



USAID
FROM THE AMERICAN PEOPLE

NEPAL: SUPPORT FOR HIV/AIDS COMMODITY SECURITY

December 2005

This publication was produced for review by the United States Agency for International Development. It was prepared by Linda Allain, Ruslan Malyuta, and Eric Takang.



NEPAL: SUPPORT FOR HIV/AIDS COMMODITY SECURITY

The author's views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

DELIVER

DELIVER, a six-year worldwide technical assistance support contract, is funded by the U.S. Agency for International Development (USAID).

Implemented by John Snow, Inc. (JSI), (contract no. HRN-C-00-00-00010-00) and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], and Social Sectors Development Strategies, Inc.), DELIVER strengthens the supply chains of health and family planning programs in developing countries to ensure the availability of critical health products for customers. DELIVER also provides technical management of USAID's central contraceptive management information system.

This document does not necessarily represent the views or opinions of USAID. It may be reproduced if credit is given to DELIVER.

Recommended Citation

Allain, Linda, Ruslan Malyuta, and Eric Takang. December 2005. *Nepal: Support for HIV/AIDS Commodity Security*. Arlington, Va.: DELIVER, for the U.S. Agency for International Development.

TABLE OF CONTENTS

TABLE OF CONTENTS	v
ACRONYMS	vii
ACKNOWLEDGEMENTS	viii
EXECUTIVE SUMMARY	ix
INTRODUCTION	1
1. Background on Health Product Management	3
2. Antiretroviral Drugs	4
2.1 Antiretroviral Therapy	4
2.1.1 Teku Hospital	5
2.1.2 Bheri Zonal Hospital	6
2.2 Prevention of Mother-to-Child Transmission.....	7
2.3 Post Exposure Prophylaxis	7
2.4. Funding and Procurement of Antiretroviral Drugs.....	7
2.5 Drug Availability and Regimens	8
2.6 Forecast.....	9
2.6.1 Methodology	10
3. Testing	13
3.1 Prevention of Mother-to-Child Transmission.....	14
3.1.1 Testing Protocol	15
3.1.2 Forecast	15
3.2 Voluntary Counseling and Testing	16
3.2.1 Government Voluntary Counseling and Testing.....	16
3.2.2 FHI-supported Sites.....	17
3.2.3 Other Nongovernmental Organizations.....	17
3.3 Clinical Diagnosis.....	18
3.3.1 Government.....	18
3.4 Forecast for Voluntary Counseling and Testing and Clinical Diagnosis.....	19
3.4.1 In the Pipeline.....	21
3.5 Private Voluntary Counseling and Testing and Clinical Diagnosis Testing.....	21
3.6 Blood Safety	22
3.7 Sentinel Surveillance	22
3.7.1 HIV Sentinel Surveillance of STI Clients	22
3.7.2 HIV Sentinel Surveillance of ANC Clients.....	23
4. Sexually Transmitted Infections	24
4.1 Service Delivery	24
4.2 Forecasting Sexually Transmitted Infection Drug Requirements.....	25
4.2.1 Methodology	25
4.2.2 Case Estimation and Data Collection	25
4.2.3 Results	26
4.3 Procurement, Storage, and Distribution.....	27
5. Opportunistic Infections.....	28
5.1 Some Clinical Signs of Opportunistic Infections	28
5.2 Forecast.....	29
5.2.1 Forecast Methodology	29
5.2.2 Case Estimation and Data Collection	29
5.2.3 Forecast Results.....	31
6. Regulatory Process and Quality Assurance	32

6.1 Quality Assurance.....	32
7. Supply Chain Analysis.....	34
7.1 Financing	34
7.1.1 Antiretroviral Drugs	34
7.1.2 HIV Tests	34
7.2 Forecasting.....	35
7.2.1 Antiretroviral Drugs	35
7.2.2 HIV Tests	35
7.3 Procurement.....	35
7.3.1 Antiretroviral Drugs	35
7.3.2 HIV Tests	36
7.4 Distribution.....	36
7.4.1 Logistics Management Information System.....	36
7.4.2 Inventory Control	37
7.4.3 Warehouse and Storage.....	37
7.4.4 Transport	38
7.5 Funding of Logistics Functions	38
8. Conclusion and Recommendations.....	40
Appendix—Organizations visited.....	42
Kathmandu	42
Nepalgunj	43
Pokhara	43

ACRONYMS

AIDS	acquired immune deficiency syndrome
ANC	antenatal care
ART	antiretroviral treatment
ARV	antiretroviral
ARVs	antiretroviral drugs
BPKIHS	B.P. Koirala Institute of Health Science
BZH	Bheri Zonal Hospital
CDC	Centers for Disease Control and Prevention
DDA	Department of Drug Administration
DFID	British Department for International Development
DHS	Department of Health Services
EU	European Union
FEFO	first-to-expire, first-out
FHI	Family Health International
FPAN	Family Planning Association of Nepal
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	human immunodeficiency virus
HMGN	His Majesty's Government of Nepal
HMIS	Health Management Information System
HSS	HIV sentinel surveillance
JICA	Japan International Cooperation Agency
JSI	John Snow, Inc.
LMD	Logistics Management Division
LMIS	logistics management information system
MASS	Management support Services (P) Ltd.
MOH	Ministry of Health
NCASC	National Center for AIDS and STD Control
NGO	nongovernmental organization
NPHL	National Public Health Laboratory
OI	opportunistic infection
ORS	oral rehydration solution
PEP	post exposure prophylaxis
PMTCT	prevention of mother-to-child transmission
QA	quality assurance
RTI	reproductive tract infection
STI	sexually transmitted infection
U.S.	United States of America
UNAIDS	United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
UTI	urinary tract infection
VCT	voluntary counseling and testing
WHO	World Health Organization

ACKNOWLEDGEMENTS

The team would like to thank all those who shared their precious time and expertise with us to make this mapping and forecasting exercise possible. We would also like to thank the National Center for AIDS and STD Control of the Ministry of Health of Nepal for making their staff available at all times and answering our many queries.

We also wish to thank U.S. Agency for International Development (USAID)/Nepal for not only funding this work but also providing logistical and technical support during both trips and in-between. A special thank you goes to the Nepal Family Health Program/John Snow, Inc. (JSI) for also providing logistical and technical support.

