Costing Nevirapine Delivery to Infants: A Zambian Case Study

August 2004

Prepared by:

Sara Zellner, PhD
Abt Associates Inc.

Stephen Musau, B. Com, FCA
Abt Associates Inc.

Partners for Health Reform*plus*

Abt Associates Inc. ■ 4800 Montgomery Lane, Suite 600
Bethesda, Maryland 20814 ■ Tel: 301/913-0500 ■ Fax: 301/652-3916

In collaboration with:
Development Associates, Inc. ■ Emory University Rollins School of Public Health ■ Philoxenia International Travel, Inc. ■ Program for Appropriate Technology in Health ■ Social Sectors Development Strategies, Inc. ■ Training Resource Group ■ Tulane University School of Public Health and Tropical Medicine ■ University Research Co., LLC.

Funded by:
U.S. Agency for International Development

Order No. TE 048

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Mission

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- *Implementation of appropriate health system reform.*
- *Generation of new financing for health care, as well as more effective use of existing funds.*
- *Design and implementation of health information systems for disease surveillance.*
- *Delivery of quality services by health workers.*
- *Availability and appropriate use of health commodities.*

August 2004

Recommended Citation

Zellner, Sara and Stephen Musau. August 2004. *Costing Nevirapine Delivery to Infants: A Zambian Case Study*. Bethesda, MD: The Partners for Health Reform*plus* Project, Abt Associates Inc.

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Contract/Project No.: HRN-C-00-00-00019-00

Submitted to: USAID/Zambia

and: Debrah Lans
Maternal Child Health Division
Office of Health, Infectious Disease and Nutrition

Karen Cavanaugh, CTO
Health Systems Division
Office of Health, Infectious Disease and Nutrition
Center for Population, Health and Nutrition
Bureau for Global Programs, Field Support and Research
United States Agency for International Development

Abstract

The United States Agency for International Development invited the Partners for Health Reform*plus* to estimate costs associated with the packaging of infant doses of Nevirapine in Zambia. The costs of following four scenarios were examined in this exercise: 1) preparation and administration of Nevirapine by a nurse immediately after birth, 2) preparation of Nevirapine in batches prepared by either a nurse or nurse's aide, 3) a semi-automated approach of pre-filled and packaged Nevirapine syringes, and 4) a fully automated approach using UnijectDP pre-filled with Nevirapine. Findings show that, at all dose levels, administration by a nurse after birth is the most cost-effective scenario. However, if other important factors, such as limited access to hospital facilities, are taken into consideration, then the semi-automated or Uniject approaches may be more suitable.

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Acronyms

FTE	Full-time Equivalent
NVP	Nevirapine
PATH	Program for Appropriate Technology in Health
PHR*plus*	Partners for Health Reform*plus*
PMTCT	Prevention of Mother-to-Child Transmission
USAID	United States Agency for International Development

Currency Conversion:

4,745 Zambian Kwacha (ZMK) = 1 U.S. Dollar

Acknowledgments

The authors would like to extend special gratitude to Priscilla Banda and Steve Brooke for providing the data needed for this study and sharing their expertise about the subject matter. We would also like to thank Amanda Gibbons, Deborah Lans, Bryn Sakagawa, Gilbert Kombe, Paurvi Bhatt, Nancy Pielemeier, Catherine Connor, Yann Derriennic, and Caytie Decker for their guidance through the report and presentation process.

Executive Summary

The United States Agency for International Development (USAID) is participating in a public/private-sector collaboration with Program for Appropriate Technology in Health (PATH), Population Services International, Boehringer Ingelheim, Axios International, and a number of other partners to develop a pre-filled, pediatric Nevirapine (NVP) oral suspension. Administration of the pediatric dose of NVP oral suspension in resource-limited settings is often problematic for a number of reasons, such as the requirement to deliver infant doses within 72 hours of birth, the high prevalence of home births, and the reluctance of health workers to open multi-dose bottles for single use due to wastage concerns. Given these issues, the consortium has hypothesized four scenarios to prepare and administer NVP to infants: 1) preparation and administration of NVP by a nurse immediately after birth, 2) preparation of NVP in batches prepared by either a nurse or nurse's aide, 3) a semi-automated approach of pre-filled and packaged NVP syringes, and 4) a fully automated approach using UnijectDP pre-filled with NVP. USAID's Partners for Health Reform*plus* project was asked to determine the costs of each scenario, and Zambia was chosen for the case study.

