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Preventing Perinatal Transmission of HIV—Costs and Effectiveness of a Recommended Intervention

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SYNOPSIS

Objective. To calculate the national costs of reducing perinatal transmission of human immunodeficiency virus through counseling and voluntary testing of pregnant women and zidovudine treatment of infected women and their infants, as recommended by the Public Health Service, and to compare these costs with the savings from reducing the number of pediatric infections.

Method. The authors analyzed the estimated costs of the intervention and the estimated cost savings from reducing the number of pediatric infections. The outcome measures are the number of infections prevented by the intervention and the net cost (cost of intervention minus the savings from a reduced number of pediatric HIV infections). The base model assumed that intervention participation and outcomes would resemble those found in the AIDS Clinical Trials Group Protocol 076. Assumptions were varied regarding maternal seroprevalence, participation by HIV-infected women, the proportion of infected women who accepted and completed the treatment, and the efficacy of zidovudine to illustrate the effect of these assumptions on infections prevented and net cost.

Results. Without the intervention, a perinatal HIV transmission rate of 25% would result in 1750 HIV-infected infants born annually in the United States, with lifetime medical-care costs estimated at $282 million. The cost of the intervention (counseling, testing, and zidovudine treatment) was estimated to be $67.6 million. In the base model, the intervention would prevent 656 pediatric HIV infections with a medical care cost saving of $105.6 million. The net cost saving of the intervention was $38.1 million.

Conclusion. Voluntary HIV screening of pregnant women and ziovudine treatment for infected women and their infants resulted in cost savings under most of the assumptions used in this analysis. These results strongly support implementation of the Public Health Service recommendations for this intervention.

In the United States, nearly all new human immunodeficiency virus (HIV) infections in children are acquired through perinatal (mother-to-infant) transmission. Each year, approximately 7000 infants are born to HIV-infected women in the United States.[1] Without intervention, an estimated 15–30% of these infants would become infected.[2]

In 1994, results of the AIDS Clinical Trial Group (ACTG) Protocol 076

showed that treatment of infected pregnant women and their infants with zidovudine (ZDV) reduced the rate of perinatal HIV transmission from 25% to 8%.[3,4] Following these findings, the Public Health Service (PHS) issued recommendations for ZDV therapy to prevent perinatal HIV transmission[5] and for HIV counseling and voluntary testing of pregnant women.[6]

The potential cost of HIV counseling and voluntary testing of pregnant women in the United States has not been determined, nor has the cost-effectiveness of such screening combined with recommended ZDV treatment for preventing perinatal HIV transmission.[4] Because medical care for HIV infection is costly, savings resulting from HIV infections prevented can be substantial. The estimated annual costs for an HIV-infected adult are $5,000 for persons who have not developed AIDS and $35,000 for those with AIDS.[7] For an HIV-infected child, direct costs per year are $9,400 before development of AIDS and $38,000 after AIDS.[8]

Data from various sources were used to calculate both the intervention costs and the resulting pediatric medical care cost savings. The intervention costs included HIV counseling and voluntary testing services for pregnant women, ZDV treatment prenatally and during labor and delivery for those who are infected, ZDV treatment for their infants, and recommended laboratory testing during ZDV treatment.[5,6] To determine the savings from preventing pediatric infections, the costs associated with treatment for infants perinatally infected without the intervention were compared with treatment costs for infants who became infected despite the intervention.

Methods

Actual costs for HIV counseling, testing, ZDV treatment, and medical treatment of infected infants were included without regard to who would pay for them (societal perspective). The time horizon for the intervention costs was one year. To determine the lifetime savings from prevented pediatric infections, we included the present value of medical care that would have been incurred in the future. We did not consider the additional costs of treating HIV-infected women who would not have learned of their infection until later in the course of their illness, nor any additional benefits resulting from the intervention (for example, reduced HIV transmission to sexual or needle-sharing partners of infected women).[9,10]

Intervention costs. The intervention was divided into two cost components: *(a)* the direct costs associated with HIV counseling and voluntary testing services for pregnant women receiving first and second trimester prenatal care; and *(b)* the costs associated with ZDV treatment (that is, oral ZDV prenatally and intravenous ZDV during labor and delivery for infected women, oral ZDV for HIV-exposed newborns, and recommended laboratory testing during ZDV therapy) (see Box).