It is our sincere hope that the recommendations proposed in this report are implemented as swiftly as possible so that all people living with HIV/AIDS in Nepal can have access to uninterrupted treatment, care and support.

Linda Allain, Coordinator for Country Programs, DELIVER
Ruslan Malyuta, HIV/AIDS Specialist, JSI
Eric Takang, Pharmaceutical and Logistics Advisor, DELIVER

EXECUTIVE SUMMARY

Human immunodeficiency virus (HIV) prevalence in Nepal is estimated at 0.5 percent of the general population, but according to the United Nations Programme on HIV/AIDS/World Health Organization, the infection is concentrated in specific groups, mainly injecting drug users, sex workers, and labor migrants.

The *National Strategy for HIV/AIDS in Nepal (2002–2006)* highlights the need for a comprehensive and multisectoral approach. A major component of this strategy is ensuring that HIV/AIDS prevention, care, and treatment services are available to all Nepalese who need them, including HIV testing, the provision of antiretroviral treatment, the treatment of sexually transmitted infections (STIs), and the treatment of opportunistic infections (OIs). A key element is ensuring that products required for HIV/AIDS prevention, care and treatment are available and affordable.

DELIVER/JSI was invited by USAID and His Majesty's Government of Nepal to prepare a three-year forecast of HIV tests for the public sector and a few specific nongovernmental organizations, and to prepare a three-year forecast of antiretroviral drugs (ARVs), and STI and OI drugs. In addition, DELIVER/JSI was asked to assess the supply chain for these products and make recommendations for their logistics management.

In the absence of a logistics system for the HIV/AIDS program commodities, consumption data did not exist. As a result, the forecasts that have been prepared are based on either program targets or morbidity data, or a combination of both, including informed assumptions from service providers and other stakeholders. As soon as a logistics system is established and consumption data becomes available, the forecasts should be reviewed and revised as needed.

The result of the forecast provides estimates of drugs required to attain the goals set by the program and also provides a tool for resource mobilization to secure funding for the uninterrupted supply of these products. The data shows that there will be no shortage of HIV tests or ARVs for the calendar year 2006 if the existing procurement plans put in place are executed taking into consideration that funding for these supplies are available. For the STI and OI drugs, additional information is required in order to ascertain whether funding has been secured to meet the needs for 2006.

Quality assurance (QA) is a key to successful programming, and it is important that procedures for HIV tests, as established in the national *Guidelines for Voluntary HIV/AIDS Counseling and Testing*, be followed. In the same vein, manufacturers' directives should be followed precisely to ensure correct use of the tests. QA for drugs is also very important, not only to ensure that the patient obtains safe products but also to prevent the development of resistance and treatment failure.

Finally, for the HIV/AIDS program to run smoothly, a logistics system needs to be put in place. This will allow programs to have a continuous flow of essential commodities, and it will allow for the expansion of programs and help meet their strategic goals. A design workshop should be

held to establish the logistics management information system and the inventory control system. In addition, national guidelines for pediatric ARVs and for the treatment of OIs need to be finalized so that forecasts based on nationally recognized protocols can be developed.

INTRODUCTION

Limited data shows that human immunodeficiency virus (HIV) prevalence in Nepal is approximately 0.5 percent of the general population, but according to United Nations Programme on HIV/AIDS (UNAIDS)/World Health Organization (WHO), the infection is more highly concentrated in specific groups, mainly injecting drug users, sex workers, and labor migrants. According to their data, HIV prevalence among female sex workers increased from 0.7 percent in 1992 to 17 percent in 2002 while among injecting drug users, HIV prevalence reached 50 percent in 2002 and current estimates put it at about 68 percent. Many of factors have been identified that predispose individuals to the epidemic. These include high rate of male migration, prostitution, poverty, low socio-economic status for women, and illicit drug trafficking. Most estimates state that approximately 62,000 adults are living with HIV/AIDS in Nepal, most of whom are not aware of their status since stigma, discrimination, lack of services, and difficult access to existing services (geographic and economic) discourage people from seeking testing.

The *National Strategy for HIV/AIDS in Nepal (2002–2006)* highlights a need for a comprehensive and multisectoral response. Among the many interventions planned by the Ministry of Health (MOH) is the expansion of the provision of antiretroviral treatment (ART) as well as of voluntary counseling and testing (VCT) services.

Intermediate Result 2.3 of the U.S. Agency for International Development (USAID)/Nepal's Program Results Framework has the objective: "Increased HIV/STI prevention and control practices by high-risk groups in targeted areas." Within the context of the *National Strategy* and in support of this strategy, USAID/Nepal has requested DELIVER's support in developing a commodity security approach for HIV/AIDS products so that ART and VCT services can expand as smoothly as possible. DELIVER was asked to look at not only the public sector services, but also services provided by the NGO community. DELIVER was requested specifically to assist the National Center for AIDS and STD Control (NCASC), the National Public Health Laboratory (NPHL), and their partners to:

- Prepare a multi-year forecast for antiretroviral (ARV) drugs, HIV tests, and sexually transmitted infection (STI) and opportunistic infection (OI) drugs
- Work with a logistics advisor working at the NCASC (position to be filled) and a logistics consultant working at Family Health International (FHI) to provide technical support and assistance and facilitate coordination between public and nongovernmental organization (NGO) service providers in the area of supply chain management of HIV/AIDS program products
- Analyze the supply chain requirements for commodity security of HIV/AIDS program products, including system development and logistics management information system (LMIS) requirements, and make recommendations for the establishment of a logistics system for HIV/AIDS program commodities.

The scope of the work to be carried out is extensive, and it was agreed that it would be completed after at least two visits. The first visit took place from September 19 to October 7,

2005, by the DELIVER team consisting of Linda Allain and Ruslan Malyuta. The second visit by Linda Allain and Eric Takang occurred from November 4 to 19, 2005. As a result, this report maps out two HIV/AIDS program inputs, antiretroviral drugs (ARVs) and HIV testing; provides a three-year forecast for ARVs, HIV tests, and STI and OI drugs; and analyzes the supply chain for HIV/AIDS program commodities. The consultants met with key stakeholders on two occasions, once in October and once in November, to share initial findings and agree on the basic assumptions.