Analyzing data gathered from local consultants and PATH, results show that, at all dose levels, the scenario in which a nurse prepares and administers NVP is most cost effective. Thus, if cost is the top priority, preparation and administration of the drug by a nurse at a health facility is the best option. By contrast, if an automated approach that will facilitate treatment outside of the hospital setting is desired, the Semi-automated or Uniject approaches are equally viable options at 70,000 doses or greater.

1. Background

The success of clinical trials showing the antiretroviral drug Nevirapine (NVP) as an effective, low-cost, and practical therapy for reducing mother-to-child transmission of HIV-1 has resulted in an effort to incorporate its use in prevention of mother-to-child transmission (PMTCT) programs globally. However, administration of the pediatric dose of NVP oral suspension in resource-limited settings is often problematic for a number of reasons, such as the requirement to deliver infant doses within 72 hours of birth, the high prevalence of home births, and the reluctance of health workers to open multi-dose bottles for single use due to wastage concerns.

Based on the hypothesis that pre-filled, single-dose packaging would contribute to overcoming these obstacles, the United States Agency for International Development (USAID) with Program for Appropriate Technology in Health (PATH), Boehringer Ingelheim, BD Pharmaceutical Systems, Population Services International, Axios International, and other partners have formed a public-private partnership to identify, evaluate, and introduce a cost-effective,[1] pre-filled single-dose packaging capable of delivering the pediatric dose of NVP oral suspension. It is thought that such pre-filled single-dose presentations of NVP could be distributed to facilities and potentially to mothers and other community members (e.g., traditional birth attendants) to facilitate the administration of pediatric doses of NVP at home to infants within 72 hours of birth.

Other options for the preparation of NVP infant doses include the use of pre-filled UnijectDP (dropper tip) or syringes. In 2003, the Uniject™-DP device, a single-dose dispensing device produced by BD Pharmaceutical Systems, was selected as the lead candidate for a feasibility evaluation for single-dose packaging based on its dose expression accuracy and ease of use. Another option that the partnership is exploring how PMTCT programs can improve pre-filling and distribution of NVP oral suspension in standard oral dosing syringes.

The purpose of this study, carried out by USAID's Partners for Health Reform*plus* (PHR*plus*) project, therefore, is to determine the total costs of four single pediatric-dose NVP scenarios as a first step for evaluating the overall cost-effectiveness and impact of these strategies.

[1] "Cost-effective" is defined as being economical in terms of the services received for the money spent.

2. Study Methods

2.1 Scenarios

The four scenarios that are costed for this exercise are described below:

- Individual Scenario (Individual): Facility-based, individually prepared method. In this scenario, the nurse fills the syringe with NVP on a case-by-case basis. S/He provides the NVP dose to the infant after delivery but before discharge from the hospital. Alternately, if the infant is born at home, the mother is requested to return to the hospital/clinic, bringing the newborn for the infant dose. The nurse must fill the syringe with the appropriate amount of NVP, 0.2ml/kg birth weight, and administer the dose to the infant.

- Batches Scenario (Batches): Facility-based, batch packaging method. In this scenario, the nurse or nurse's aide pre-fills take-home oral dosing syringes with NVP (0.6 ml NVP for the average birth weight of 3 kg) in batches to be distributed to HIV-infected expectant mothers who visit the facility for check-ups and counseling. Syringes are wrapped in a brown bag and given to mothers along with dosing directions. Costs are calculated for packaging by nurses, and by nurse's aides.

- Semi-automated Scenario (Semi-automated): Centrally pre-packaged Nevirapine oral dosing syringe. In this scenario, the NVP is pre-packaged in oral dose syringes at a central location using a semi-automated approach. The key issue is central pre-packaging and distributing pre-filled syringes to health facilities as opposed to sending multi-dose bottle NVP and empty syringes to clinics. Only pre-packaged syringes, manually wrapped in plastic/foil laminate, are analyzed in this scenario. These pre-packaged syringes are delivered to the health centers and given to the mother along with dosing directions.

- Uniject Scenario (Uniject): Centrally pre-packaged Nevirapine UnijectDP. In this scenario, the NVP is pre-packaged in UnijectDP at a central location. UnijectDP can only be pre-filled using a fully automated approach. These pre-packaged syringes, which are always pouched in a plastic/foil laminate, are delivered to the health centers and given to the mother along with dosing directions.

2.2 Costing Methodology

The costing method applied to each scenario was the "ingredients" approach. In this approach, data are collected on all the resources required to produce a dose of Nevirapine. For example, the 4.8 minutes of counseling time and syringes required would constitute two of the ingredients of the cost per dose.

