation of the Programme (minimum 0.32 years and maximum 1.02 years). That is why the expenditures per child born to an HIV + mother are so low during the implementation of the Programme, amounting to 2,537 €.

If the Programme is not implemented, the number of children who will be infected by vertical transmission is greater (minimum 6.85 and maximum 21.85), resulting in higher expenditures for lifelong care and treatment. The lifelong expenditures for each HIV + child amount to 46,730 €, 44,193 € more per child than during the implementation of the Programme.

On average, one diagnosis of the mother saves 34,977 € for the minimum assessed number of pregnant women and 39,881 € for the maximum assessed number of pregnant women in the form of expenditures for care of children, and in addition to this, there is a gain of 25.3 years of children's lives (Tables 14 and 15).

Table 14.

Evaluation of lifelong expenditures and years of life for the minimum number of HIV + women and their children depending on whether the women's infection is detected during pregnancy, according to international prices

Evaluation for the minimum number of HIV + pregnant women who give birth n = 16/year	Expected expenditures per woman/child in €			Expected lifespan		
	Woman	Child	Total	Woman	Child	Total
Woman's HIV infection detected in pregnancy (Programme implementation)*	36,332	2,537	38,869	18.25	70.79	89.04
Woman's HIV infection undetected in pregnancy (non-implementation of Programme)*	27,116	46,730	73,846	17.63	45.49	63.12
Difference	9,216	-44,193	-34,977	0.62	25.30	25.92

*Expenditures for the Programme calculated on the basis of average value for all three listed antiretroviral therapies

Table 15.

Evaluation of lifelong expenditures and lifespan for the maximum number of HIV + women and their children depending on whether woman's infection is detected during pregnancy, according to international prices

Evaluation for the maximum No. of HIV + pregnant women who give birth n = 51/year	Expected expenditures per woman/child in €			Expected lifespan		
	Woman	Child	Total	Woman	Child	Total
Woman's HIV infection detected in pregnancy (Programme implementation)*	31,298	2,537	33,835	18.25	70.79	89.04
Woman's HIV infection undetected in pregnancy (non-implementation of Programme)	26,986	46,730	73,716	17.63	45.49	63.12
Difference	4,312	-44,193	-39,881	0.62	25.30	25.92

* Expenditures for the Programme calculated on the basis of an average value for all three listed antiretroviral therapies

D.5. Evaluation of effects based on the participation of women and healthy-born children in the labour market

The implementation of the Programme would also ensure other measurable effects such as (1) effects based on the inclusion of healthy-born children in the labour market and (2) effects based on a higher quality of life and possibility of including HIV + mothers in the labour market during their expected lifespan after childbirth.

The calculation of effects of healthy-born children were made on the basis of a presumed GNP growth in the coming 65 years, i.e., the period that includes the years of the healthy-born children's growth, schooling and working life. It is presumed that the participation in the labour market of these children will start at the age of 19 (upon completion of secondary education), i.e. of 25 (upon completion of university education). Direct effects are reflected in the sum of wages that these children will realise during their working life. For the sake of comparison with the Programme expenditures, the projected wage was discounted by 2% per annum as the wages are presented in EUR, thus representing the current value of the effect. The net benefit from healthy-born children (implementation vs. non-implementation) on the basis of their inclusion in the labour market upon completion of their education amounts to between 12.3 and 44.2 million € (current value) and 26 years of life of children for an average lifespan.

The calculation of effects based on the wages of the treated, and treatment of HIV + women identified during their pregnancy during the period of the Programme implementation includes the period of their average expected lifespan (18 years in the implementation and non-implementation of the Programme from the moment of identification of the woman's HIV infection). On the basis of wages of treated women during implementation of the Programme, current value of the effects, i.e., net benefit from women who will be included in the labour market (implementation vs non-implementation), in the case of the minimum number of HIV + women amounts to 3.04 million € (current value) and 9.69 million € (current value) for the maximum number of HIV + women.

The current value of the total effects on the basis of participation on the labour market of the healthy-born children and treated women during the period of the Programme implementation amount to 15.34 million € in the case of the minimum number of HIV + women and children and 53.90 million € in the case of the maximum number of HIV + women and children (Table 16).

Table 16.

Net benefit based on the inclusion of HIV + women and healthy-born children in the labour market during the period of Programme implementation

	HIV + Children		HIV + Women	
	Min No. implementation (n = 0.32/year) / non-implementation (n = 6.85/year)	Max No. implementation (n = 1.02/year) / non-implementation (n = 21.85/year)	Min No. (n = 16/year)	Max No. (n = 51/year)
Implementation	31,913,716	106,379,054	10,569,763	33,691,119
Non-implementation	19,614,592	62,166,214	7,529,351	23,999,808
Difference (implementation vs non-implementation) in €	12,299,124	44,212,840	3,040,412	9,691,311

D.6. Immeasurable effects

We believe that the implementation of the Programme would have significant indirect and immeasurable effects. They are primarily related to awareness raising of the population to undertake preventive measures for protection against HIV transmissions and contracting AIDS. So-called horizontal transmission to more than one million persons of fertile age, which constitute some 15% of the entire population of the Republic can only be prevented through direct contacts. If information on the ways to become infected by HIV were conveyed to closer relatives and friends, the effects would be far greater.

E.

SOURCES OF FUNDS FOR THE IMPLEMENTATION OF THE PROGRAMME

A portion of the funds allocated for the realisation of the national project funded by the Global Fund to the amount of \$60,000 (47,640 € at the average exchange rate in January 2004) are intended for the testing of pregnant women until the end of 2004. These funds would cover some 56% of the expenditures for the testing, including counselling.

The expenditures for the Programme implementation will, we believe, be around 0.003% of the GDP for the maximum assessment of the number of HIV+ mothers and children according to the average lifespan in the specified period. The expenditures for the Programme implementation in the first ten years are not high because HAART is not administered to mothers during that period, and the largest part of the funds are only intended for testing. Considering that the net effects for the state are negative in the first five years of the Programme implementation with regard to the minimum assessment, or first four years with regard to the maximum assessment, a portion of funds during that period should be covered by donations. It is assessed that the Republic would be able to continue the funding of further implementation of the Programme from its own sources from sixth, i.e. fifth, year thereof.

The Health Protection Fund of the Republic of Serbia spent 3,360,000 € for the treatment of HIV+ persons in 2003. This included out-patient examinations and medicines according to domestic prices for 400 patients. With the reduction of the prices of medicines on the market (in accordance with the recommendations of this analysis) the Fund could reduce these expenditures significantly, redirecting the savings toward support of preventive activities such as reduction of mother to child HIV transmission. . If this were to take place, full financing of the Programme from the budget of the Republic of Serbia could begin in the first years of its implementation.

F.

CONCLUSIONS AND RECOMMENDATIONS

Our results confirm the economic cost-effectiveness of the Programme implementation in preventing mother to child transmission of HIV with the application of the routine (universal) and voluntary testing for HIV of pregnant women using the "Opt-out" model in the Republic under the following preconditions:

- High percentage of acceptance of the test by pregnant women
- Low price of the test
- High percentage of acceptance of the proposed measures of the PMTCT Programme by the HIV + pregnant women

These preconditions will enable timely diagnoses of all HIV+ pregnant women in the population and reduce the possibility of vertical transmission of HIV infections from 40% to 2%. Low price of the procured tests would significantly reduce the State's expenditures on testing. This testing is necessary to identify the relatively few HIV+ pregnant women and enable full financing of the Programme from the national budget from the very start of its implementation.

Testing based on the physician's risk assessment of pregnant women has proven to be unsuitable. In twelve years only one HIV+ pregnant woman was detected, while 14 HIV+ children whose mothers were not aware of their HIV+ status at childbirth were later diagnosed. The implementation of the voluntary counselling and testing for HIV of pregnant women by the "Opt-out" model should include the entire territory of the Republic, since this is the only way to successfully identify HIV+ pregnant women from the rest.

By all accounts, the Republic has a relatively low level of HIV+ pregnant women (2/10,000 pregnant women according to the minimum assessment and 6.4/10,000 pregnant women according to the maximum assessment). It is for this reason that the annual cost of identifying each HIV+ pregnant woman is relatively high. According to the minimum predictions, this amounts to 112,100 € for the 20 expected HIV+ pregnant women in the population and 112,716 € for the 64 expected HIV+ pregnant women according to the maximum predictions.

Even if these expenditures are directly payable from the national budget, analysis of net benefit of Programme implementation (compared to non-implementation) over a ten-year period indicates savings of thousands, perhaps even millions, of Euros. The magnitude of savings is highly dependent on the source and price of tests and medicaments, as well as the number of HIV+ pregnant women and HIV+ children eventually included in screening and treatment. The Programme becomes economically cost-effective beginning in the sixth year if the minimum estimates are accurate and beginning in the fifth year for the maximum estimated number of HIV+ pregnant women.