1. Background on Health Product Management

The *National Strategy for HIV/AIDS in Nepal (2002–2006)* was designed to guide the expanded response to the HIV/AIDS epidemic in Nepal. The strategy calls for the commitment of all sectors within and outside government, as well as the coordinated support of external development partners.

The Ministry of Health has created the National Center for AIDS and STD Control to coordinate the national effort in the fight against HIV/AIDS. This center is not integrated into the Department of Health Services (DHS) of the MOH, where most other health programs are managed, but is a separate body reporting directly to the Minister of Health. Among its many tasks, NCASC is responsible for ensuring the availability of HIV/AIDS program commodities.

Within the DHS, the Logistics Management Division (LMD) ensures the logistics management of full-supply health commodities, such as contraceptives and oral rehydration solution (ORS), as well as essential drugs. The LMD has a functioning logistics system, including a logistics management information system, world standard warehouses, and a well-functioning distribution system.

ARVs, HIV tests, and STI and OI drugs are managed separately from the LMD because of the NCASC's particular status and because of the complexity of the commodities themselves. In fact, these products are consigned to the NCASC, at times stored either in a small room at the NCASC or at the Management Support Services (P) Ltd. (MASS) warehouse, and distributed by the NCASC or MASS to the service delivery sites. There is no logistics system in place for the management of these products.

Family Health International, supported by USAID, supports NGOs that provide VCT and STI services. These NGOs obtain their HIV tests via FHI, but obtain their STI drugs from the NCASC. There is no logistics system in place to support these NGOs.

2. Antiretroviral Drugs

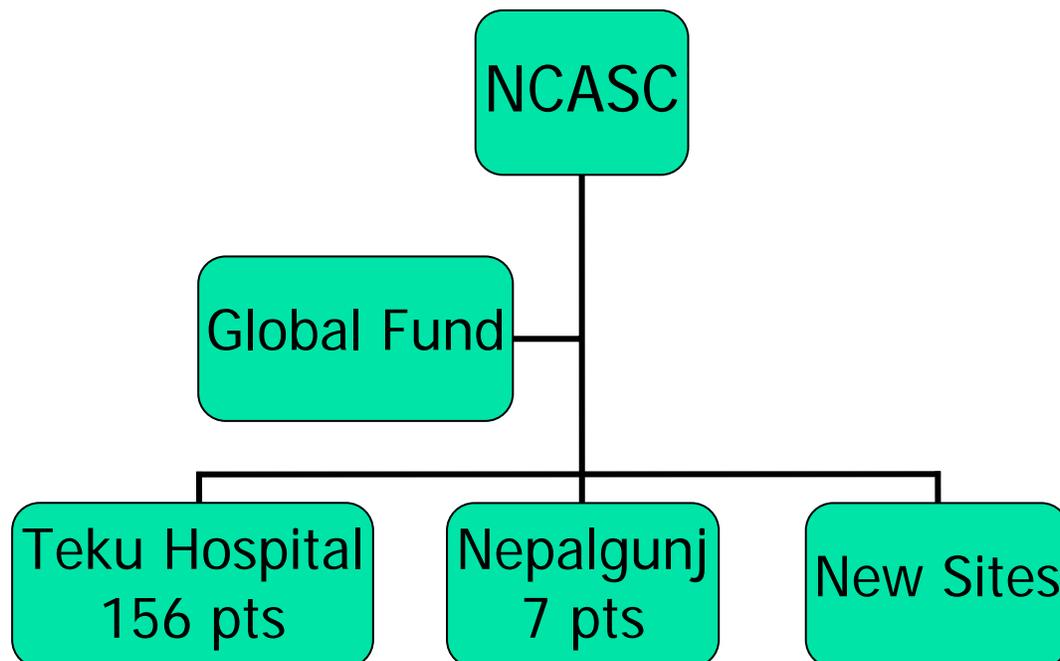
Antiretroviral drugs are available in Nepal as part of ART, prevention of mother-to-child transmission (PMTCT), and post exposure prophylaxis (PEP).

Antiretroviral drugs are provided by the public and purely private sectors. The consultants paid special attention to the provision of ARVs by the public sector, as the private sector was beyond the scope of work. However, to get as good a grasp as possible of the situation in Nepal, some private organizations were visited.

To date, ARVs are not on His Majesty's Government of Nepal's (HMGN) essential drugs list, which was updated in February, 2005, but the draft *National ARV Protocols and Guidelines* follow WHO-recommended treatment guidelines. In addition, guidelines on adverse reactions have been developed and are in line with the National ARV protocols and guidelines.

2.1 Antiretroviral Therapy

Figure 1. Map of Antiretroviral Therapy



In the public sector, only two facilities are currently providing ARV treatment: Teku Hospital in Kathmandu and the Bheri Zonal Hospital (BZH) in Nepalgunj. On September 30, there were a total of 104 patients on ART: 94 at Teku Hospital and 10 at BZH. By mid-November, the number had increased to 163: 156 from Teku Hospital and seven from BZH (two passed away and one defaulted). Plans are in place to add three new sites once additional drugs become

available. The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) plans to initially procure ARVs for a total of 750 patients for a one-year period. Some ARVs arrived in Nepal in early December 2005 and the rest of the first shipment is expected in January 2006.

Many of the drugs that are currently distributed as part of ART were procured by NCASC of the Ministry of Health. These ARVs were procured locally with MOH funds from Yetichem Distributors and were manufactured by Cipla in India. The exact quantities are unknown to the consultants.

According to the *National Guidelines on ARV Therapy*, criteria for accessing ARVs is a CD4 count of less than 200, and if this not available, total lymphocytes was mentioned as an alternative criteria. WHO Stage IV irrespective of CD4 count or total lymphocyte count allows access. If CD4 testing is not available, WHO Stage III disease, irrespective of total lymphocyte count is allowable. There is only one CD4 counter in Nepal, situated at the National Public Health Laboratory, next to Teku Hospital in Kathmandu, and to date, they have been collecting blood for CD4 count one day a month. Because of the increased demand, they intended to increase the days to twice a month starting in October 2005. Some of the people interviewed pointed out that this situation has not been conducive to patients having their CD4 count done on a regular basis because of the distances that people outside of Kathmandu need to travel, and because of lack of confidentiality, e.g., if someone is seen at the NPHL on the CD4 day, they are immediately assumed to be HIV positive. To address the travel situation, GFATM intends to procure three additional CD4 machines to be placed in different areas of the country.