To simplify comparisons across all four scenarios, the volume of NVP pediatric cases is held constant throughout the scenarios and based on the annual requirements for infant NVP determined

by the estimated number of HIV-positive births with data from the 2004 UNAIDS/WHO Epidemiological Fact Sheet for Zambia.[2] This estimated number of cases per also assumes that 80 percent of HIV-positive infants receive treatment.

2.2.1 Capital Costs

Capital costs include the training for machine operation and equipment depreciation spread over five years. These costs are only relevant to the Semi-automated and Uniject Scenarios.

2.2.2 Labor Costs

To obtain data on salaries and estimates of the time spent preparing, counseling, and administering NVP pediatric doses, PHR*plus* conducted a survey of one clinic and three hospitals in rural and urban Zambia.[3] These facilities were selected based on their work with HIV-positive newborns and prior contact on other PHR*plus* activities. Interviewers gathered data on the time taken by staff to perform various activities related to the preparation and administration of NVP doses. Additionally, salary information was obtained from human resources officers. Interviews were conducted July 19-30, 2004.

2.2.3 Data on Automated Packaging

Data concerning production, raw materials, and machinery costs related to the Semi-automated and Uniject Scenarios are listed below.

2.2.3.1 Semi-automated Scenario

Costs of equipment related to the Semi-automated Scenario are shown below in U.S. dollars:

BAXA Repeater Pump filling machine (including fixtures, etc.)	4,125.00
Additional spare parts for BAXA Repeater Pump	1,000.00
Pouch Sealing Machine: Fuji Impulse OPL-300-5	5,395.00
Precision balance, miscellaneous small lab equipment	1,000.00
	11,520.00
Export packing, shipping, duties at 25% of value (rough estimate)	2,880.00
Total Equipment	**14,400.00**

[2] The following formula is used to calculate the estimated number of Nevirapine pediatric cases assuming 80 percent treatment: total population x $\frac{\text{crude birth rate}}{1000}$ x $\frac{\text{\% estimated HIV infection}}{100}$ x .80.

[3] The questionnaires are found in Annexes A and B.

Staffing required and output: Maximum output for filling and pouching oral dosing syringes with Semi-automated Scenario equipment will be about six units/minute or 360/hour. Daily output on an eight-hour shift with 6.5 hours of production run time will be 2,340 units. Given 20 work days in a month, maximum yearly production is thus estimated at 561,600 units.

A licensed pharmacist should supervise the overall filling and packaging operation; however, this would only require 20 percent-40 percent of the pharmacist's time. Actual filling and pouching would require two technicians with pharmacy technician or laboratory technician training. Documentation, inventory control, and administration might require between 25 percent and 100 percent of an additional full-time equivalent (FTE) depending on volume of work (time devoted to this task is estimated at 62.5 percent).

Training for filling and pouching operations: Assuming the chosen staff meet the above qualifications, overall training in using Semi-automated Scenario equipment should take five days.

Machine maintenance: A basic set of spare parts has been included in the equipment cost estimate. The two technicians can complete additional maintenance such as calibration and cleaning during the 1.5 hours of non-production time during each eight-hour shift. A catastrophic failure of either the filling machine or pouch-sealing machine could require machine replacement, but this is a low probability event. To be conservative, additional maintenance costs should be budgeted based on total cost of equipment at rate of 20 percent for the first year, 15 percent for years 2-4, and 20 percent for years 5-end of life.

Space requirements: Space requirements for equipment are estimated at 1 m^2 class 1000, 5 m^2 basic lab, all air-conditioned.

2.2.3.2 Uniject Scenario

Costs of equipment related to the Uniject Scenario are shown below in U.S. dollars:

Uniject single nozzle small scale filling and sealing machine (Actual range from $60,000 to over $100,000)	75,000.00
Additional spare parts for Uniject filling machine (PATH rough estimate)	10,000.00
Fixtures and hand held manual labeling equipment	1,000.00
Manual trimming arbor press with 5 dies (PATH estimate based on stability study filling)	1,500.00
Pouch sealing machine: Fuji Impulse OPL-300-5 (Quote to PATH, December 2003)	5,395.00
Precision balance, miscellaneous small lab equipment and supplies	2,000.00
PATH rough estimate	94,895.00
Export packing, shipping, duties at 25% of value (rough estimate)	23,723.75
Total Equipment	**118,618.75**

Staffing required and output: Maximum output for filling and pouching UnijectDP devices with Uniject Scenario equipment will be about 10 units/minute or 600/hour. Daily output on an eight-hour shift with 6.5 hours of production run time will be 3,900 units. Given 20 work days in a month, maximum yearly production is thus estimated at 936,000 units.