The greatest gain of the implementation of the Programme represents the minimum 65 and maximum 210 healthy-born children, i.e., children who were protected from the mother's HIV+ infection by therapy and procedures, and who would have otherwise been born infected by HIV.

It is estimated that expenditures for the universal, voluntary testing of pregnant women in the Republic could be covered by the Health Insurance Fund. Since no programmes currently exist for the prevention of vertical transmission, we must rely on estimates that indicate a minimum of 6.85 and a maximum of 21.85 children are infected with HIV each year. Funds that the state already allocates for its treatment and social care, which would be saved with the implementation of the Programme, should be redirected towards prevention by way of testing pregnant women.

This Programme foresees the obligation of doctors to offer testing for HIV to every pregnant woman. It will be extremely important to collect and analyze the following data:

- **how many pregnant women accepted doctors' advice and how many did not**
- **amongst those who accepted, how many were identified as HIV +**
- **what has become of pregnant women (and their children) who refused to undergo testing, what are the additional expenditures of treatment and care if it is discovered that amongst those pregnant women who refused to undergo testing there are more HIV + pregnant women and subsequently HIV + children than amongst those who agreed to be tested, etc.**

Therefore, it is of extreme importance to establish the screening of both pregnant women who agreed to be tested and those who rejected it. The prevalence of HIV + pregnant women in both groups, the degree of transmission, the reasons for rejecting the test, etc, must be established in order to discovery of any possible mistakes in the realisation of the Programme.

We believe that the implementation of the Programme would provide a clear picture of the situation regarding HIV + women in the Republic. Thus, in the long term, the implementation of this model would be based on data from local sources and examination of controlled indicators and not on data extrapolated from studies abroad on how these conclusions may apply in our State.

It is very important for all measures to be adequately carried out during the implementation of the Programme.

Key conclusions and recommendations:

- Testing of pregnant women according to epidemiological indications is ineffective.
- The health care expenditures during the life of a child infected by HIV are assessed at 18,514 € for medical treatment and 28,216 € for social care.
- Routine (universal) and voluntary testing of pregnant women could prevent these expenditures and enable an increase of the lifespan of HIV+ mothers and children.
- The state would save through the implementation of the Programme in a ten-year period from 8.14 million € to 27.93 million € for the medical treatment and social care for HIV+ mothers and children.
- The state would save, on average, between 1.4 and 4.5 million € in expenditures for the care of HIV+ children by implementing this Programme.
- Between 65 and 210 additional HIV-infected children are born with the non-implementation of the Programme.
- Additional benefits, based on the inclusion of children in the labour market upon the completion of their education and the earnings of treated HIV+ mothers, range from 15.34 million € to 53.90 million €.
- The relatively high cost of testing pregnant women during Programme implementation are offset by the cost of therapy for children that would be infected if the programme were not implemented.
- Revision of the prices of tests and medicines in domestic market, government procurement of similar tests and medicaments from foreign suppliers, or relaxing of customs duties and other import barriers that may be discouraging private commercial acquisition of these items for domestic consumption..
- Savings due to lower prices of tests and medicines, as well as due to reduced needs for the treatment of HIV+ children (owing to Programme implementation, a smaller number of HIV+ infants are born).
- Funding of the Programme implementation from domestic sources is feasible beginning in the third year of its implementation, becoming cost beneficial from the sixth year for the minimum estimated number of HIV+ pregnant women and from the fifth year according to maximum estimated number.
- The implementation of the Programme will give a clear picture of the actual situation regarding HIV+ women and children in the population of the Republic.

ANNEXES

Table P0.

Testing for HIV and prevalence of HIV infections amongst pregnant women by year

Year	Pregnant women No. tested	HIV + (%)
1987	/	/
1988	/	/
1989	/	/
1990	25	0
1991	1,789	0
1992	566	0
1993	681	0
1994	5,820	0
1995	2,559	0
1996	NA	NA
1997	1,551	1 (0.06)
1998	1,773	0
1999	1,112	0
2000	389	0
2001	649	0
2002	749	0

Source: Institute for Health Care "Dr. Milan Jovanovic Batut" of the Republic of Serbia

Annex 1 – Assessment of the number of HIV + pregnant women in Serbia

According to the WHO software package, it is assessed that in Serbia today there are between 539 (assessment of minimum number) and 1,685 (assessment of maximum number) HIV + women of childbearing age. Since the fertility rate of HIV + women is 20% lower than the fertility rate of healthy women of childbearing age in Serbia (47.4/1,000), it is expected that there will be 20 HIV infected pregnant women according to the assessment of minimum number, i.e. 64 according to the assessment of the maximum number of HIV + pregnant women. Also, it is presumed that 20% of HIV + pregnant women will opt for abortion once they become aware of their HIV status. Therefore, the minimum expected number of childbirths is 16 and the maximum expected number of childbirths 51 (Table P1).

Table P1

Assessment of the number of pregnant women infected by HIV in Serbia

	Assessment of minimum no.	Assessment of maximum no.
Assessment of no. of women living with HIV/AIDS, age from 15 to 49 years	539	1,685
Expected No. of HIV + pregnant women (fertility rate 37.92/1000)	20	64
No. of pregnant women infected by HIV who opt for abortion during one year, after learning of their HIV status	4	13
No. of pregnant women infected by HIV who give birth during one year, after learning of their HIV status	16	51

Source: Republican Institute for Health Care "Dr. Milan Jovanovic Batut"

Annex 2 – Assessment of the number of children who become HIV-infected by vertical transmission, as a function of whether or not the Programme is implemented.

Since there is no system study related to HIV/AIDS in Serbia, assessment of the expected number of children to be infected by vertical transmission are based on data from the American Society of Gynaecologists and Obstetricians and the American Academy of Paediatricians. The rate of transmission for untreated pregnant women giving birth vaginally is 29%, and 20% for those giving birth by caesarean section. The percentage of pregnancies among general population which end with a caesarean section is 15%. Between 1/3 and 1/2 of all diseases transmitted from mother to child are transmitted through breastfeeding. The rate of abandonment of breastfeeding among the general population ranges from 25% to 30%.

Therefore, according to the above assessments the expected number of HIV + children at the annual level would be 6.85 for the minimum assessments and 21.85 according to the maximum assessments (Table P2).

Table P2.

Expected number of newborn infants of HIV+ mothers (healthy/who avoided being HIV infected) with the implementation and non-implementation of the Programme

ANNUALLY	Assessment of minimum number	Assessment of maximum number
Expected no. of HIV + pregnant women	20	64
Expected no. of childbirths (80%)	16	51
Expected no. of HIV + children for non-implementation of the programme	6.85	21.85
Natural delivery 85%	13.60	43.35
(a) transmission rate 29%	3.94	12.57
Caesarean section 15%	2.40	7.65
(b) transmission rate 20%	0.48	1.53
After pregnancy and childbirth no. of HIV + children (a + b)	4.42	14.10
Children breastfed by 70% women	8.10	25.83
(c) rate of transmission 30%	2.43	7.75
After pregnancy, childbirth and breastfeeding (a + b + c)	6.85	21.85
Expected no. of healthy children, non-implementation of the programme	9.15	29.15
Expected no. of HIV + children, implementation of the programme	0.32	1.02
Expected rate of transmission 2%	0.32	1.02
Expected no. of healthy children, implementation of the programme	15.68	49.98

During the implementation of the Programme, the percentage of transmission is reduced from 40% to 2%.

The expected number of HIV+ children, at the annual level, in case of Programme implementation, would be 0.32 for the minimum and 1.02 for the maximum number of HIV + pregnant women.

For this reason, in case of non-implementation of the Programme, from 68.5 to 218.5 HIV + children would be born in the period of ten years, as opposed to the option of the Programme being implemented, when, despite all preventive measures, 3.2 HIV + children would be born for the minimum number of HIV + pregnant women and 10.2 HIV + children for the maximum number of HIV + pregnant women.

For everything set forth thus far, it is evident that the implementation of the Programme would ensure that between 65 and 210 children born to HIV + mothers would altogether avoid infection by HIV.

Owing to the implementation of the Programme, 98% of HIV + pregnant women would give birth to healthy children, i.e., during ten years of implementation, 157 healthy children would be born and only three infected by HIV according to the minimum assessment, i.e. 500 healthy children and as few as 10 HIV infected according to the maximum assessment. However, with the non-implementation of the Programme, 91 healthy and 69 HIV infected children would be born during the same period according to the minimum assessment, i.e. 291 healthy and 220 HIV infected children according to the maximum assessment.