2.1.1 Teku Hospital

Teku Hospital has the greatest amount of patients on ARVs. The hospital has followed about 700 HIV positive patients so far from Kathmandu and other areas of the country. ART services began in February 2004 with 24 patients accessing drugs. Currently 156 adults are on ARV therapy. Patients get one month's supply and are asked to pick up their drugs two to three days prior to finishing their supply. Some of the patients who obtain their ARVs from Teku Hospital come from outside the Kathmandu Valley, and many need to travel great distances. This is a huge hardship to them financially and in time.

In September, 94 patients were on the following regimens:

ZDV+3TC+NVP	66 patients
d4T(30)+3TC+NVP	20 patients
d4T(40)+3TC+NVP	2 patients
ZDV+3TC+EFV-600	5 patients
ZDV+3TC+EFV-800	1 patient

To date, a total of 270 patients have met the clinical criteria for accessing ARV treatment. Some 150 were initially enrolled, but 50 did not come forward for ART. Teku Hospital is trying to contact these 50 potential patients. There are approximately 64 patients on the waiting list of Teku Hospital, and when additional drugs become available, they will be able to start treatment as soon as possible. Some estimates state that approximately 1,000 children are HIV positive in

Nepal, and according to UNICEF, 90 are targeted to receive ART. The treating physician at Teku Hospital stated that 30 of his HIV positive patients are children and three have met the criteria for treatment. Unfortunately, there are no pediatric drugs available in Nepal, and no children are receiving treatment through the public sector. Guidelines for treating pediatric patients are currently being developed, and as soon as they are ready, pediatric ARVs will be ordered.

Four doctors were trained to provide ARV treatment, but only two of them are directly involved in the provision of clinical care. There is a separate HIV/AIDS clinic on the grounds of the hospital where the treating physician and/or the attending nurse dispense ARVs directly to the patients.

There is a small cupboard in the nurse's room where ARVs are kept. A small quantity is also kept at the hospital store. Patient and stock records were kept manually, and the nurse was practicing first-to-expire, first-out (FEFO).

Because Teku Hospital is in the same compound as the NCASC, where some ARVs are stored, it is not difficult for the nurse or physician to pick up their supplies. This has worked relatively well with the few patients that are on treatment, but even then, the consultants were told that at times ARVs were not available at Teku Hospital or at the NCASC, and the patients would turn to an NGO which supplied them with ARVs until they could return to the hospital for their supplies. Without a logistics system in place, it will be extremely difficult to expand ART.

2.1.2 Bheri Zonal Hospital

Bheri Zonal Hospital in Nepalgunj had 10 adults on ARV treatment in September. During the second visit, the consultants were informed that two patients had passed away and one defaulted, leaving seven patients on ARVs.

Three physicians have been trained to provide ART, but only one was actively treating patients. The consultants did not get the exact number of patients on the waiting list, but there is some indication that at least 50 patients qualified for ARV treatment, but only 10 were placed on treatment, and there may be more patients who qualify.

In September, the 10 patients on ARVs were on the following regimens:

ZDV+3TC+NVP	9 patients
d4T(30)+3TC+NVP	1 patient

When the team traveled to Nepalgunj during the first visit, all 10 patients were on the following regimen: ZDV+3TC+NVP as Duovir N. The physician in charge informed the team that one of the patients was experiencing severe anemia with this regimen and required blood transfusion, which was very expensive for the patient. The physician was not aware that the hospital had drugs other than ZDV, 3TC, and NVP, either in combination or single dosage. The consultants informed the physician that there was enough d4T as well as 3TC and NVP in single dose form for one patient for three months at the hospital storage room and more in Kathmandu. The

consultants were told on the following day that the patient in question had been moved to the following regimen: d4T+3TC+NVP, which should help his problem with anemia.

Again, the lack of a nationwide logistics system contributed to crucial data not being available to the treating physician.

2.2 Prevention of Mother-to-Child Transmission

Three sites, supported by UNICEF and WHO, provide PMTCT services: the Maternity Hospital in Kathmandu, BZH in Nepalgunj, and B.P. Koirala Institute of Health Science (BPKIHS) in Dharan. Within this program, they offer counseling, testing, and drugs for the mother and child and drugs for PEP. (See following section for additional information on the testing aspect of the PMTCT program). UNICEF has forecasted the quantities of ARVs by assuming that 1 percent of women tested would be positive, and assuming that 100 percent of the first-time antenatal care (ANC) clients agree to be tested. The drugs listed in table 1 have been distributed in the following manner:

Table 1. UNICEF Drugs Distributed for PMTCT

Drug	Maternity Hospital	Bheri Zonal Hospital	BPKIHS
Nevirapine 200 mg	240 tablets	120 tablets	120 tablets
Nevirapine (10 mg/ml bottle 240 ml)	6 bottles	4 bottles	3 bottles
ZDV (50 mg/5 ml) oral solution	38 bottles	18 bottles	11 bottles
PEP			
ZDV+3TC	900 tablets	480 tablets	420 tablets
Nelfinavir	4,590 tablets	2,430 tablets	2,160 tablets

At the writing of this report, the consultants were told that none of these drugs had been dispensed by the hospitals.

2.3 Post Exposure Prophylaxis

Post exposure prophylaxis is available in most large hospitals. A limited quantity of drugs has been made available with the institutions' own funding, but this is likely to change. With the planned procurement by GFATM, hospitals will receive some ARV drugs for PEP free of charge.

2.4. Funding and Procurement of Antiretroviral Drugs

In the past, NCASC procured ARVs with its own funding from Yetichem Distributors. The drugs were manufactured by Cipla in India. In addition, the consultants were informed that WHO

donated a small quantity ARVs to the NCASC in the past. GFATM procured a limited quantity of emergency ARVs through UNICEF to supplement the NCASC stock, which were delivered in September 2005, and plans to provide ARVs for some 750 patients for one year. Again, these drugs are procured through UNICEF. In addition, UNICEF and WHO have procured, through UNICEF, ARVs for the PMTCT program.

According to information received, most ARVs, whether used by the public sector or the private sector, come from India, and the company most cited was Cipla.