HIV counseling and voluntary testing costs. The number of eligible women was defined as the number of pregnant women of more than 13 weeks gestation[11] who receive prenatal care.[12] We estimated this number by adding the fetal losses and induced abortions occurring after 13 weeks gestation[13] to the number of annual live births in the United States.[12] This sum was then multiplied by the proportion of women (.939) who receive first or second trimester prenatal care.[12]

We made the following assumptions for the analysis: *(a)* all pregnant women entering prenatal care during the first

Annual Cost Estimates of HIV Counseling and Testing of All Pregnant Women in the United States and of Zidovudine (ZDV) Treatment of Infected Women and Their Infants

Counseling and testing	
Number of pregnancies[a]	4,522,823
Number in prenatal care[b]	4,246,930
Number counseled and tested[c]	3,312,606
Number positive[d]	5,666
Number negative[d]	3,306,940
(a)Total cost[e]	$65,068,921
ZDV treatment	
Number of women eligible[f]	4,958
Number accepting ZDV during pregnancy[g]	3,371
(b)Cost of ZDV during pregnancy[h]	$1,858,466
(c)Cost of laboratory monitoring[i]	$448,392
Number receiving ZDV during labor and delivery	2,849
(d)Cost of ZDV during labor and delivery[j]	$131,366
Number receiving neonatal ZDV	2,407
(e)Cost of neonatal ZDV[k]	$40,486
Total cost of ZDV regimen	$2,478,709
Total annual cost (a+b+c+d+e)	$67,547,629

[a]Including pregnancies terminated or ending in fetal loss after the first trimester; these women would be eligible for HIV counseling and testing (HIV CT).[11,13]

[b]Assumes all pregnant women entering prenatal care during the first two trimesters are offered HIV CT.[12]

[c]Assumes that pregnant women accept HIV CT in the same proportion as that reported for other populations, 78%.[20,21]

[d]Adjusted for the sensitivity and specificity of the HIV tests and recommended test sequence;[17] assumes HIV seroprevalence of 1.7 per 1000 births.

[e]Cost for HIV CT: positive, $103; negative, $19.50.[17] (Adjusted as described in paper.)

[f]Number positive adjusted for fetal losses and induced abortions occurring after 13 weeks gestation.[13]

[g]Assume 68% of infected pregnant women accept prenatal ZDV if offered.[22]

[h]ZDV treatment cost—$551.25 per woman during pregnancy.

[i]Complete blood count at $21 per test (2 per woman and 1 per child) and chemistry profile at $35 per test (2 per woman)

[j]ZDV treatment cost—$46.11 per woman during labor and delivery; assumes 84.5% of women receiving ZDV during pregnancy also receive ZDV during labor and delivery.[4]

[k]ZDV treatment cost—$16.82 per newborn; assumes 71.4% of children born to infected mothers receiving ZDV during pregnancy receive ZDV neonatally.[4]

or second trimester would be offered HIV counseling and testing; *(b)* women who had previously tested HIV seronegative would require retesting during each pregnancy; and *(c)* the number of HIV-infected pregnant women who knew their serostatus at entry into prenatal care would be small compared with total births. Since empirical data were lacking, we also assumed that HIV screening would not affect reproductive decision-making and that HIV seroprevalence was the same for women accepting and those refusing HIV tests.

HIV counseling and testing costs for seropositive women differ from those for seronegative women. In addition, client-based[14,15] counseling costs are greater for uninfected women at high risk (more extensive counseling) than for those at low risk. To determine the cost of HIV counseling and testing of uninfected women, a weighted average was calculated as follows—since 55% of U.S. women who give birth reside in states with relatively high HIV seroprevalence rates (more than one HIV-infected pregnant woman per 1000 live births),[16] we assumed that all seronegative pregnant women in these states would receive full counseling with costs comparable to those found in publicly funded clinics, or $33 per person.[17] This included the cost of pretest counseling, one enzyme-linked immunosorbent assay (ELISA), and post-test counseling on a return visit. For the 45% of women who give birth in states with low seroprevalence rates (less than one HIV-infected pregnant woman per 1000 live births), we assumed the costs of counseling seronegative women to be subsumed into routine prenatal care. Therefore, we assigned a cost of $6 per person (the cost of the ELISA) for seronegative women in these states.[17] Thus, the overall national cost estimate for HIV counseling and testing of seronegative women was $19.50 per person. For seropositive women, the cost of HIV counseling and testing was $103, which included additional costs for post-test counseling and confirmatory tests (ELISA and Western blot).[17]