A licensed pharmacist should supervise the overall filling and packaging operation; however, this would only require 40 percent of the pharmacist's time. Actual filling, labeling, trimming, and pouching would require three technicians with pharmacy technician or laboratory technician training. Documentation, inventory control, and administration might require between 25 percent and 100 percent of an additional FTE depending on volume of work (time devoted to this task is estimated at 62.5 percent). A medical equipment or pharmaceutical equipment engineer/master technician should be trained in detailed programming and maintenance of the Uniject filling and sealing machine. Perhaps 20 percent FTE of this person's time would be required for oversight, monitoring, and troubleshooting of the filling machine.

Training for filling and pouching operations: Assuming the chosen staff meet the above qualifications, overall training in using and maintaining Uniject equipment should allow 7-10 days.

Machine maintenance: A basic set of spare parts has been included in the equipment cost estimate. The three technicians can complete additional maintenance such as calibration and cleaning during the 1.5 hours of non-production time during each eight-hour shift. The suggested 20 percent FTE for a pharmaceutical equipment engineer will also cover some maintenance needs. To be conservative, additional maintenance costs should be budgeted based on total cost of equipment at rate of 20 percent for the first year, 15 percent for years 2-4, and 20 percent for years 5-end of life.

Space requirements: Space requirements for equipment are estimated at 2 m^2 class 1000, 8 m^2 basic lab, all air-conditioned.

2.3 Assumptions for the Cost Analysis

The following assumptions apply to *all scenarios*:

- Costs are estimated for Zambia only.
- Because both NVP and the generic equivalent produced by Cipla are currently donated, drug costs and issues related to shelf-life are not included in analyses.
- Sustainability is excluded from the work.
- Days worked are assumed to be 214 (260 working days – 10 public holidays – 36 vacation days/year).
- The currency exchange rate was obtained at the following website accessed on August 20, 2004: http://www.oanda.com/convert/classic. One U.S. dollar is equivalent to 4,745 Zambian Kwacha (ZMK).

The assumptions below pertain to the *Individual and Batches Scenarios* only:

- Length of time to prepare and administer a single dose in the Individual Scenario is 4.8 minutes.

- In the Batches Scenario, it is assumed that the amount of time spent preparing one dose in a batch is also 4.8 minutes.
- It is also assumed in the Batches Scenario that the batch is prepared by one person, for one facility only.
- The amount of time spent counseling mothers about the NVP infant dose is 4.8 minutes in the Batches Scenario.
- Counseling costs pertain specifically to the time a nurse spends informing and instructing an expectant mother about how to administer NVP to her infant after birth.
- For packaging for the Batches Scenario, the study estimated the cost of brown bags. However, through the interviewers used in the Provider Survey, the study team learned that many hospitals use plastic sandwich bags.
- Costs of both nurses and nurse's aides are provided in the Batches Scenario.
- Facility-based batch packaging method labor costs only compare using nurses versus nurse's aides in the Batches Scenario.
- In the Batches Scenario, the dosage administered is 0.6 ml, the standardized amount for an assumed 3kg average newborn weight.

These assumptions apply to the *Semi-automated and Uniject Scenarios* only:

- In the Semi-automated and Uniject Scenarios, production takes place in a hospital lab facility/pharmacy. Therefore, there are no added costs for space.
- Analysis will assume that machinery is located in Zambia for the Semi-automated and Uniject Scenarios.
- The amount of time spent counseling mothers about the NVP infant dose is 4.8 minutes.
- Counseling costs pertain specifically to the time a nurse spends informing and instructing an expectant mother about how to administer NVP to her infant after birth.
- Distribution costs for the Semi-automated and Uniject Scenarios depend on the production location relative to the health facility and are not included in this costing exercise.
- Similarly, the study does not consider the distribution/export costs to surrounding countries that would be likely in the production of a large number of units.
- Any wastage of NVP that may occur during manual preparation or sporadic or limited production times is not explored.
- Utility costs are estimated at 122 Kwacha/kWh (http://www.zesco.co.zm/tariffs.html). Consumption is therefore roughly $ 0.03/kwh.
- In the Semi-automated and Uniject Scenarios, the dosage administered is 0.6 ml, the standardized amount for an assumed 3kg average newborn weight.

3. Results

3.1 Summary of Scenarios

Table 1 summarizes the costs of all four scenarios. Focusing on the costs per dose, results show that at 80 percent treatment of HIV-positive births (60,130 cases), costs are lowest for the Individual Scenario ($17,636.52) and highest for the Batches (nurse) Scenario ($24,234.45). Thus, based on costs per dose, the Individual Scenario is the most cost effective, at $0.29 per unit. In contrast, the Uniject and Batches (nurse) Scenarios are the least cost-effective methods, at $0.40 per dose.