2.5 Drug Availability and Regimens

In September, 72 percent of the public sector patients were on an initial first line regimen (ZDV+3TC+NVP), 20 percent were on an alternative first line regimen (d4T(30)+3TC+NVP), 2 percent were on d4T(40)+3TC+NVP, 5 percent were on ZDV+3TC+EFV-600, and only 1 percent was on ZDV+3TC+EFV-800.

To date, there are no public sector patients on second line treatment as there are no second line drugs in the public sector system. Some private sector patients are receiving second line ARVs, but the quantity is unknown.

It is not possible to assess the actual number of patients receiving ARVs from the purely private sector, but from the limited information gathered by the consultants, it could be significant. Three private organizations visited reported a total of 85 patients on ARVs, and one private practitioner mentioned that he had an additional 40 patients on ARVs. Only one of these patients was on second line treatment. It is possible that when more patients can be absorbed by the public sector, some of these private sector patients will transfer to the public sector sites, but the regimens that they are following is unknown.

In September, ARVs were stored in the following sites: NCASC (small room); MASS, a privately-owned company contracted by FHI, at the Teku Hospital; and the Nepalgunj Hospital. Although all sites kept records of stock on hand, there was no consolidated report with the quantity of each drug available. The consultants proceeded to carry out an inventory count of all ARVs in the public sector, and as table 2 shows, the following ARVs were in stock:

Table 2. Current Stock of ARVs Held by the Public Sector as of September 30, 2005

Drug formula	Brand Name	Number of Pills on Stock				Total stock
		NCASC	MASS	Nepalgunj	Teku Hospital	
d4T/3TC	LamivirS 30	5,400	720	180	4680	10,980
d4T/3TC	LamivirS 40	720	180	0	840	1,740
ZDV+3TC	Duovir	60	960	150	4920	6,090
ZDV+3TC+NVP	Duovir-N	7,950	0	10,900	2190	21,040
d4T+3TC+NVP	Triomune 40	90	840	0	480	1,410
d4T+3TC+NVP	Triomune 30	240	4,320	0	1650	6,210

EFV	Efavir 600	2,220	0	0	1680	3,900
EFV	Efavir 200	690	0	0	1500	2,190
NVP	Nevimune	6,430	1,740	180	960	9,310
NFV	Nelfinavir				600	600
PEP						
NFV	Nelfinavir	0	9,180	0	0	9,180
ZDV/3TC	Duovir	0	1,800	0	0	1,800

In addition, there was no sharing of information; therefore, no one knew exactly the quantity of each ARV in stock or the months of stock available for the patients that were on treatment. NCASC was under the impression that there were enough ARVs in the public sector to cover the existing 104 patients for five months and to add an additional 100 patients for five months. When the consultants counted all public sector ARVs in the four locations where they are stored, they found that the actual amount of drugs was sufficient to cover the current patients for six months. An additional 15 patients could be added for six months, but not on the first line regimen of ZDV+3TC+NVP, which was sufficient for the current patients only. During the November 2005 visit, the consultants learned that an additional 59 patients were on treatment for a total of 163.

With the first shipment of GFATM-procured ARVs arriving in country in December, there are now sufficient ARVs to cover the needs of all patients for some time.

2.6 Forecast

The *National HIV/AIDS Action Plan and Budget 2005–2006* has targeted 3,000 patients to be on ARVs. To achieve this goal by the end of 2006, a rapid scale-up of VCT services would be needed. Based on the following assumptions that were discussed and agreed upon by the Director of the NCASC, the number of people that would need to be tested in order to reach the targeted 3,000 patients on ART can be estimated:

- More at-risk populations will be targeted for testing (intravenous drug users, commercial sex workers, and migrant workers).
- The targeted population has a 15 percent HIV prevalence rate.
- Fifteen percent of the HIV-positive patients identified will be clinically eligible for ART.
- One hundred percent of the clinically eligible HIV-positive patients will agree to go on treatment.

Based on these assumptions, it is clear from the following list that 120,000 people would need to be tested to put an additional 2,700 patients on ARVs to reach the 3,000 target:

- Existing patients on ART = 300 (163 current and 137 potential on waiting list)
- Target by end 2006 = 3,000 patients on ART
- New patients needed to reach target = 2,700
- People that need to be tested for HIV to reach 2,700 new ART patients = 120,000*

*Calculation:

2,700 new patients on ART = 2,700 clinically eligible patients;
 2,700 = 15 percent of 18,000 HIV-positive patients;
 18,000 = 15 percent of 120,000 people tested

Currently, the most successful VCT centers conduct on average of 700 HIV tests per year. At this rate, a total of 171 VCT centers would need to be operational and focus on the high risk populations, if the public sector is to reach its goal of 3,000 patients on ARVs. Alternatively, the existing sites would need to significantly increase the number of clients tested in a year.

It is highly improbable that an additional 2,700 AIDS patients will be identified for ART by the end of 2006. Therefore, forecasting for ARV drugs will be based on the actual capacity of the health care system for recruitment of new HIV patients over the next three years.

2.6.1 Methodology

Based on historical information on HIV detection in Nepal, the progression of HIV to AIDS, and the capacity of the health sector to scale up HIV testing, it is possible that the following number of patients requiring ART in the next three years can be identified:

2006	876 patients
2007	1,510 patients
2008	2,207 patients

It is important to note that these figures are cumulative. NCASC and GFATM have agreed to enroll a total of 750 patients on ARVs by September 2006. It is possible to surpass this number if testing services continue to expand and the ART sites are able to support the uptake in patient numbers.

Taking into account these numbers and the regimens that the current patients are actually following, a three-year forecast was calculated based on the following assumptions (see table 3):

- In 2006, 98 percent of patients will be on first line, while 2 percent will be on second line
- In 2007 and 2008, 95 percent of patients will be on first line, while 5 percent will be on second line
- Ninety five percent of the patients will be adults and 5 percent will be children

Table 3. Assumptions for Quantifying Antiretroviral Drugs

Total Population	100%	27,800,000	28,356,000	28,923,120
Population in reproductive age group (15-60 yrs)	54%	15,012,000	15,312,240	15,618,484.80
Paediatric population (0-14 yrs)	41%	11,398,000	11,625,960	11,858,479.20
National HIV prevalence	0.50%			
Total PLWHA		62,000	62,000	62,000
Patients on Treatment Sept 05		104		