Annex 3 – Expected lifespan

Since there are no system studies related to HIV/AIDS in Serbia, this analysis referred to available international papers¹⁸ for the expected life spans of mother and child (without therapy or during therapy).

Table P3.

Expected lifespan of an HIV infected child

	Minimum lifespan HIV + child (in years)	Maximum lifespan HIV + child (in years)	Average lifespan HIV + child (in years)
Mother's HIV infection undetected during pregnancy	5.94	18.54	10.09
Mother's HIV infection identified during pregnancy	6.32	23.81	11.66

The above Table shows that HIV + children whose growth has been screened since birth can expect to live longer than infected children whose mothers were not diagnosed as HIV + during pregnancy¹⁹.

Table P4.

Expected lifespan of an HIV + woman

	Minimum lifespan of an HIV + woman (in years)	Maximum lifespan of an HIV + woman (in years)	Average lifespan of an HIV + woman (in years)
HIV infection not diagnosed during pregnancy	15.28	20.88	17.63
HIV infection diagnosed during pregnancy	15.41	25.48	18.25

HIV testing of a pregnant woman in the early period of pregnancy incurs additional expenditures, at the same time increasing the quality and length of her life²⁰.

¹⁸ Gibb DM, Ades AE, Gupta R, Sculpher M. Costs and benefits to the mother of antenatal HIV testing: estimates from simulation modeling. AIDS 1999;13:1569-1576 (Medline);

Ratcliffe J, Ades AE, Gibb D, Sculpher M, Briggs A. Prevention of mother-to-child transmission of HIV infection: alternative strategies and their cost-effectiveness. AIDS 1998;12:1381-1388 (Medline)

¹⁹ Sculpher M, Gibb D, Ades AE, Ratcliffe J, Duong T. Modeling the costs of pediatric HIV Infection and AIDS: comparison of infected children born to screened and unscreened mothers. AIDS 1998; 12:1371-1380 (Medline)

Annex 4 – Calculation of expenditures for the testing of pregnant women

The total number of pregnancies in the Republic, according to the data of the Institute for Health Care of the Republic of Serbia, averages some 100,000 annually. In 2003, there were 72,000 registered childbirths and 22,000 registered abortions (conducted for whatever reasons).

The basic indicators of demographic trends of population calculated as the rate of live newborn babies, the birth-rate, the rate of fertility and the natural population increase were all steeply declined over the last ten years. Of the total number of registered childbirths, it is assessed that 10% relate to children from the refugee population²¹. Considering that the number of childbirths in the Republic in 2000 represented an 18.4% decrease from 1991, we can expect that the average number of childbirths per annum in the ten-year period of the Programme implementation will be 60,000.

Since the Programme anticipates that 90% of pregnant women will agree to take HIV test, expenditures account for the testing of 54,000 pregnant women annually.

According to Institute for Infectious and Tropical Diseases in Belgrade estimates on the costs of the ELIZA test for HIV, the Western Blot test for HIV and a specialist in gynaecology²² universal and voluntary testing of 54,000 pregnant women would cost 1,241,730 € per annum after the first phase of testing. This includes counselling of pregnant women by a specialist lasting an average of 6 minutes. The expenditures for the application of the second test and 30-minute counselling would amount to between 3,907 € (minimum number of HIV+ pregnant women, n=16) and 12,455 € (maximum number of HIV+ pregnant women, n=51). Therefore, total testing expenditures, including counselling before and after the test, would range between 1,245,637 € for the minimum and 1,254,185 € for the maximum number of pregnant women (Table 3). The expenditures for operating supplies were not included in the calculation because the Programme foresees that blood samples for both routine analyses and HIV testing be done at the same time.

If we were to take into calculation international prices (listed in the Brochure²³) instead of the domestic ones, the costs of routine testing and counselling would be far lower (some 15 times -Table 3). The total testing expenditures, including counselling before and after the tests, would be between 84,455 € and 84,925 €.

However, it must be emphasised that one package of tests can rarely be fully utilised. The analysis of expenditures, according to the data obtained from the Institute for Infectious and Tropical Diseases in Belgrade, takes into account that the package containing 96 ELIZA tests is used on 70 tested persons on average, while the package of Western Blot test, which contains 20 tests, is used on 15 tested persons on average. With regard to everything advanced thus far, testing expenditures at the annual level according to the prices from the Brochure would be higher, ranging between 112,100 € for the minimum and 112,716 € for the maximum number of pregnant women.

²¹ Vida Parezanovic: Birth and Death of Children and Adolescents in Yugoslavia 1918-1999, *Federal Bureau for Protection and Promotion of Health*, Belgrade 2000

²² GAK "Narodni Front" Belgrade

²³ *Sources and Prices of Selected Medicines and Diagnostics for People Living With HIV/AIDS*, June 2003

Table P5.

Expenditures for routine (universal) and voluntary testing and counselling of pregnant women by “Opt-out” model

Type of test	No. of tested persons	Price in € in Serbia	Total expenditures, domestic prices	International prices ²	Total expenditures international prices	
Total expenditures for first phase of testing of all pregnant women, scope of test 90% - Elisa			1,241,730		84,240	
Type of test in routine testing	Elisa test for HIV ³	54,000	22.81	1,231,740	1.38	74,250
Price of counselling (6 min.)		54,000	0.19	9,990	0.19	9,990
Total – WB (n = 16)			3,907		215	
Type of confirmatory test	Western Blot (WB) test for HIV ⁴	16	243.29	3,893	12.50	200
Price for counselling (30 min.)		16	0.93	15	0.93	15
Total testing expenditures for minimum assessment of HIV + pregnant women (n = 16)			1,245,637		84,455	
Total – WB (n = 51)			12,455		685	
Type of confirmatory test	Western Blot test for HIV ⁴	51	243.29	12,408	12.50	638
Price of counselling (30 min.)		51	0.93	47	0.93	47
Total expenditures for testing, maximum assessment HIV + pregnant women (n = 51)			1,254,185		84,925	
Total tests expenditures in €						
Minimum assessment				1,235,633	74,450	
Maximum assessment				1,244,148	74,888	

¹Source: Institute for Infectious and Tropical Diseases, Belgrade - Administrative Department, GAK “Narodni Front”, Belgrade²Prices taken from: *Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS*, June 2003 (ELIZA test page 42, Western Blot test page 43) and increased by 2.5 times under presumption elaborated on page3, paragraph 2.³ELIZA test: Genescreen HIV Ag-Ab, BioRad⁴Western-Blot test: Pepti-lav 1-2, BioRad

Note: Total expenditures obtained by multiplying the number of tested persons with price of test/counselling.

Annex 5 – Expenditures for antiretroviral treatment of mothers

The decision to use Zidovudin in this model as medicine for the prevention of vertical transmission²⁴, and not HAART, was made on the basis of Protocol 076 of the study²⁵. Although there is genomic evidence of the resistance of mothers to Zidovudin, this medicine is verified in the prevention of mother to infant HIV transmission. There are numerous studies in the US that prove 100% success in the prevention of mother to child vertical HIV transmission with the application of HAART during pregnancy. However, long-term negative effects (malignancy?) of HAART application during pregnancy are still being studied. Both for medical and economic reasons, Zidovudin was chosen for the prevention of mother to child HIV transmission. If combined antiretroviral therapy (HAART) were to be used during pregnancy (a period of some 5 months), the impact on the model would be limited and the assessed total Programme expenditures would increase by 4.4 times. This would mean a rise in the price of the Programme²⁶ by 106,178 € for the minimum and 338,444 € for the maximum number of HIV + pregnant women.

Table P6.

Expenditure for antiretroviral treatment of mothers aimed at preventing vertical transmission of HIV infection, according to international prices, per annum

	Minimum assessment (n = 16/year)	Maximum assessment (n = 51/year)
Assessed no. of pregnant women who agree to therapy (75%)	12.00	38.25
Duration of treatment in months	5.00	5.00
Price of monthly treatment of pregnant women with Zidovudin capsules, in €	51.87	51.87
Expenditures for treatment during pregnancy	3,112.20	9,920.14
Evaluation of Zidovudin application during delivery (100%)	16.00	51.00
Price of an ampoule of Zidovudin per delivery, in €*	35.82	35.82
Expenditure for treatment during delivery	573.12	1,826.82
Total expenditure for treatment of mothers, in €	3,685.32	11,746.96

Note: Prices taken from *Sources and Prices of Selected Medicines and Diagnostics for People Living with HIV/AIDS*,

*Protocol: During the first hour of delivery pregnant women receive Zidovudin intravenously – 2mg/kg of body weight, and subsequently 1mg/kg of body weight until the end of delivery. The presumption is that the average weight of a pregnant woman is 70 kg and that the delivery lasts on average 8 hours. On average, 3.15 vials of 20 ml, dilution strength 10 mg/ml, are used per each pregnant woman.