We also assumed that all HIV-infected pregnant women receiving prenatal care in the first or second trimester would be offered ZDV treatment, regardless of their CD4+ T-lymphocyte counts or prior use of ZDV. Women who experienced fetal loss, who chose to terminate their pregnancies, or who entered prenatal care during the third trimester or later were excluded.

ZDV treatment costs. Average duration of ZDV therapy used in the ACTG Protocol 076[4] and average weights for a woman (50 kilograms) and newborn infant (4 kilograms) were used in calculating the cost of the ZDV regimen. The defined regimen involved oral ZDV for infected women during pregnancy (100 milligrams per dose multiplied by 5 doses per day multiplied by 12 weeks [420 100-milligram capsules]); intravenous ZDV for women during labor and delivery (2 milligrams per kilogram plus 1 milligram per kilogram per hour for 12 hours [700 milligrams ZDV]); and oral ZDV for HIV-exposed newborns (2 milligrams per kilogram per dose multiplied by 4 doses per day multiplied by 6 weeks [134 cubic centimeters of syrup]).

We contacted five principal investigators of the original ACTG Protocol 076 (from geographically representative areas) to obtain the current wholesale costs of the recommended preparations of ZDV from their hospital pharmacies. The following average ZDV treatment costs per person were used: *(a)* $551 for maternal treatment during pregnancy; *(b)* $46 for maternal treatment during labor and delivery; and *(c)* $17 for newborn treatment. Costs involved in administering intravenous ZDV were not included.

Using standard hospital laboratory cost data, we estimated the costs for laboratory testing during ZDV therapy (two 20-test chemistry profiles for the mother, two complete blood counts (CBC) for the mother, and one CBC for the infant[5] as follows: *(a)* $35 for each chemistry profile; and *(b)* $21 for each CBC.

Costs of medical care treatment for HIV-infected infants. We adapted reported annual costs for HIV-infected children[8] to estimate lifetime costs for a perinatally infected child (Table 1). Based on information from the revised classification system for HIV infection in children[18] as well as reported symptomatic disease progression,[19] the following average profile was developed for a child infected at birth: no symptoms in the first 9 months of life followed by mild HIV symptoms in months 10 to 13, moderate symptoms in months 14 to 57, and AIDS development at months 58 to 113 (average life span, 113 months).

Table 1. Annual and lifetime medical costs for perinatally infected children

Year of life	*Symptoms by age in months*[a]	*Undiscounted costs*[b]	*5% discounted costs*
1	1–9, none; 10–12, mild HIV	$ 1,759	$ 1,675
2	13, mild; 14–24, moderate HIV	11,337	10,283
3	25–36, moderate HIV	11,728	10,131
4	37–48, moderate HIV	11,728	9,648
5	49–57, moderate HIV; 58-60, AIDS	18,278	14,321
6	61–72, AIDS	37,928	28,302
7	73–84, AIDS	37,928	26,955
8	85–96, AIDS	37,928	25,671
9	97–108, AIDS	37,928	24,449
10	109–113, AIDS	15,803	9,702
Total		222,344	161,137

[a]See references 18, 19.

[b]Medical costs for treatment of HIV infection before development of AIDS: $9382 per year = $782 per month x 0.75 = $586.38 per month (mild); $782 x 1.25 = $977.29 per month (moderate). Medical costs for treatment of AIDS: $37,928 per year = $3,161 per month. See reference 8.

Because no data exist to differentiate between costs for children with mild versus moderate symptomatic HIV disease, the following percentages were used: 75% of reported monthly medical costs for mild-symptom months and 125% for moderate-symptom months. Using a discount rate of 5%, we estimated the present value of lifetime medical care treatment costs for one perinatally infected infant and determined that the medical care costs-saved from preventing one pediatric HIV infection were $161,137.