TOTAL TARGETS FOR TREATMENT		876	1,510	2,207
TOTAL PATIENTS				
Total No. Patients		876	1,510	2,207
Percent on 1st Line Regimens	98%	98%	95%	95%
Percent on 2nd Line Regimens	2%	2%	5%	5%
Percent Adults	95%	95%	95%	95%
Percent Children	5%	5%	5%	5%
# Adults on 1st Line Regimens		816	1,363	1,992
# Adults on 2nd Line Regimens		17	72	105
# Children on 1st Line Regimens		43	72	105
# Children on 2nd Line Regimens		1	4	6
PMTCT		2006	2007	2008
New ANC attendees		74,307	74,307	74,307
% Pregnant women tested	100%	74,307	74,307	74,307
#Pregnant women tested positive	1%	743	743	743
# PMTCT mothers on NVP/labor	50%	372	372	372
# PMTCT mothers on AZT	50%	372	372	372
# PMTCT infants	100%	743	743	743
PEP				
Total No of Patients	100			
AZT /3TC	50%	50	50	50
AZT /3TC + IDV 400	25%	25	25	25
AZT/ 3TC + NFV 250	25%	25	25	25

As shown in table 4:

- Eighteen percent of patients will require Efavirenz[®] because of TB co-infection or because of toxic reaction to nevirapine
- Sixty six percent of patients on first line will be on Zidovudine[®]
- Thirty four percent of patients on first line will be on Stavudine[®]
- Of those on Stavudine, 80 percent will weigh less than 60 kg and 20 percent will weigh more than 60 kg
- Not every patient will begin treatment on the same day, therefore patients are phased in on a quarterly basis
- Provide for a 6 month buffer stock in case of delays in supply and/or an increase in patient intake
- Forecast is carried out by the following categories: first line, second line, PMTCT and PEP

Table 4. Additional Assumptions for Quantifying ARVs

		2006	2007	2008		% phasing in	2006	2007	2008
Options	1st Line Regimens (Adults)								
	Total No. Patients	816	1,363	1,992		Quarter 1	40%	25%	25%
A1	d4T (30mg)/3TC/NVP <60kg	19%	19%	19%		Quarter 2	20%	25%	25%
A2	d4T (40mg)/3TC/NVP >60kg	3%	3%	3%		Quarter 3	20%	25%	25%
B	AZT/3TC/NVP	60%	60%	60%		Quarter 4	20%	25%	25%
C1	d4T(30)/3TC+EFV	9%	9%	9%		Total	100%	100%	100%
C2	d4T (40)/3TC+EFV	3%	3%	3%					
D	AZT/3TC+EFV800	6%	6%	6%					
	2nd LINE REGIMENS (Adults)	2006	2007	2008					
	Total No. Patients	17	72	105		Phasing-In by %	2006	2007	2008
						Quarter 1	3%	15%	15%
E1	ABC + ddl + NFV < 60kg	77%	75%	75%		Quarter 2	12%	20%	25%
E2	ABC + ddl + NFV>60kg	23%	25%	25%		Quarter 3	25%	30%	25%
						Quarter 4	60%	35%	35%
						Total	100%	100%	100%

Based on the assumptions highlighted in table 3 and 4, table 5 presents the quantity of ARVs that will be required over the next three years.

Table 5. Forecast of ARVs Required by Year

		2006		2007		2008	
	Unit cost	Final Qty	Total Cost	Final Qty	Total Cost	Final Qty	Total Cost
	USD	Required	USD	Required	USD	Required	USD
Drug Product							
TRIUMUNE 30 (d4T(30)/3TC/NVP)	0.217	125,054	27,136.69	253,160	54,936	383,916	83,309.77
LAMIVIR S 30 (d4T(30)/3TC)	0.135	62,361	8,418.79	124,831	16,852	187,502	25,312.79
NEVIMUNE (NVP)	0.108	388,025	41,906.67	803,347	86,761	1,188,936	128,405.13
TRIUMUNE 40 (d4T(40)/3TC/NVP)	0.208	19,745	4,107.03	39,973	8,314	60,618	12,608.61
LAMIVIR S 40 (d4T(40)/3TC)	0.160	20,901	3,344.22	40,748	6,520	61,510	9,841.60
DUOVIR (AZT/3TC)	0.217	403,727	87,608.74	887,380	192,561	1,315,376	285,436.50
EFAVIRENZ (EFV 200mg)	0.50	17,594	8,797.08	39,553	19,777	60,618	30,309.16
EFAVIRENZ (EFV 600mg)	0.95	54,987	52,237.37	119,499	113,524	181,855	172,762.19
ZIDOVUDINE (AZT 300mg)	0.25	19,660	4,915.00	49,154	12,289	49,154	12,288.52
DIDANOSINE 250mg	0.425	2,930	1,245.19	20,092	8,539	38,813	16,495.45
DIDANOSINE 400mg	0.425	875	371.94	6,580	2,796	12,938	5,498.48
NELFINAVIR (NFV 250mg)	0.260	49,075	12,759.51	277,740	72,212	528,529	137,417.58
ABACAVIR (ABC 300mg)	1.215	3,805	4,623.08	26,671	32,406	51,750	62,876.76
INDINAVIR (IDV 400mg)	0.252	6,615	1,666.98	6,615	1,667	6,615	1,666.98
NEVIMUNE (NVP) 10mg/ml	17.520	20	350.40	39	690	39	689.85
Total Cost			259,488.68		629,844.3		984,919.35

3. Testing

Testing for HIV is taking place in a variety of programs throughout the country, the main ones being: PMTCT, VCT, clinical diagnosis, blood donor safety, and sentinel surveillance. The programs are funded by different donors, and operate independently. In all cases, only a licensed laboratory technologist is authorized to administer HIV tests, and the testing protocol is different for different organizations. While government and some NGOs use serial testing, other NGOs use parallel testing. Both protocols are in use depending on the specimen used. *National Guidelines for Voluntary HIV/AIDS Counseling and Testing* recommends serial testing for venous blood sample (serum or plasma) and parallel testing for whole blood samples. The *National Guidelines for Prevention of Mother-to-Child Transmission of HIV in Nepal* states that HIV testing will follow the *National Guidelines for VCT* and recommends the use of serial rapid tests. The consultants brought to the attention of the NCASC and other stakeholders, including the donor community and FHI that from a logistical point of view having different protocols further complicates forecasting and logistics management.