Table 1. Summary of Scenarios

	Scenario			
	Individual (1)	***Batches (2)***	***Semi-automated (3)***	***Uniject (4)***
Units produced/year	60,130	60,130	60,130	60,130
Cost for production (nurse)	$17,636.52	$24,235.45	$23,299.12	$23,920.79
Cost for production (nurse's aide)	–	$22,640.89	–	–
Cost per dose (nurse)	**$0.29**	**$0.40**	**$0.39**	**$0.40**
Cost per dose (nurse's aide)	–	**$0.38**	–	–

3.1.1 Individual and Batches Scenarios

Table 2 displays the results of the costing exercise for the Individual and Batches Scenarios. In the Individual Scenario, the only costs involved are the labor costs of a nurse preparing and administering an infant dose of NVP and the cost of the syringe. The per dose cost for this scenario is $0.29. It is estimated that the equivalent of 14 full-time nurses would be needed to treat 60,130 cases.

The Batches Scenario comprises packaging and counseling costs in addition to preparation costs. If a nurse prepares the infant doses of NVP in this scenario, the cost per dose is $0.40; if a nurse's aide prepares them, the cost per dose is $0.38. The counseling component would require twice as many FTE nurses (28 nurses), or 14 nurse's aides and 14 nurses under the nurse's aide option to treat 60,130 cases.

Table 2. Costing of the Individual and Batches Scenarios

	Scenarios		
	Individual (1)	***Batches (2)***	***Batches (2)***
		(Nurse)	***(Nurse's aide)***
# doses - one year (assume 80% of HIV+ infants receive treatment)	60,130	60,130	60,130
Capital costs			
None	–	–	–
Recurrent costs			
Production			
Est. labor costs (preparing+administering) for HIV+ births/month - Nurse (4.8 min/birth)	$6,211.79	$6,211.79	–
Est. labor costs (administering) for HIV+ births/month - Nurse's Aide (4.8 min/birth)	–	–	$4,617.22
Est. labor costs (counseling) for HIV+ births/month - Nurse (4.8 min/birth)	–	$6,211.79	$6,211.79
Materials			
Syringes - cost per HIV+ birth/month ($.19/syringe)	$11,424.70	$11,424.70	$11,424.70
Packaging - Brown bags (500 bags/$3.18)	–	$387.14	$387.14
Total costs	$17,636.49	$24,235.42	$22,640.85
Cost per dose	**$0.29**	**$0.40**	**$0.38**
Level of effort (minutes/month)	288,624.00	577,248.00	577,248.00
Number of FTE nurse or nurse's aides needed full time to handle total doses	14.05	28.10	28.10

3.1.2 Semi-automated and Uniject Scenarios

Cost findings for the Semi-automated and Uniject Scenarios are found in Table 3. Under the Semi-automated approach, it is again estimated that 60,130 doses will be produced. Because this number of doses is less than the level of maximum yearly production, maintenance costs and salaries associated with production have been adjusted based on the number of doses produced. Capital costs for this scenario include the initial training for machine operation and equipment depreciation spread over five years. In terms of labor costs, two pharmacy technicians will perform work and maintenance on the machinery full-time. Additional labor costs include the nurse's cost of counseling the mother for five minutes, inventory control performed by a pharmacy technician, and pharmacist supervision of production. Other production costs include parts for machine maintenance and utility costs. Materials costs include the cost of syringes and tubing sets needed for filling the syringes and the plastic/foil laminate and labels for packaging. Given these inputs, the cost per dose for the Semi-automated Scenario is $0.39.

The Uniject Scenario includes all of the factors in the Semi-automated Scenario except:

- Three pharmacy technicians operate and maintain the Uniject machinery;
- A biomedical engineer maintains and makes repairs, constituting 20 percent of his/her time; and
- UnijectDP and tubing sets are substituted for the costs of syringes and their tubing sets.

Taking these factors into account, the final cost per dose is $0.40 for the Uniject Scenario.