June 2003 (Zidovudin, page 10) and increased by 2.5 times according to the presumption from page 3, paragraph 2.

According to the proposed protocol, the cost of treating HIV + pregnant women for five-months range from 3,112 € for the minimum to 9,920 € for the maximum estimated number of HIV + pregnant women. Expenditures for the treatment with Zidovudin during delivery range from 573 € to 1,827 €. The total expenditure for the antiretroviral treatment of HIV + pregnant women during pregnancy and delivery range from 3,685 € for the minimum to 11,747 € for the maximum assessed number of HIV + pregnant women.

²⁴ Conor EM Sperling RS, Gelber R, Keslev P Scott G, O Sullivan MJ, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type I with zidovudin treatment. Pediatric AIDS Clinical Trials Group Protocol 076 Study Group. N Engl J Med 1994;331:1173-1180 (Abstract).

²⁵ Sperling RS, Shapiro DE MC Sherry GD, Britto P, Cunningham BE, Culnane M, et al. Safety of the maternal-infant zidovudin regimen utilized in the Pediatric AIDS Clinical Trial Group o76 Study. AIDS 1998; 12: 1805-1813 (Medline).

²⁶ Same

The medicine Zidosan is produced in Serbia and it can serve as a substitute for the imported Retrovir (Zidovudin). Zidosan is frequently administered in the treatment of HIV infected patients.

Table P7 presents a comparative review of expenditures for the treatment of pregnant women with these two medicines for the maximum and minimum assessed number of HIV+ pregnant women according to current domestic prices. The use of the domestic medicine enables large savings that range from 8,868 € to 28,268 € per annum.

Table P7.

Expenditures for antiretroviral treatment of mothers, aimed at preventing vertical transmission of HIV infection, according to domestic prices, per annum

Medicines in the Serbian market	Zidosan - manufactured in Serbia		Retrovir (Zidovudin) - imported	
No. of HIV + pregnant women	Minimum assessment (n = 16/year)	Maximum assessment (n = 51/year)	Minimum assessment (n = 16/year)	Maximum assessment (n = 51/year)
Assessed number of pregnant women who will agree to therapy (75%)	12.00	38.25	12.00	38.25
Duration of treatment in months	5.00	5.00	5.00	5.00
Price of monthly treatment of pregnant woman with medicines available in the Serbian market – Zidovudin and substitutes, in €	80.59	80.59	228.40	228.40
Expenditures for treatment during pregnancy, in €	4,835.65	15,413.64	13,704.00	43,681.50

Source: Pharmacy Institution Belgrade (Zidosan), Hemofarm (Retrovir)

The expenditures for a five-month treatment of pregnant women with Zidovudin, according to international prices, are even lower than the expenditures for treatment with domestic medicine (Zidosan). Unfortunately, Zidovudin ampoules cannot be found on domestic market, and therefore we were not able to provide a comparison of expenditures for childbirth medicines according to the international and domestic prices.

Table P8.

Childbirth expenditures for an HIV+ pregnant woman in case of implementation of the Programme on prevention of mother to child HIV transmission, per annum

No. of HIV + pregnant women	Minimum assessment (n = 16/year)	Maximum assessment (n = 51/year)
Delivery expenditures for an HIV+ pregnant woman according to Protocol, in € *	2,729.25	8,699.48
Natural delivery, in €	164.18	523.31
No. of natural deliveries (10%)	1.60	5.10
Price of natural delivery, in € **	102.61	102.61
Childbirth by caesarean section, in €	2,565.07	8,176.17
No. of deliveries by caesarean section (90%)	14.40	45.90
Price of deliveries by caesarean section, in €***	178.13	178.13

Source: Gynaecological-Obstetrics Clinic "Narodni Front", Belgrade

* Programme foresees that 90% of childbirths will be conducted by caesarean section, and 10% as vaginal deliveries

** Table P10

*** Table P11

Table P9.

Childbirth expenditures for pregnant women amongst general population when, their HIV status is not detected during pregnancy/non-implementation of the Programme/they are not tested, per annum

No. of HIV + pregnant women	Minimum assessment (n = 16/year)	Maximum assessment (n = 51/year)
Childbirth expenditures amongst general population, in € *	1,823.01	5,810.84
Natural delivery, in €	1,395.50	4,448.14
No. of natural deliveries (85%)	13.60	43.35
Price of natural delivery **	102.61	102.61
Childbirth by caesarean section, €	427.51	1,362.69
No. of deliveries by caesarean section (15%)	2.40	7.65
Price of deliveries by caesarean section ***	178.13	178.13

Source: Gynaecological-Obstetrics Clinic "Narodni Front", Belgrade

*Childbirths by caesarean section constitutes 15% in the general population total deliveries

** Table P10

*** Table P11

Table P10.

Price of natural delivery with episiotomy

Type of service	No. interventions	Price in €	Total
Conducting of childbirth	1	16.1	16.1
Childbirth	1	5.0	5.0
III and IV childbirth age	1	3.7	3.7
Episiotomy	1	6.4	6.4
CTG	2	5.7	11.4
Ultra sound	1	4.6	4.6
Hospital day – intensive care	2	21.8	43.5
Hospital day – semi-intensive care	1	11.9	11.9
Total u €			102.6

Source: GAK "N.Front" Administrative Department, from the pricelist of services of the Republican Bureau of Health Insurance

Table P11

Price of caesarean section

Type of service	No. of interventions	Price in €	Total
Conducting of childbirth	1	16.1	16.1
Childbirth, operative S.C.	1	43.1	43.1
III and IV childbirth age	1	3.7	3.7
General anaesthesia	1	14.2	14.2
CTG	2	5.7	11.4
Ultra sound	1	4.6	4.6
Hospital day – intensive care	3	21.8	65.3
Hospital day – semi-intensive care	1	11.9	11.9
Hospital day – regular care	1	7.9	7.9
Total u €			178.1

Source: GAK "N.Front" Administrative Department, from the pricelist of services of the Republican Bureau of Health Insurance

Table P12.

Expenditures for analysis of an HIV + mother

		Domestic price ¹	Total
PCR RNK	2x during pregnancy	99.1	198
PCR RNK	4x per year	99.1	396
CD4 + lymphocytes	4x per year	33.1	132
Biochemical blood analysis	6x per year	32.7	196
Complete blood picture	6x per year	3.0	18
Total u €			942

¹ Prices obtained from the Administrative Department of the Clinic for Infectious and Tropical Diseases**Table P13.**

Annual expenditures for therapy per person by domestic and international prices

Therapy	Medicines and daily dosage	Domestic prices ¹	International prices ²
HAART1	Zerit (40mgx2)	3,143	148
	Ziagen (300mgx2)	4,222	1,954
	Stocrin (200mgx3)	4,580	1,070
	Total in €	11,945	3,172
Therapy in HAART2 Institute for Infectious and Tropical Diseases	Ziagen (300mgx2)	4,222	1,954
	Zerit (40mgx2)	3,143	148
	Crixivan (800mgx2)	3,170	926
	Norvir (100mgx2)	929	165
	Total in €	11,465	3,193
Therapy in HAART2 Institute for Infectious and Tropical Diseases	Videx (400mg)	3,513	536
	Epivir (150mgx2)	2,798	266
	Storcin (200mgx3)	4,580	1,070
	Total in €	10,891	1,873

¹ Prices obtained from the Administrative Department of the Clinic for Infectious and Tropical Diseases² Prices taken from brochure *Sources and prices of selected medicines and diagnostics for people living with HIV/* June 2003, *AIDS* (Zerit, Storcin, Crixivan, Epivir page.10, Ziagen page.9, Norvir page. 12 in annex 6, Videx page. 9 in annex 6) multiplied by 2,5 times under presumption from page 3, paragraph 2 of the same brochure

Table P14.