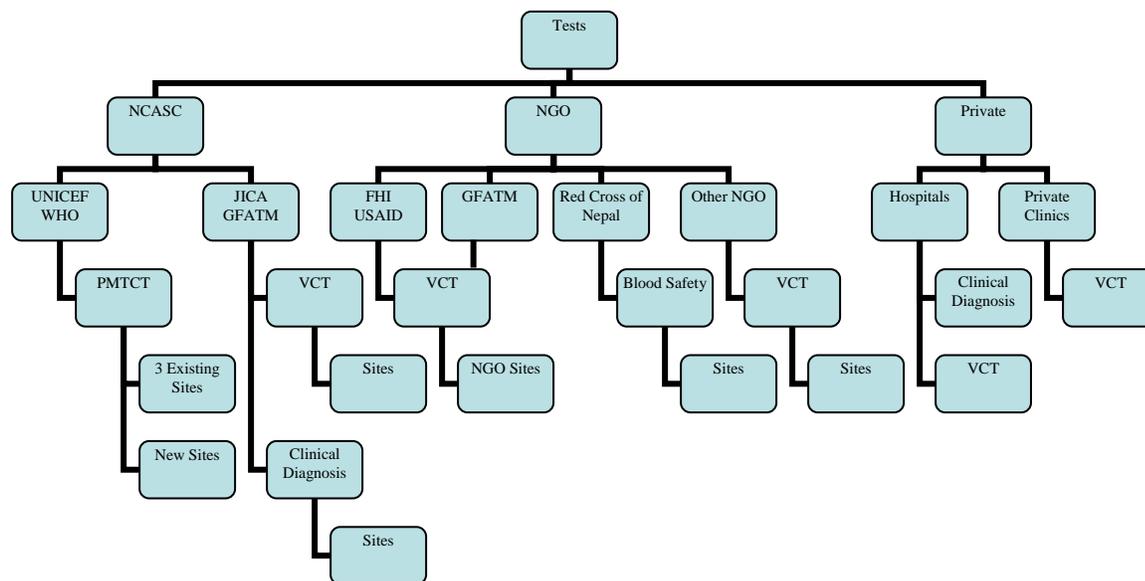
The NGO sites supported by FHI use the Dry Blood Spot methodology as a form of quality assurance (QA). All positive samples and 10 percent of negative samples are collected on special filter paper and sent to the National Public Health Lab in Kathmandu for retesting. This is new to Nepal, and as of November 2005, the NPHL had not completed the reconstitution and testing process, therefore, results were unknown. The *National Guidelines for Voluntary HIV/AIDS Counseling and Testing* contains specific procedures for QA for both public and private laboratories.

In many of the NGO sites and in one of the government sites visited, the laboratory technicians were not following the manufacturer's procedures for the administration of the Determine[®] test. In these cases, the staff tested whole blood following the procedures for serum, meaning that they did not add chase buffer to the sample. In addition, some did not use a pipette or capillary tube to measure the exact quantity of blood required to carry out the test. This was brought to the attention of both FHI (for the NGO sites) and UNICEF (for the government site). In both cases, measures were taken to ensure that the tests were administered following the manufacturer's procedures.

In all the sites visited, testing is carried out by certified laboratory technicians who normally do not carry out counseling activities. Staffing at the NGO sites appears to be adequate for the volume of tests carried out, and there is even room for expansion. At the Government facilities, however, HIV testing has been added on to the laboratory staff's regular duties, which has put a strain on laboratory personnel. The consultants learned that this has had an impact on staff morale and that in some cases laboratory personnel have refused to administer HIV tests unless they receive additional compensation. The staff at NCASC is aware of this and is attempting to bring a resolution to the situation.

Figure 2 displays how HIV testing is taking place in Nepal.

Figure 2. Map of HIV Testing in Nepal



3.1 Prevention of Mother-to-Child Transmission

UNICEF and WHO support the PMTCT program and supply the commodities, including the HIV tests, which are procured through UNICEF. PMTCT interventions are guided by the draft *National Guidelines for the Prevention of Mother-to-Child Transmission of HIV in Nepal*.

The PMTCT program was established in July 2005 at the Maternity Hospital in Kathmandu, the BZH in Nepalgunj, and in BPKIHS in Dharan. In addition to these three sites, UNICEF plans to on support three new sites in 2006 and three additional sites in 2007. Discussions are underway between UNICEF and NCASC on the location of the new sites.

Counseling and testing takes place during antenatal care clinics. Already, the program is quite successful despite its newness. Reports from BZH and BPKIHS show that approximately 60 percent of women agreed to be tested during the first months, and the numbers are increasing. The situation at the Maternity Hospital is different. Only 219 women out of 882 who participated in counseling sessions agreed to be tested in the month of August. The low number can be explained by the fact that women had to pay 300 rupees (approx. U.S.\$4.50) for the test. The consultants were advised that the board of directors of the Maternity Hospital agreed to reduce the cost to 100 rupees (approx. U.S.\$1.40). UNICEF staff member has reminded the director of the hospital that within this PMTCT program, the tests need to be free of charge. The director was to bring this up with her board at their next meeting.

Both Maternity Hospital and BZH reported that none of the women tested were positive, while BPKIHS hospital reported that out of 1027 tested, two women turned out to be positive. This is much less than the 1% assumed by UNICEF. This needs to be monitored regularly so that procurement plans can be adjusted if needed. To date, linkages with NGOs working with more at

risk populations are weak, but UNICEF is beginning to address this issue. Since only 30 percent of pregnant women attend ANC in Nepal, many women are still not screened.

In both the Maternity Hospital and BZH, women who came to deliver at the hospital, but were not part of the ANC program, were not tested. The consultants did not visit BPKIHS and therefore do not know whether this was also the practice. The director of the Maternity Hospital brought this up at a regular quarterly meeting of practitioners from different parts of the country, which was held on October 3; it was agreed that this would be corrected by providing additional training to the staff attending the labor and delivery ward. The consultants learned during the November visit that this had been addressed and women who did not attend an ANC clinic, but do go to the hospitals for labor and delivery, are offered HIV counseling and testing.