Assumptions affecting outcomes. The following assumptions were made for the base model: *(a)* 78% of pregnant women offered HIV counseling and testing will accept;[20,21] *(b)* 68% of HIV-infected women identified through such screening who are offered ZDV treatment will accept and complete the first treatment component (oral ZDV during pregnancy);[22] *(c)* perinatal HIV transmission rates were 8% with the complete (maternal and infant) ZDV regimen[4], 25% with no ZDV[4], and 16.5% with maternal oral ZDV during pregnancy and either maternal intravenous ZDV during labor and delivery or oral ZDV for the infant (based on evidence that some reduction in transmission can occur without completion of all three components of the protocol;[23,24] *(d)* ZDV efficacy in women with CD4+ T-lymphocyte counts more than 200 cells per milliliter or with prior ZDV therapy was the same as that for women with higher CD4+ counts and no previous ZDV therapy; and *(e)* the proportion of patients completing all components of the ZDV regimen (pregnancy, labor and delivery, neonatal) was the same as that observed in ACTG Protocol 076: 84.5% of women who completed oral ZDV during pregnancy received intravenous ZDV during labor and delivery, and 71.4% of infants born to women who completed oral ZDV during pregnancy received the oral ZDV newborn regimen.[4]

The assumptions from the base model were varied as follows: *(a)* in the no partial effect model, the perinatal transmission rate was 25% unless all three components of the ZDV regimen were completed, and *(b)* in the complete treatment model, all eligible women and infants completed all three ZDV treatment components and the transmission rate was 8%.

Four sensitivity analyses were developed on the base model only. First, because maternal HIV seroprevalence rates among states vary from more than 5 per 1000 (New York) to less than 0.1 per 1000 (Utah), this rate was varied from the national average of 1.7 per 1000. Next, the proportion of women who accept HIV counseling and testing was varied upward from the base case of 78%. Third, the proportion of women who receive ZDV treatment was varied upward from the base case of 68%. Finally, the lifetime cost of medical treatment for a perinatally infected infant was varied up and down from the base-case value, since the only published estimate of pediatric lifetime medical costs[8] is not based upon age-specific cost data.

Results

Without the intervention, 1750 HIV-infected infants would require treatment (7000 births annually to HIV-infected women, with a 25% perinatal transmission rate). Using the present value of lifetime medical treatment costs of $161,137 per infant, the total cost of treating these children was $282 million.

In the base model, the intervention would prevent 656 perinatally transmitted HIV infections (Table 2), resulting in medical care cost savings of $105.6 million (calculated from Table 3 as $282 million without the intervention less $176.4 million with the intervention). When these medical care cost savings are subtracted from the cost of the intervention ($65.1 million for HIV counseling and testing plus $2.5 million for the complete ZDV treatment regimen), the net cost of the intervention is -$38.1 million. Thus, the intervention is cost-saving.

In the no partial effect model, the costs to provide HIV counseling and testing and ZDV treatment were the same as in the base model, but only 574 infections were prevented (Tables 2 and 3). This resulted in a cost saving of $24.9 million.

Table 2. Number of HIV-infected infants resulting from intervention effects

Model	Mother not tested[a]	False-negative test results[a]	No ZDV (mother or infant)[a]	Partial ZDV treatment[b]	Full ZDV treatment[c]	Total infected infants	Infections prevented[d]
Base case[e]	343.3	2.8	396.6	159.1	192.6	1094.4	655.6
No partial effect[f]	343.3	2.8	396.6	241.0	192.6	1176.3	573.7
Complete treatment[g]	343.3	2.8	—	—	396.6	742.7	1007.3

[a]25% transmission rate.
[b]16.5% transmission rate [50% reduction - includes maternal ZDV during pregnancy plus either maternal ZDV during labor and delivery or neonatal ZDV].
[c]8% transmission rate.
[d]Infected infants without intervention (1750) minus total infected infants.
[e]Assumes parameters of ACTG protocol 076 and 50% efficacy from partial ZDV treatment.
[f]Assumes parameters of ACTG protocol 076 and no effect from partial ZDV treatment.
[g]Assumes parameters of ACTG protocol 076 and that women eligible for ZDV complete all components.