Programme implementation expenditures for women whose HIV infection is diagnosed during pregnancy, for average lifespan of HIV + women, by domestic prices

	WOMAN WHOSE HIV INFECTION IS DIAGNOSED IN PREGNANCY	
	Average expected lifespan of an HIV + woman in years (18,25)	
	Min no. of women (n = 16/year)	Max no. of women (n = 51/year)
ELIZA test for HIV for 54,000 pregnant women, per annum, including counselling of pregnant woman by doctor	12,420,000	12,420,000
Western Blot test for HIV	38,928	124,083
PCR RNK administered two times during pregnancy	31,706	101,064
Retrovir (therapy during pregnancy)	137,040	436,815
Zidovudin (therapy at childbirth)	5,731	18,268
Expenditures for delivery by protocol higher than for general population	9,060	28,879
Lifelong expenditures for analyses of HIV + pregnant women whose infection is discovered during pregnancy (Screening of viral, immunity and clinical status: PCR RNK, CD4 + lymphocytes, biochemical blood analyses, complete blood analyses)	2,141,347	6,825,543
Expenditures HAART 1	9,556,294	30,460,687
Expenditures HAART 2	9,172,323	29,236,780
Expenditures for therapy most frequently applied in Clinic for Infectious and Tropical Diseases in Belgrade	8,713,090	27,772,973
TOTAL EXPENDITURES in €		
Version 1 (Expenditures HAART 1)	24,340,106	50,415,339
Version 2 (Expenditures HAART 2)	23,956,135	49,191,432
Version 3 (Expenditures for therapy most frequently applied in Clinic for Infectious and Tropical Diseases in Belgrade)	23,496,902	47,727,625
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES	23,931,048	49,111,465
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES INCREASED BY 5% for: cost of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	25,127,600	51,567,039

Table P15

Expenditures for diagnosing HIV infection of a child during Programme implementation

		Domestic prices ¹	Total	Manufacturer prices ²	Total
PCR DNK ¹	4x during first 6 months	99.1	396	99.1	396
ELIZA	1x with diagnosis	22.8	22.8	1.4	1.4
Western-Blot	1x with diagnosis	243.3	243.3	12.5	12.5
Total in €			662		410

¹ Prices obtained from the Administrative Department of the Clinic for Infectious and Tropical Diseases

² Prices taken from brochure *Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS* June 2003 (ELIZA test: Genescreen HIV Ag-Ab, BioRad page 42, Western Blot test: Pepti-lav 1-2, BioRad page 43) increased 2,5 times under presumption from page 3, paragraph 2 of same brochure

Note: PCR DNK for HIV is administered to infants born to HIV infected mothers. A child carries its mother's antibodies for another 1,5 years approximately, although it is possible that it is not infected. This test confirms whether the infant is really infected, that is, whether it has started creating its own antibodies. Several controls are carried out: at birth, after 7 days, after one month and after three months. Therefore, a total of four checkups in the first six months, as the virus develops, until the sixth month at latest. If the test is positive, the baby is subject to PCR RNK.

Table P16.

Expenditures for antiretroviral therapy for children with Zidovudin

Assessed number of infants who will be using Zidovudin	Minimum assessment (n = 16/year)	Maximum assessment (n = 51/year)
Duration of treatment in months	1.50	1.50
Price of monthly treatment with Zidovudin (syrup), in € *	2.87	2.87
Expenditures for antiretroviral treatment of newborn babies, in €	68.88	219.56

Note: Prices taken from: *Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS*, June 2003 (Zidovudin page 10) and increased by 2.5 times under presumption from page 3, paragraph 2. Zidovudin syrup cannot be found in the domestic market so that the comparison of expenditures for the medicine for treatment of newborn babies according to international and domestic prices was not possible.

*Protocol: Zidovudin syrup is administered at 8mg/kg body weight per day. Assessment: average weight of newborn baby 3,5kg.

Table P17.

Diet expenditures for children of HIV+ mothers who, according to the PMTCT Protocol and informed choice are not breastfed, per annum

	Minimum assessment (n = 16/year)	Maximum assessment (n = 51/year)
No. of children in population of HIV+ mothers that will be fed with milk substitute (95%)	15.20	48.45
Expenditures for diet with milk substitute for six months, in €*	453.00	453.41
Total diet expenditures, in €	6,885.60	21,967.91

Source: Gynaecological-Obstetrics Clinic «Narodni Front» in Belgrade. Note: for determining the price of substitute milk, the average price of the two most frequently used products was taken: «Bebelac» and «Aptamil».

* Table P18

Table P18.

Diet expenditures for a baby with milk substitute during first six months

Age of infant	Amount per meal in millilitres	No. of meals	Total milk per day in litres	Total milk	Expenditures of baby's diet by average price of a box of Bebelac and Aptamil ¹
I week	90	8	0.72	5.0	773
II – IV week	120	8	0.96	20.2	3,093
II month	150	8	1.20	36.0	5,524
III month	180	8	1.44	43.2	6,629
IV month	200	8	1.60	48.0	7,365
V month	210	8	1.68	50.4	7,733
Diet expenditures in first 6 months in CSD					31,118
Diet expenditures in first 6 months in €					453

¹ A package of Bebelac 400gr costs CSD 236.17. When diluted, it makes 2l milk. A package of Aptamil 600gr costs CSD 566.39. When diluted, it makes 3l milk.

Source: GAK "N.Front" Administrative Department from pricelist of the Republican Bureau for Health Insurance

Table P19.

Screening expenditures of an HIV+ child (clinical, immunological and viral screening) during a one-year period

		Prices ¹	Total
PCR RNK	4x year	99.1	396
CD4 + lymphocytes	4x year	33.1	132
Biochemical blood analysis	6x year	32.7	196
Complete blood picture	6x year	3.0	18
Total in €			744

¹ Prices obtained from Administrative Department of the Clinic for Infectious and Tropical Diseases; these expenditures were also used in the analysis with international prices.

Note: Expenditures for screening situation of HIV+ child for one year are the same for implementation and non-implementation of Programme

Table P20.

Expenditures linked to the children of HIV + mothers whose infection is diagnosed during pregnancy owing to Programme implementation, for average lifespan of HIV+ children, according to domestic prices

	CHILDREN BORN TO HIV + MOTHERS PROGRAMME IMPLEMENTATION	
	Min no. of HIV + women (n = 16/year)	Max no. of HIV + women (n = 51/year)
	Min no. of HIV + children (n = 0,32/year)	Max no. of HIV + children (n = 1,02/year)
	Average expected lifespan of an HIV + child (11.66)	
Expenditures for diagnostic analyses for all children born to HIV + mothers (PCR DNK, ELIZA, Western-Blot)	105,920	337,620
Expenditures for antiretroviral treatment for all newborn babies of HIV + mothers	689	2,196
Expenditures for diet of infants by Protocol higher than expenditures for general population	48,924	155,832
Expenditures for analyses of an HIV + child (Screening of viral, immunity and clinical status: PCR RNK, CD4 + lymphocytes, biochemical blood analysis, complete blood picture)	145,136	462,620
Expenditures HAART 1	191,126	609,214
Expenditures HAART 2	183,446	584,736
Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	174,262	555,459
TOTAL EXPENDITURES in €		
Version 1 (Expenditures HAART 1)	461,091	1,469,770
Version 2 (Expenditures HAART 2)	453,412	1,445,292
Version 3 (Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	444,227	1,416,016
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES	452,910	1,443,693
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES INCREASED FOR 5% for: cost of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	475,556	1,515,877

Table P21.

Expenditures for HIV infection diagnosis of a child in case of non-implementation of the Programme

		Domestic prices ¹	Total	Manufacturer prices ²	Total
ELIZA	1x at diagnosis	22.8	22.8	1.4	1.4
Western-Blot	1x at diagnosis	243.3	243.3	12.5	12.5
Total in €			266		14

¹Prices obtained from the Administrative Department of the Clinic for Infectious and Tropical Diseases

²Prices taken from brochure *Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS* June 2003 (ELIZA test: Genescreen HIV Ag-Ab, BioRad page 42, Western Blot test: Pepti-lav 1-2, BioRad p. 43) increase by 2,5 times under presumption elaborated on page 3, paragraph 2 of the same brochure

Table P22.

Expenditures for treating an HIV + woman whose infection is not diagnosed during pregnancy due to non-implementation of the Programme, for an average lifespan, by domestic prices

	WOMEN WHOSE INFECTION IS NOT DIAGNOSED DURING PREGNANCY Average expected lifespan of an HIV + woman (17,63)	
	Min no. of women (n = 16)	Max no. of women (n = 51)
ELIZA test for HIV For 1400 pregnant women that are, on average per annum, currently being tested in Serbia	257,600	257,600
Western Blot test for HIV (confirmatory test for HIV infection)	31,142	99,266
Lifelong expenditures for analyses for HIV + mothers (Screening of viral, immunity and clinical status: PCR RNK, CD4 + lymphocytes, biochemical blood analyses, complete blood picture)	1,522,736	4,853,720
Expenditures HAART 1	7,645,035	24,368,550
Expenditures HAART 2	7,337,858	23,389,424
Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	6,970,472	22,218,379
TOTAL EXPENDITURES in €		
Version 1 (Expenditures HAART 1)	9,456,513	29,579,136
Version 2 (Expenditures HAART 2)	9,149,336	28,600,010
Version 3 (Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	8,781,950	27,428,965
AVERAGE TOTAL EXPENDITURES FOR NON-IMPLEMENTATION OF THE PROGRAMME	9,129,266	28,536,037
AVERAGE TOTAL EXPENDITURES FOR NON-IMPLEMENTATION OF THE PROGRAMME INCREASED BY 5% for: costs of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	9,585,730	29,962,839

Table P23.