Table 3. Costing of the Semi-automated and Uniject Scenarios

	Scenario	
	Semi-automated (3)	***Uniject (4)***
Total production - # doses (assume 80% of HIV+ infants receive treatment)	60,130	60,130
Capital costs		
Training for machines	$1.62	$3.40
Equipment depreciation (5 years)	$240.00	$1,976.98
Recurrent costs		
Production		
Labor -2 technicians (6.5 hrs work, 1.5 hrs maintenance/day)	$498.53	–
Labor -3 technicians (6.5 hrs work, 1.5 hrs maintenance/day)		$448.68
Est. labor costs (counseling) for HIV+ births/month - Nurse	$6,211.80	$6,211.80
Machine maintenance - labor (Included in "labor" above)	–	–
Machine maintenance - parts	$215.85	$1,066.84
Inventory control etc. @ 62.5% FTE of Pharm Tech	$155.79	$93.47
Pharmacist supervision @ 40% of time	$267.23	$160.34
Engineer supervision @ 20% of time	–	$29.91
Utility costs (Scenario 3: 1.5 ZMK/1000 units; Scenario 4: 2.1 ZMK/1000 units)	$2.32	$3.25
Materials		
Syringes (BAXA Excata-Med oral dosing syringes, amber, 1ml or 3ml size with tipcap ($.19/syringe)	$11,424.72	–
Tubing sets for BAXA syringe filling - need new set every 25000 doses or 1 month of use ($30/set)	$72.16	–
UnijectDP (BD, sold in reels of 1500, order quantity of 25,000 units ($.16/Uniject))	–	$9,620.81
Tubing sets for Uniject filling - need new set every 25,000 doses or 1 month of use ($40/set)	–	$96.21
Packaging		
Plastic/foil laminate ($.05/pouch)	$3,006.50	$3,006.50
Labels ($.02/label)	$1,202.60	$1,202.60
Cost per month	$23,299.12	$23,920.79
Cost per dose	**$0.39**	**$0.40**

3.2 Economies of Scale

To provide a more comparable picture of the costs per dose across scenarios, the number of doses has been standardized at various levels and the corresponding costs per dose presented in Table 4. Because there is no mechanical production associated with the Individual and Batches Scenarios, the costs per dose remain constant in these scenarios regardless of the number of doses. Therefore, the costs regardless of the number of doses are $0.29 for the Individual Scenario, and $0.40 and $0.38 for the Batches nurse and nurse's aide scenarios respectively.

Conversely, the Semi-automated and Uniject Scenarios do vary by the amount of doses produced. In the Semi-automated and Uniject Scenarios, when producing 1,000 pediatric doses of NVP, the costs per dose are $0.63 and $2.35 respectively. At 10,000, costs per dose fall to $0.41 for the Semi-automated Scenario and $0.56 for the Uniject scenario. The dose costs of the two scenarios narrow at 60,130 doses and become equal in unit cost ($0.39) at 70,000 doses. By 100,000 doses, the Uniject Scenario surpasses the the Semi-automated approach in cost-effectiveness. Finally, at the maximum yearly production of the Uniject scenario, 936,000 doses, the per dose cost of the Semi-automated appoach is $0.38 and is $0.37 for the Uniject Scenario. These small changes in the costs from 100,000 to almost 1,000,000 in the two scenarios emphasize the leveling off of per dose costs as doses increase into the hundreds of thousands and beyond.

Table 4. Estimated Dose Costs by Number of Doses and Scenario

# of doses	Scenario (amounts in USD)			
	Individual (1)	***Batches* (2)***	***Semi-automated (3)***	***Uniject (4)***
1,000	$0.29	$0.40 ($0.38)	$0.63	$2.35
10,000	$0.29	$0.40 ($0.38)	$0.41	$0.56
60,130	$0.29	$0.40 ($0.38)	$0.39	$0.40
70,000	$1.29	$0.40 ($0.38)	$0.39	$0.39
100,000	$0.29	$0.40 ($0.38)	$0.39	$0.38
936,000	$0.29	$0.40 ($0.38)	$0.38	$0.37

* Amount in parentheses represents cost per unit if a nurse's aide is used

3.3 Sensitivity Analysis

Table 5 displays results examining how a 10 percent increase in particular scenario components affects overall costs per dose.[4] With a 10 percent increase in salaries, the Batches-Nurse Scenario show the greatest change in dose costs at 5.1 percent. In terms of cost changes for syringes or Uniject (including the required tubing), the Individual scenario has the greatest change in dose costs at a 6.5 percent increase given the 10 percent increase in syringes. Overall, however, changes in dose costs remain under 10 percent; thus, it can be said that these two factors do not significantly influence the overall costs in the scenarios.

[4] Other factors, such as equipment and packaging, were also analyzed for sensitivity. However, salary and syringes/Uniject showed the greatest change and were therefore selected to be highlighted in the analysis.