Table 3. Cost and effectiveness of intervention for pregnant women in the United States

Model	Counseling and testing	ZDV treatment	Medical costs: With intervention	Medical costs: Without intervention	Medical costs saved[e]	Net costs[f]	Infections prevented
Base case[b]	$65,068,921	$2,478,709	$176,346,305	$281,989,750	$105,643,445	−$38,095,816	655.6
No partial effect[c]	65,068,921	2,478,709	189,552,758	281,989,759	92,436,992	−24,889,363	573.7
Complete treatment[d]	65,068,921	3,704,444	119,679,701	281,989,759	162,310,049	−93,536,684	1007.3

[a]Negative net costs represent cost savings.
[b]Assumes parameters of ACTG protocol 076 and 50% efficacy from partial ZDV treatment.
[c]Assumes parameters of ACTG protocol 076 and no effect from partial ZDV treatment.
[d]Assumes parameters of ACTG protocol 076 and that women eligible for ZDV complete all components.
[e]Medical costs without intervention minus costs with intervention.
[f]Cost of counseling, testing, and ZDV treatment minus medical costs saved.

In the complete treatment model, the counseling and testing costs were also the same as in the base model, but the ZDV treatment costs were higher ($3.7 million compared with $2.5 million), since all eligible HIV-infected women and -exposed infants received the complete ZDV treatment regimen (Table 3). In this model, a larger number of infections were prevented (1007), resulting in a greater medical care cost-saving ($162.3 million) and a net cost-saving of $93.5 million.

Table 4 shows the effect of varying rates of maternal HIV seroprevalence on the number of pediatric infections prevented and the net cost of the intervention. The net cost ranged from $58.6 million at a seroprevalence rate of 0.1 per 1000 to a cost-saving of $235.6 million at a seroprevalence rate of 5 per 1000. The intervention became cost-saving at an HIV seroprevalence rate of 1.1 per 1000.

The effects of changing other assumptions in the sensitivity analysis of the base model are also shown in Table 4. Increasing the proportion of women who receive counseling and testing during pregnancy had only a modest effect on the net cost of the intervention. The cost savings increased from $38.1 million with a 78% acceptance rate (the base model) to $42.7 million with a 94% acceptance rate. However, as the proportion of HIV-infected women receiving ZDV treatment increased from 68% (the base model) to 95%, the cost savings of the intervention increased substantially from $38.1 million to $68.5 million. Changes in the estimate of the lifetime medical costs of treating a perinatally HIV-infected child had a large impact on the net cost of the intervention. The cost savings varied from $14.4 million with a treatment cost of $125,000 per infected child to $80 million with a cost of $225,000 per child.

Discussion

We calculated the annual cost of HIV counseling and voluntary testing for pregnant women and the cost of ZDV treatment for HIV-infected women and their infants. These intervention costs were compared with the medical care costs saved from the resulting reduction in the number of pediatric HIV infections. For the United States, with a maternal HIV seroprevalence of 1.71 per 1000 births, the cost-savings of the intervention ranged from $24.9 million to $93.5 million, depending on the assumptions made regarding the effectiveness of ZDV and the participation of HIV-infected pregnant women (Table 3). Thus, the intervention was cost-saving for both the base and the alternative models. Sensitivity analyses of four major input parameters showed that the intervention remained cost-saving under most of our alternative assumptions (Table 4).

HIV counseling and testing of seronegative women constituted a primary cost component of the intervention, accounting for 95% of the total in the base case. The model was very sensitive to assumptions made about counseling costs. The time allotted for a client-based[14,15] HIV counseling session will depend on the client's risk, and the cost will vary according to session length. There are no data available on the cost of HIV counseling in the private sector and very little on cost in the public sector.[15,17] The purpose of counseling associated with HIV testing has gradually changed as the epidemic evolved[25] and may differ considerably among testing sites. In addition, the cost effectiveness of a HIV counseling and testing strategy has been shown to be dependent on the inherent goal of testing.[17] Therefore, to determine the cost and cost-effectiveness of implementing HIV screening of pregnant women and ZDV treatment for infected women and infants more precisely, it is imperative to clarify the purpose, time allotted, and cost for counseling associated with HIV testing in this setting and to define precisely the goal of HIV counseling and voluntary testing of pregnant women.