Expenditures linked to a child infected by HIV if its mother's infection is not detected during pregnancy, due to non-implementation of the Programme, for average lifespan of HIV+ children, by domestic prices

	CHILDREN INFECTED BY HIV Mother's infection undetected during pregnancy	
	Average expected lifespan of HIV + child (10.09)	
	Min no. of children (n = 6.85)	Max no. of children (n = 21.85)
Expenditures for diagnostic analyses (ELIZA, Western-Blot) for children sent for testing because of clinical symptoms	84,736	270,096
Expenditures for analyses of clinical, immunity and viral evaluation of an HIV+ child (PCR RNK, CD4 + lymphocytes, biochemical blood analysis, complete blood picture)	325,961	1,039,743
Expenditures HAART 1	2,782,076	8,874,214
Expenditures HAART 2	2,670,293	8,517,648
Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	2,536,598	8,091,193
TOTAL EXPENDITURES in €		
Version 1 (Expenditures HAART 1)	3,192,773	10,184,052
Version 2 (Expenditures HAART 2)	3,080,989	9,827,487
Version 3 (Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	2,947,295	9,401,032
AVERAGE TOTAL EXPENDITURES FOR NON-IMPLEMENTATION OF THE PROGRAMME	3,073,686	9,804,190
AVERAGE TOTAL EXPENDITURES FOR NON-IMPLEMENTATION OF THE PROGRAMME INCREASED BY 5% for: costs of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	3,227,370	10,294,400

Table P24.

Programme implementation expenditures for women whose HIV infection is diagnosed during pregnancy owing to implementation of the Programme, for the minimum and maximum lifespan of HIV + woman, by international prices

	WOMEN WHOSE HIV INFECTION IS DIAGNOSED DURING PREGNANCY			
	Minimum expected lifespan of an HIV + woman in years (15.41)		Maximum expected lifespan of an HIV + woman in years (25.48)	
	Min no. of women (n = 16/year)	Max no. of women (n = 51/year)	Min no. of women (n = 16/year)	Max no. of women (n = 51/year)
ELIZA test for HIV for 54,000 pregnant women per annum, including counselling of pregnant woman by doctor	1,117,800	1,117,800	1,117,800	1,117,800
Western Blot test for HIV	2,814	8,971	2,814	8,971
PCR RNK administered 2 times during pregnancy	31,706	101,064	31,706	101,064
Retrovir (therapy during pregnancy)	31,122	99,201	31,122	99,201
Zidovudin (therapy at childbirth)	5,731	18,268	5,731	18,268
Expenditures for childbirth according to Protocol higher than for general population	9,060	28,879	9,060	28,879
Lifelong expenditures for analyses of HIV + pregnant women whose infection is detected during pregnancy (Screening of viral, immunity and clinical status :PCR RNK, CD4 + lymphocytes, biochemical blood analysis, complete blood picture)	1,784,456	5,687,953	2,974,093	9,479,921
Expenditures HAART 1	2,537,600	8,088,600	2,537,600	8,088,600
Expenditures HAART 2	2,554,400	8,142,150	2,554,400	8,142,150
Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	1,498,400	4,776,150	1,498,400	4,776,150
TOTAL EXPENDITURES in €				
Version 1 (Expenditures HAART 1)	5,520,290	15,150,736	6,709,927	18,942,704
Version 2 (Expenditures HAART 2)	5,537,090	15,204,286	6,726,727	18,996,254
Version 3 (Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	4,481,090	11,838,286	5,670,727	15,630,254
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES	5,179,490	14,064,436	6,369,127	17,856,404
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES INCREASED BY 5% for: costs of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	5,438,465	14,767,658	6,687,583	18,749,224

Table P25

Expenditures linked to children of HIV+ mothers whose infection is diagnosed during pregnancy, owing to Programme implementation, for the minimum and maximum lifespan of HIV+ children, by international prices

	CHILDREN BORN TO HIV + MOTHERS DURING PROGRAMME IMPLEMENTATION			
	Minimum expected lifespan of an HIV + child (6.32)		Maximum expected lifespan of an HIV + child (23.81)	
	Min no. of children (n = 16/year)	Max no. of children (n = 51/year)	Min no. of children (n = 16/year)	Max no. of children (n = 51/year)
	Min no. of HIV + children (n = 0.32/year)	Max no. of HIV + children (n = 1.02/year)	Min no. of HIV + children (n = 0.32/year)	Max no. of HIV + children (n = 1.02/year)
Expenditures of diagnostic analyses for all children born to HIV + mothers (PCR DNK, ELIZA, Western-Blot)	65,600	209,100	65,600	209,100
Expenditures of antiretroviral treatment for all newborn babies of HIV + mothers	689	2,196	689	2,196
Expenditures for diet of children according to Protocol higher than expenditures for general population	48,924	155,832	48,924	155,832
Expenditures for analyses for HIV + child (Screening of viral, immunity and clinical status: PCR RNK, CD4 + lymphocytes, biochemical blood analyses, complete blood picture)	131,812	420,150	173,687	553,627
Expenditures HAART 1	50,752	161,772	50,752	161,772
Expenditures HAART 2	51,088	162,843	51,088	162,843
Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	29,968	95,523	29,968	95,523
TATAL EXPENDITURES in €				
Version 1 (Expenditures HAART 1)	249,812	796,277	291,687	929,754
Version 2 (Expenditures HAART 2)	250,148	797,348	292,023	930,825
Version 3 (Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	229,028	730,028	270,903	863,505
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES	242,996	774,551	284,871	908,028
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES INCREASED BY 5% for: costs of hospitalisation, therapy and prophylaxis of oportune infections, treatment of infectious and non-infectious complications, tumours	255,146	813,279	299,115	953,429

Table P26.

Expenditures for treating an HIV + woman whose infection is not diagnosed during pregnancy, due to non-implementation of the Programme, for minimum and maximum lifespan, by international prices

	WOMEN WHOSE INFECTION IS NOT DIAGNOSED DURING PREGNANCY			
	Minimum expected lifespan of an HIV + woman, in years (15.28)		Maximum expected lifespan of an HIV + woman, in years (20.88)	
	Min no. of women (n = 16)	Max no. of women (n = 51)	Min no. of women (n = 16)	Max no. of women (n = 51)
ELIZA test for HIV for 1,400 pregnant women, the number currently being tested on average per annum in Serbia	28,980	28,980	28,980	28,980
Western Blot test for HIV (confirmatory test for HIV infection)	2,252	7,177	2,252	7,177
Lifelong expenditures for analyses for HIV + mothers (Screening of viral, immunity and clinical status: PCR RNK, CD4 + lymphocytes, biochemical blood analyses, complete blood picture)	1,237,223	3,943,647	1,808,249	5,763,792
Expenditures HAART 1	1,522,560	4,853,160	1,522,560	4,853,160
Expenditures HAART 2	1,532,640	4,885,290	1,532,640	4,885,290
Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	899,040	2,865,690	899,040	2,865,690
TOTAL EXPENDITURES in €				
Version 1 (Expenditures HAART1)	2,791,014	8,832,964	3,362,040	10,653,109
Version 2 (Expenditures HAART 2)	2,801,094	8,865,094	3,372,120	10,685,239
Version 3 (Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	2,167,494	6,845,494	2,738,520	8,665,639
AVERAGE TOTAL EXPENDITURES FOR PROGRAMME NON-IMPLEMENTATION	2,586,534	8,181,184	3,157,560	10,001,329
AVERAGE TOTAL EXPENDITURES FOR PROGRAMME NON-IMPLEMENTATION INCREASED BY 5% for: costs of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	2,715,861	8,590,243	3,315,438	10,501,395

Table P27.