Table 5. Sensitivity Analysis Assuming 10 Percent Increases in Salary and Syringes/Uniject

	Scenario				
	Individual (1)	***Batches (2)***	***Batches (2)***	***Semi-automated (3)***	***Uniject (4)***
		Nurse	***Nurse's aide***		
Original position	$0.29	$0.40	$0.38	$0.39	$0.40
Unit costs after 10% increase in salaries	$0.30	$0.42	$0.39	$0.40	$0.41
% Change in unit costs	*3.5%*	*5.1%*	*4.8%*	*3.0%*	*2.9%*
Unit costs after 10% increase in cost of syringes or UnijectDP	$0.31	$0.42	$0.40	$0.41	$0.41
% Change in unit costs	*6.5%*	*4.7%*	*5.0%*	*4.9%*	*4.1%*

4. Conclusion

To summarize findings, the economies of scale table (Table 4) shows that, at all dosage levels, the Individual Scenario is most cost effective. Thus, if the cost issues are the overriding factor to consider, preparation and administration of the drug by a nurse at a health facility is the best choice. However, one must keep in mind the supply of nurses in a given area; therefore, a higher the number of treatment cases will require a greater number of nurses dedicating more time to preparation and administration of infant doses of Nevirapine.

By contrast, the Semi-automated or Uniject Scenarios become equally cost effective at 70,000 doses. Either of these scenarios would be ideally suited for geographic areas where women have limited access to hospitals. In this instance, however, the shelf life of NVP must be taken into account coupled with distribution costs both within and across country borders. Other important regulatory and drug registration issues also would need to be addressed before either of these two scenarios is implemented. Given the current annual requirements for infant PMTCT NVP doses, however, high volumes of production may only be justified if the surplus production can be exported to other users in the region. Moreover, regulatory and other drug registration issues will be important considerations to the feasibility of automated production. Zambia is a member of the Common Market for East and Southern Africa (COMESA) and Southern Africa Development Community (SADC) and for this reason may be able to export in this trade area.

Finally, dose costs do not appear to be very sensitive to cost changes in any of the variables. This finding indicates that increases up to 10 percent in the cost of salaries and syringes/Uniject will not have a significant effect on the per dose cost.

From a financial standpoint, it is therefore recommended that the Individual Scenario should be implemented for maximum cost-effectiveness. For cases where limited access to hospital must be taken into consideration, the Semi-automated or Uniject scenario would be an ideal method of delivery.

Annex A: Human Resources Questionnaire

ZAMBIA NEVIRAPINE STUDY
HUMAN RESOURCES QUESTIONNAIRE

Hello. My name is (name of person conducting survey). I am working with the Zambian Integrated Health Program to collect information about your facility's human resource capacity and use of the antiretroviral drug, Nevirapine, on newborn infants. I would like you to ask you a few questions about the staff at your facility as well as some questions pertaining to HIV/AIDS services. Please note that the information required will be applicable to the year 2004. All information collected will be kept confidential and will only be used for the intended purpose.

1. Name of Facility: _____
2. Name of Respondent: _____
3. Date of Interview: _____

4. Of the total number of staff, how many are working on each PMTCT or PMTCTplus HIV/AIDS service?

Staff Type	PMTCT	PMTCTplus
Doctors		
Nurses		
Lab Technicians		
Pharmacists		
Counselors		
Social Workers		

5. What is the current yearly salary of a nurse, including extra allowances? _____
6. What is the current yearly salary of a nurse's aide, including extra allowances? _____

Thank you for participating in our survey. Have a nice day.

Annex B: Health Clinician's Questionnaire

ZAMBIA NEVIRAPINE STUDY
HEALTH CLINICIAN QUESTIONNAIRE

***(NOTE TO INTERVIEWER**: IN THE FOLLOWING QUESTIONS, SIMPLY CIRCLE THE RESPONSE THAT CORRESPONDS WITH THE ANSWER GIVEN BY THE RESPONDENT. IF THE ANSWER IS NOT LISTED IN THE CHOICES PROVIDED, WRITE THE RESPONSE GIVEN BY THE RESPONDENT ON THE LINE "OTHER (SPECIFY).")*

Interviewer, please read the following to the respondent:

"Hello. My name is (name of person conducting survey). I am working with the Zambian Integrated Heath Program to collect information about your facility's use of the antiretroviral drug, Nevirapine, among newborn infants. I would like you to ask you a few questions about the preparation, administering, and counseling of Nevirapine for newborns. Please note that the information required will be applicable to the year 2004. All information collected will be kept confidential and will only be used for the intended purpose.

First of all, do you work in the preparation, administering, or counseling of Nevirapine for newborn infants?"

- If the respondent says "no," thank the person for their time, but tell them you are looking for people who work with Nevirapine and newborns. Ask them if they know of someone else who does this type of work who they could recommend you to talk to.
- If the respondent says "yes," continue with the survey.