The number of children who will be perinatally infected and, thus, the total costs of pediatric HIV treatment as estimated by our model are affected both by the number of women who are not tested and the proportion who receive no or partial ZDV treatment. Data are needed on the independent effect of each component (pregnancy, labor and delivery, neonatal) of the ZDV regimen.

The overall cost–effectiveness of the intervention varies according to maternal HIV seroprevalence. In most geo-

Table 4. Effect of modifying model assumptions on the net cost of the intervention

Modifications	*Net cost*
Maternal seroprevalence	
0.00010	$58,590,167
0.00100	4,564,485
0.00170	−38,095,816
0.00200	−55,486,746
0.00300	−115,523,387
0.00500	−235,611,260
Proportion of pregnant women accepting HIV counseling and testing	
0.78	−38,095,816
0.82	−39,242,885
0.86	−40,389,955
0.90	−41,537,024
0.94	−42,684,093
Proportion of HIV-infected women accepting ZDV treatment during pregnancy	
0.68	−38,095,816
0.70	−40,350,747
0.75	−45,988,075
0.80	−51,625,403
0.85	−57,262,731
0.90	−62,900,058
0.95	−68,537,386
Lifetime medical care treatment costs for a perinatally infected child	
$125,000	−14,403,944
140,000	−24,238,133
165,000	−40,628,448
180,000	−50,462,636
195,000	−60,296,825
210,000	−70,131,014
225,000	−79,965,203

graphic regions, the intervention was cost-saving except for areas with very low HIV seroprevalence rates. The intervention was also found to be cost-saving when a slightly different model and locally determined costs were analyzed in an urban setting.[26]

A similar cost-effectiveness analysis for the prevention of perinatally transmitted hepatitis B virus (HBV) infection[27] estimated that maternal screening and infant treatment would save more than $100 million annually if indirect costs from lost productivity and premature death were included. Our analysis was far more conservative, using only the direct costs of medical treatment for pediatric HIV infections and no indirect costs. The national maternal HBV seroprevalence is 2 per 1000, which is very similar to maternal HIV seroprevalence, and prenatal HBV screening is an accepted public health practice. In comparison, prenatal HIV screening is substantially more cost-effective and compares favorably with other life-saving interventions.[28]

This model may underestimate costs since it excluded those associated with a visit by a health-care professional to HIV-infected pregnant women identified through screening to explain the ZDV treatment regimen, obtain informed consent, explain the protocol, and prescribe the ZDV. Also, our ZDV treatment costs did not include administration costs or costs associated with additional visits by health-care professionals or complications resulting from therapy.

Benefits from HIV counseling of pregnant women that were not included in this analysis, such as behavior changes that can reduce HIV transmission to the sexual or needle-sharing partners of infected women, have been estimated to exceed the benefits for infants.[9,10] We limited our analysis to prevention of perinatal HIV transmission and, therefore, have underestimated the total benefits of the intervention.

We did not attempt to address the human costs of HIV infection such as the emotional and cost burden of infection for the patient as well as the patient's family, friends, and care givers. Nor did we address the indirect costs such as those associated with orphaned children and years of productive labor lost due to illness and premature death. The model focuses on the first year of the intervention only. Any changes in behavior or maternal seroprevalence resulting from the intervention are not included in the analysis. Finally, our model does not address any, as yet unknown, long-term detrimental health effects associated with ZDV given to uninfected children.

A reduction in the rate of perinatal HIV transmission through ZDV treatment represents a major breakthrough for HIV prevention. Translating the findings of the ACTG Protocol 076 into public health interventions that can maximize the opportunity for treatment of the 7000 HIV-infected U.S. women who give birth each year requires a number of systematic steps. The first steps of developing public health policies in response to the research findings have been taken. The ability to implement these policies into national and local prevention interventions depends in part on their cost. This analysis demonstrates a cost-savings to society when the costs of the intervention are compared with the medical care costs saved by reducing the number of pediatric HIV infections. These findings strongly support implementation of the PHS recommendations for the prevention of perinatal HIV infection.

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