Expenditures linked to a child infected by HIV if its mother's infection is undetected during pregnancy, due to non-implementation of the Programme, for minimum and maximum lifespan of HIV + children, by international prices

	CHILDREN INFECTED BY HIV			
	Mother's infection undetected during pregnancy			
	Minimum expected lifespan of an HIV + child (5.94)		Minimum expected lifespan of an HIV + child (5.94)	
	Min. no. of children (n = 6.85)	Min. no. of children (n = 6.85)	Min. no. of children (n = 6.85)	Min. no. of children (n = 6.85)
Expenditures of diagnostic analyses (ELIZA, Western-Blot) for children who were sent for testing because of clinical symptoms	52,480	167,280	52,480	167,280
Expenditures of analyses for clinical, immunity and viral evaluation for HIV + child (PCR RNK, CD4 + lymphocytes, biochemical blood analyses, complete blood analysis)	162,980	519,871	692,666	2,209,454
Expenditures HAART 1	695,302	2,217,862	869,128	2,772,328
Expenditures HAART 2	699,906	699,906	699,906	699,906
Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	41,562	1,309,602	513,202	1,637,002
TOTAL EXPENDITURES in €				
Version 1 (Expenditures HAART1)	910,763	2,905,014	1,614,274	5,149,062
Version 2 (Expenditures HAART 2)	915,366	1,387,057	1,445,052	3,076,639
Version 3 (Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	626,022	1,996,753	1,258,348	4,013,736
AVERAGE TOTAL EXPENDITURES FOR PROGRAMME NON-IMPLEMENTATION	817,384	2,096,275	1,439,225	4,079,812
AVERAGE TOTAL EXPENDITURES FOR PROGRAMME NON-IMPLEMENTATION INCREASED BY 5% for: costs of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	858,253	2,201,088	1,511,186	4,283,803

Table P28.

Programme implementation expenditures for women whose HIV infection is diagnosed during pregnancy owing to implementation of the Programme, for the minimum and maximum lifespan of HIV + woman, by domestic prices

	WOMAN WHOSE HIV INFECTION IS DIAGNOSED DURING PREGNANCY			
	Minimum expected lifespan of an HIV + woman, in years (15.41)		Maximum expected lifespan of an HIV + woman, in years (25.48)	
	Min no. of women (n = 16/year)	Max no. of women (n = 51/year)	Min no. of women (n = 16/year)	Max no. of women (n = 51/year)
ELIZA test for HIV for 54,000 pregnant women per annum, including counselling by doctor	12,420,000	12,420,000	12,420,000	12,420,000
Western Blot test for HIV	38,928	124,083	38,928	124,083
PCR RNK administered two times during pregnancy	31,706	101,064	31,706	101,064
Retrovir (therapy during pregnancy)	137,040	436,815	137,040	436,815
Zidovudin (therapy at delivery)	5,731	18,268	5,731	18,268
Expenditures for delivery according to Protocol, higher than for general population	9,060	28,879	9,060	28,879
Lifelong expenditures for analyses for HIV + pregnant woman whose infection is detected during pregnancy (Screening of viral, immunity and clinical status: PCR RNK, CD4 + lymphocytes, biochemical blood analyses, complete blood picture)	1,784,456	5,687,953	2,974,093	9,479,921
Expenditures HAART 1	9,556,294	30,460,687	9,556,294	30,460,687
Expenditures HAART 2	9,172,323	29,236,780	9,172,323	29,236,780
Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	8,713,090	27,772,973	8,713,090	27,772,973
TOTAL EXPENDITURES in €				
Version 1 (Expenditures HAART1)	23,983,215	49,277,749	25,172,852	53,069,717
Version 2 (Expenditures HAART 2)	23,599,244	48,053,841	24,788,881	51,845,810
Version 3 (Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	23,140,011	46,590,035	24,329,648	50,382,003
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES	23,574,157	47,973,875	24,763,794	51,765,843
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES INCREASED BY 5% for: costs of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	24,752,865	50,372,569	26,001,983	54,354,136

Table P29.

Expenditures linked to children of HIV + mothers whose infection is diagnosed during pregnancy, owing to implementation of the Programme, for the minimum and maximum lifespan of HIV + children, by domestic prices

	CHILDREN BORN TO HIV + MOTHERS DURING PROGRAMME IMPLEMENTATION			
	Minimum expected lifespan of an HIV + child (6.32)		Maximum expected lifespan of an HIV + child (23.81)	
	Min no. of children (n = 16/year)	Max no. of children (n = 51/year)	Min no. of children (n = 16/year)	Max no. of children (n = 51/year)
	Min no. of HIV + children (n = 0.32/year)	Max no. of HIV + children (n = 1.02/year)	Min no. of HIV + children (n = 0.32/year)	Max no. of HIV + children (n = 1.02/year)
Expenditures of diagnostic analyses for all children born to HIV + mothers (PCR DNK, ELIZA, Western-Blot)	105,920	337,620	105,920	337,620
Expenditures of antiretroviral treatment for all newborn babies of HIV + mothers	689	2,196	689	2,196
Expenditures of diet for children according to Protocol, higher than expenditures for general population	48,924	155,832	48,924	155,832
Expenditures for analyses for clinical, immunity and viral evaluation of an HIV + child (PCR RNK, CD4 + lymphocytes, biochemical blood analyses, complete blood analysis)	131,812	420,150	173,687	553,627
Expenditures HAART 1	191,126	609,214	191,126	609,214
Expenditures HAART 2	183,446	584,736	183,446	584,736
Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	174,262	555,459	174,262	555,459
TOTAL EXPENDITURES in €				
Version 1 (Expenditures HAART1)	447,767	1,427,300	489,643	1,560,778
Version 2 (Expenditures HAART 2)	440,088	1,402,822	481,963	1,536,300
Version 3 (Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	430,903	1,373,546	472,779	1,507,023
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES	439,586	1,401,223	481,462	1,534,700
AVERAGE TOTAL PROGRAMME IMPLEMENTATION EXPENDITURES INCREASED BY 5% for: costs of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	461,565	1,471,284	505,535	1,611,435

Table P30.

Expenditures for treating an HIV+ woman whose infection was not diagnosed during pregnancy, due to non-implementation of the Programme, for the minimum and maximum lifespan, by domestic prices

	WOMEN WHOSE INFECTION IS NOT DIAGNOSED DURING PREGNANCY			
	Minimum expected lifespan of an HIV + woman, in years (15.28)		Maximum expected lifespan of an HIV + woman, in years (20.88)	
	Min no. of women (n = 16)	Max no. of women (n = 51)	Min no. of women (n = 16)	Max no. of women (n = 51)
ELIZA test for HIV for 1,400 pregnant women that are on average tested in Serbia	322,000	322,000	322,000	322,000
Western Blot HIV test (confirmatory test for HIV infection)	31,142	99,266	31,142	99,266
Lifelong analyses expenditures for HIV + mothers (Screening of viral, immunity and clinical status: PCR RNK, CD4 + lymphocytes, biochemical blood analyses, complete blood picture)	1,237,223	3,943,647	1,808,249	5,763,792
Expenditures HAART 1	5,733,776	18,276,412	5,733,776	18,276,412
Expenditures HAART 2	5,503,394	17,542,068	5,503,394	17,542,068
Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	5,227,854	16,663,784	5,227,854	16,663,784
TOTAL EXPENDITURES in €				
Version1 (Expenditures HAART1)	7,324,142	22,641,326	7,895,167	24,461,471
Version2 (Expenditures HAART2)	7,093,759	21,906,981	7,664,785	23,727,126
Version 3 (Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	6,818,219	21,028,698	7,389,245	22,848,842
AVERAGE TOTAL EXPENDITURES FOR PROGRAMME NON-IMPLEMENTATION	7,078,707	21,859,002	7,649,732	23,679,146
AVERAGE TOTAL EXPENDITURES FOR PROGRAMME NON-IMPLEMENTATION INCREASED BY 5% for: costs of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	7,432,642	22,951,952	8,032,219	24,863,104

Table P31.

Expenditures linked to a child infected by HIV if mother's infection is undetected during pregnancy, due to non-implementation of the Programme, for the minimum and maximum lifespan of HIV + children, by domestic prices

	CHILDREN INFECTED BY HIV Mother's infection undetected during pregnancy			
	Minimum expected lifespan of an HIV + child (5.94)		Maximum expected lifespan of an HIV + child (18.54)	
	Min. no. of children (n = 6.85)	Max. no. of children (n = 21.85)	Min. no. of children (n = 6.85)	Max no. of children (n = 21.85)
Expenditures of diagnostic analyses (ELIZA, Western-Blot) for children sent for testing because of clinical symptoms	84,736	270,096	84,736	270,096
Expenditures of analyses for clinical, immunity and viral evaluation of an HIV + child (PCR RNK, CD4 + lymphocytes, biochemical blood analyses, complete blood analysis)	162,980	519,871	692,666	2.209,454
Expenditures HAART 1	2,618,425	8,352,201	3,273,031	10,440,251
Expenditures HAART2	2,513,217	2,513,217	2,513,217	2,513,217
Expenditures for the therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade	2,387,387	7,615,240	2,984,233	9,519,050
TOTAL EXPENDITURES in €				
Version 1 (Expenditures HAART1)	2,866,141	9,142,168	4,050,433	12,919,801
Version 2 (Expenditures HAART 2)	2,760,933	3,303,184	3,290,619	4,992,766
Version 3 (Expenditures for therapy most frequently applied in the Clinic for Infectious and Tropical Diseases in Belgrade)	2,635,103	8,405,208	3,761,635	11,998,600
AVERAGE TOTAL EXPENDITURES FOR PROGRAMME NON-IMPLEMENTATION	2,754,059	6,950,187	3,700,896	9,970,389
AVERAGE TOTAL EXPENDITURES FOR PROGRAMME NON-IMPLEMENTATION INCREASED BY 5% for: costs of hospitalisation, therapy and prophylaxis of opportune infections, treatment of infectious and non-infectious complications, tumours	2,891,762	7,297,696	3,885,940	10,468,908

Table P32.