1 Name of facility: _____

2. Date of interview: _____

3. First name of respondent: _____

4. Sex of respondent: _____Male _____Female

5	What is your job title?	
	Nurse	01
	Nurse's Aide	02
	Pharmacist	03
	Counselor	04
	Other (specify)	_____
	Don't know	98

6. What is the total number of staff in 2004?

Staff Type	Number
Doctors	
Nurses	
Lab Technicians	
Pharmacists	
Counselors	
Social Workers	

7. Of the total number of staff, how many are working on each HIV/AIDS service?

Staff Type	PMTCT	PMTCTplus
Doctors		
Nurses		
Lab Technicians		
Pharmacists		
Counselors		
Social Workers		

Interviewer: "Now I am going to ask some questions about the preparation and administering of Nevirapine to infants."

PREPARATION OF NEVIRAPINE

8	Normally, who prepares infant doses of Nevirapine? **(Interviewer, read responses.)**	
	Nurse	01
	Nurse's Aide	02
	Pharmacist	03
	Other (specify)	_____
	Don't know	98
9	Do you prepare infant doses of Nevirapine?	
	Yes	01
	No	02 **(if no, go to "Administering" section)**

10	Are infant doses prepared in prefilled batches and stored for future use or are they prepared one at a time when needed? In batches One at a time when needed Other (specify) Don't know	 01 02 _____ 98
11	On average from start to finish, how long does it take you to prepare one dose of Nevirapine for infants? This includes getting and opening the Nevirapine vial, filling the syringe (and also wrapping the syringe and storing it in the proper location if prefilled).	_____minutes____ seconds
12	How much Nevirapine is discarded (thrown away) during the preparation of Nevirapine doses for infants? Amount discarded Don't know	 _____ **(in ml)** 98

ADMINISTERING NEVIRAPINE

13	Normally, who administers infant doses of Nevirapine? **(Interviewer, read responses.)** Nurse Nurse's Aide Doctor Other (specify) Don't know	 01 02 03 _____ 98
14	Do you administer infant doses of Nevirapine? Yes No	 01 02 **(if no, go to "Counseling" section)**
15	On average, per week, how many newborn infants receive Nevirapine immediately after birth? Number of births Don't know	 _____ 98
16	How much time does it take you to administer the dose to the newborn infant? This includes getting the syringe, opening it, giving it to the infant, and disposing of the syringe.	_____minutes____ seconds
17	How much Nevirapine is discarded (thrown away) after the Nevirapine is administered to the newborn? Amount discarded Don't know	 _____ (in ml) 98

COUNSELING MOTHER ON ADMINISTERING NEVIRAPINE TO HER INFANT

18	Are expectant mothers able to receive an infant dose of Nevirapine to give to their newborn infant immediately after birth and counseling about how to administer the drug at this hospital/clinic? Yes No Don't know	 01 **02** (if no, go to end) 98

19	Normally, who counsels expectant mothers about infant doses of Nevirapine? **(Interviewer, read responses.)** Nurse Nurse's Aide Counselor Other (specify) Don't know	 01 02 03 _____ 98
20	Do you counsel expectant mothers about infant doses of Nevirapine? Yes No	 01 02 **(if no, go to end)**
21	On average, per week, how many expectant mothers receive an infant dose of Nevirapine to give to their newborn infant immediately after birth and counseling about how to administer the drug? Number receiving counseling Don't know	 _____ 98
22	How much time does it take you to counsel expectant mothers about giving the Nevirapine dose to their newborn infant? This includes explaining how and why the drug is administered, what the drug does, possible side effects, and answering questions the mother may have.	**_____minutes____ seconds**

Thank you for participating in our study. Have a nice day.

****Interviewer:** Please observe preparation, administering, and counseling of Nevirapine (if possible) and answer the following questions.

23	On average from start to finish, how long does it take the nurse/nurse's aide/other to prepare one dose of Nevirapine for infants? This includes getting and opening the Nevirapine vial, filling the syringe, wrapping the dosage, and storing it in the proper location.	_____minutes____ seconds
24	How much Nevirapine is discarded (thrown away) during the preparation of Nevirapine doses for infants?	**_____ (in ml)**
25	How much time does it take the nurse/other to administer the dose to the newborn infant? This includes getting the dose, opening it, giving it to the infant, and disposing of the syringe.	**_____minutes____ seconds**
26	How much time does it take the nurse/couselor to counsel expectant mothers about giving the Nevirapine dose to their newborn infant? This includes explaining how and why the drug is administered, what the drug does, possible side effects, and answering questions the mother may have.	**_____minutes____ seconds**