Net effects of the implementation of the Programme in case of HAART 1 application (difference between implementation expenditures by international prices and non-implementation expenditures by domestic prices)

Year of implementation of Programme	Net effects for state	
	Average expected lifespan	
	MIN NO. OF CHILDREN AND WOMEN	MAX NO. OF CHILDREN AND WOMEN
1	156,133	253,143
2	169,291	295,086
3	105,641	162,572
4	79,291	78,518
5	52,312	-7,540
6	-57,134	-356,652
7	-167,236	-707,857
8	-276,993	-1,057,965
9	-387,436	-1,410,258
10	-498,578	-1,764,784
11	-492,994	-1,572,637
12	-381,857	-1,218,139
13	-354,498	-1,130,866
14	-467,058	-1,489,586
15	-579,157	-1,846,834
16	-608,963	-1,941,583
17	-638,293	-2,034,817
18	-668,156	-2,129,749
19	-670,600	-2,137,539
20	-673,068	-2,145,405
21	-675,566	-2,153,368
22	-486,951	-1,552,156
23	-295,825	-942,942
24	-155,451	-495,500
25	-15,077	-48,058
26	125,297	399,383
27	62,648	199,692

The Programme becomes cost-efficient in the sixth year of implementation for the minimum number of pregnant women, and in the fourth year of implementation for the maximum number of pregnant women.

Table P33.

Net effects of Programme implementation in case of applying HAART2 (difference between implementation expenditures by international prices and non-implementation expenditures by domestic prices)

YEAR OF PROGRAMME IMPLEMENTATION	NET EFFECTS FOR STATE	
	AVERAGE EXPECTED LIFESPAN	
	MIN NO. OF CHILDREN AND WOMEN	MAX NO. OF CHILDREN AND WOMEN
1	156,133	253,143
2	169,291	295,086
3	105,641	162,572
4	79,291	78,518
5	52,312	-7,540
6	-53,846	-346,165
7	-160,660	-686,883
8	-267,123	-1,026,482
9	-374,271	-1,368,267
10	-482,119	-1,712,284
11	-479,816	-1,530,602
12	-371,961	-1,186,570
13	-344,601	-1,099,298
14	-449,146	-1,432,468
15	-553,230	-1,764,167
16	-578,307	-1,843,854
17	-602,910	-1,922,026
18	-628,053	-2,001,917
19	-630,503	-2,009,729
20	-632,978	-2,017,616
21	-635,482	-2,025,600
22	-454,553	-1,448,888
23	-271,107	-864,152
24	-138,748	-442,260
25	-6,390	-20,367
26	125,969	401,525
27	62,984	200,763

Table P34.

Net effects from Programme implementation in case of applying the therapy of the Clinic for Infectious and Tropical Diseases (difference between implementation expenditures by international prices and non-implementation expenditures by domestic prices)

YEAR OF PROGRAMME IMPLEMENTATION	NET EFFECTS FOR STATE	
	AVERAGE EXPECTED LIFESPAN MIN NO. OF CHILDREN AND WOMEN	MAX NO. OF CHILDREN AND WOMEN
1	156,133	253,143
2	169,291	295,086
3	105,641	162,572
4	79,291	78,518
5	52,312	-7,540
6	-49,914	-333,622
7	-152,796	-661,797
8	-255,749	-990,200
9	-359,387	-1,320,788
10	-463,726	-1,653,609
11	-465,777	-1,485,817
12	-362,276	-1,155,674
13	-334,917	-1,068,401
14	-451,397	-1,439,615
15	-567,416	-1,809,358
16	-608,361	-1,939,632
17	-648,831	-2,068,391
18	-689,419	-2,197,522
19	-691,447	-2,203,987
20	-693,499	-2,210,529
21	-695,582	-2,217,166
22	-523,414	-1,668,383
23	-349,153	-1,112,924
24	-204,859	-652,988
25	-60,565	-193,051
26	83,729	266,885
27	41,864	133,443

Table P35.

Gained years of life during the implementation and non-implementation of the Programme, with regard to the minimum lifespan of HIV + children and average lifespan in the Republic

	Implementation				Non-implementation			
	Min No. HIV + women (n = 16/year)		Max No. HIV + women (n = 51/year)		Min No. HIV + women (n = 16/year)		Max No. HIV + women (n = 51/year)	
	No. HIV + children n	No. healthy children	No. HIV + children n	No. healthy children	No. HIV + children	No. healthy children	No. HIV + children	No. healthy children
	0.32	15.68	1.02	49.98	6.85	9.15	21.85	29.15
Minimum lifespan of children	6.32	72	6.32	72	5.94	72	5.94	72
No. gained years of life of children	2.02	1,128.96	6.45	3,598.56	40.69	658.80	129.79	2,098.80
Total gained years of life of children	1,130.98		3,605.01		699.49		2,228.59	
Gained years of life per child	70.69		70.69		43.72		43.70	

Source: Statistical Almanac of Serbia 2003, pages 43,44 and 62

Table P36.

Gained years of life during the implementation and non-implementation of the Programme, with regard to maximum lifespan of HIV + children and average lifespan in the Republic

	Implementation				Non-implementation			
	Min No. HIV + women (n = 16/year)		Max No. HIV + women (n = 51/year)		Min No. HIV + women (n = 16/year)		Max No. HIV + women (n = 51/year)	
	No. HIV + children	No. healthy children	No. HIV + children	No. healthy children	No. HIV + children	No. healthy children	No. HIV + children	No. healthy children
	0.32	15.68	1.02	49.98	6.85	9.15	21.85	29.15
Maximum lifespan of children	23.81	72	23.81	72	18.54	72	18.54	72
No. of gained years of life of children	7.62	1,128.96	24.29	3,598.56	127.00	658.80	405.10	2,098.80
Total gained years of life of children	1,136.58		3,622.85		785.80		2,503.90	
Gained years of life per child	71.04		71.04		49.11		49.10	

Source: Statistical Almanac of Serbia 2003, pages 43,44 and 62

LITERATURE

1. Dinkić Mirosinka, Primena analize troškovi-rezultati u oblasti zdravstva, «Upravljanje razvojem zajedničkih potreba – Cost-Benefit Analiza», Ekonomski institut, Beograd, 1990.
2. Health Care of the Population in « Report on Economic and Social Policy Country Profiles», Prepared for «27th Annual Meeting of the Board of Directors 12th NLO Assembly Meeting» European Centre for Social Welfare Policy and Research Chapter 3, Novembar 2001, Vienn. : G17 Institut, Beograd
3. Dinkić Mirosinka, Difficulties in the Public Health Sector in «Social Welfare Situation and Need for Donations», Yugoslav Survey, No. 4, 2000
4. Conor EM Sperling RS, Gelber R, Keslev P Scott G, O Sullivan MJ, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type I with zidovudin treatment. Paediatric AIDS Clinical Trials Group Protocol 076 Study Group. N Engl J Med 1994;331:1173-1180 (Abstract)
5. Cost effectiveness analysis of antenatal HIV screening in United Kingdom (Editorial by Peckham)
6. Gibb DM, Ades AE, Gupta R, Sculpher M. Costs and benefits to the mother of antenatal HIV testing: estimates from simulation modelling. AIDS 1999;13:1569-1576 (Medline)
7. Ratcliffe J, Ades AE, Gibb D, Sculpher M, Briggs A. Prevention of mother-to-child transmission of HIV infection: alternative strategies and their cost-effectiveness. AIDS 1998;12:1381-1388 (Medline)
8. Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS, June 2003
9. Sculpher M, Gibb D, Ades AE, Ratcliffe J, Duong T. Modelling the costs of paediatric HIV Infection and AIDS: comparison of infected children born to screened and unscreened mothers. AIDS 1998; 12:1371-1380 (Medline)
10. Universal HIV screening of pregnant women in England: cost effectiveness analysis
11. UNICEF «Rapid Assessment of Situation and Services for Children and Women on PMTCT in Serbia», 2004



Canadian
International
Development
Agency

Agence
canadienne de
développement
international

Canada