3.1.1 Testing Protocol

All three hospitals followed the same serial testing protocol utilizing Determine as the screening test. UNICEF and WHO had planned to use Serodia[®] as the confirmatory test and Uni-Gold[®] as the tie-breaker; they procured the quantities accordingly. However, after discussing each of these tests with the laboratory personnel at various sites, including some of the hospitals supported by UNICEF, the consultants learned that most laboratory technicians find Serodia cumbersome and time-consuming and, in some cases, have substituted the confirmatory test with Uni-Gold[®]. This information was shared with UNICEF and the Japan International Cooperation Agency (JICA) for VCT and sentinel surveillance. UNICEF has decided to replace Serodia with the more user-friendly and accepted Tridot[®] in its future shipments.

3.1.2 Forecast

A three-year forecast of HIV tests for PMTCT purposes was prepared. The forecast is based on the following assumptions that were agreed upon by UNICEF:

- One hundred percent of new ANC clients will agree to get tested
- One percent of clients tested will be positive
- Five percent of positive clients with discordant results will require tie-breaker
- The partners of these positive women will agree to be tested
- Thirty percent of women who do not attend ANC clinic but go to the hospital for labor and delivery will agree to get tested
- Three new sites will be added in 2006 testing 46,000 clients in that year
- Three new sites will be added in 2007 testing 50,000 clients that year
- Assume a 2 percent increase in the number of women attending the three original sites in 2006 who agree to get tested
- Assume a 5 percent increase in the number of women attending the existing six sites in 2007 who agree to get tested
- Includes 5 percent wastage rate and three month buffer stock

Based on the prior assumptions, table 6 shows the tests required for PMTCT programs.

Table 6. Tests Required for PMTCT

Test	2006		2007		2008	
	Tests	Kits	Tests	Kits	Tests	Kits
Screening (Determine)	107,107	1,080	176,421	1,770	184,361	1,850
Confirmatory (Tridot)	1,178	118	1,941	195	2,028	203
Tie-breaker (Uni-Gold)	59	6 ¹	97	9	101	9

In addition, the forecast includes the replacement of those tests that will expire in May/June 2006. This often happens in the case of a new program as it is impossible to predict the uptake, and it sometimes takes a while for clients to feel comfortable enough to agree to the new service. PMTCT is no different.

3.2 Voluntary Counseling and Testing

Nepal adopted the *National Guidelines for Voluntary HIV/AIDS Counseling and Testing* in July 2003. VCT is carried out by the public sector, NGOs, and purely private sector.

3.2.1 Government Voluntary Counseling and Testing

Documentation from the NCASC shows that there are nine government VCT centers in the following Districts: Accham, DHO Baitadi, DHO Bardia, Dadeldhura, Dailekh, Dhading, DHO Doti, Jumla, and Surkhet. In discussions with NCASC personnel, it appears that government-supported VCT is not functional. As stated above, some of the sites have not been conducting HIV tests because laboratory staff is demanding additional compensation for what they consider additional work. Some or all of these sites could have received tests procured by JICA and UNICEF in 2004, but no regular supply has taken place since that time. It was impossible for the consultants to assess the number of tests sent to these sites, the number of tests conducted, the number of positives, and the capacity for expansion. Until the labor issue is resolved, it will be impossible to forecast the requirements for these sites. It is assumed that these sites follow government testing protocols. In addition, the consultants did not see any public sector tests at NCASC or MASS.

According to the national strategy, VCT centers will be phased in at all 75 districts of Nepal. Details of this plan had not been made available to the consultants at the time of writing the report. This is another area where information is crucial for forecasting purposes.

JICA is the main supplier of public sector HIV tests and intends to procure through UNICEF.

¹ Although the number of Uni-Gold tests is not great, they come in kits of 20. Each site will require one kit, therefore the number to order is greater than the number required.

3.2.2 FHI-supported Sites

With USAID support, FHI is providing assistance to six NGOs providing VCT services in 21 sites throughout Nepal. FHI plans to increase the VCT sites to 25 by 2006. The program began in August 2003, but service start date varies by organization/site.

The consultants visited some of the FHI-supported sites in Kathmandu, Nepalgunj, and Pokhara, and in all cases, the organizations stated that they obtain a fixed sum of money from FHI to procure the required diagnostic and confirmatory tests. They added that the tie-breaker tests are provided by FHI. The protocol utilized by all FHI-supported organizations is parallel testing, meaning that on the first occasion, both Determine and Capillus[®] tests are administered. Only on the rare occasion when there is discordance, Uni-Gold will be administered, which is provided directly by FHI and procured by FHI Headquarters from the US. Since there is little discordance, FHI had a surplus of Uni-Gold tests, some of which had a December 2005 expiry date. The NGOs were advised to utilize Uni-Gold along with either Determine or Capillus for the near future as screening tests. This is a good recommendation and will help use up the soon-to-expire Uni-Gold.

As stated earlier, the consultants noted that many of the NGOs visited did not administer the Determine test according to the manufacturer's procedures. FHI addressed the situation immediately, and as a result, has decided to procure Determine tests and distribute them to the NGO sites.

Health workers at all of the sites visited stated that although they are surpassing the targets set with FHI, they had not reached their counseling and testing capacity threshold. These NGO sites use peer-educators to reach the most-at-risk populations and are seeing very good results. In fact, from the beginning of the program in August 2003 to September 2005, they have counseled a total of 5,334 clients and tested 5,007 of which 682 were found to be positive, representing 13.6 percent of clients tested. Not only are they meeting their targets, but in some cases they are surpassing them. From September 2004 to September 2005, FHI-supported facilities tested 4,064 persons and anticipate testing approximately 7,000 clients in 2006.

3.2.3 Other Nongovernmental Organizations

GFATM's procurement plan for 2006 includes HIV tests for NGOs based in the following six districts: Doti, Achham, Banke, Nawal Parasi, Chitwan, and Jhapa. Detailed information was not made available to the consultants at the time of the visits.

The Family Planning Association of Nepal (FPAN) has established eight VCT centers in the following areas: Kaski, Dang, Makwanpur, Chitwan, Morang, Rupandehi, Lalitpur (central clinic), and Sunsari. FPAN works in 32 Districts and could easily expand its VCT services to all 32 service delivery sites.

Over a six month period, 303 tests were conducted and 92 turned out to be positive, representing 30% of the population tested. JICA had provided a small grant for the establishment of these centers, but funding ended in January 2005. FPAN procured a small amount of tests with its own funds to continue the provision of services and submitted a request to be included in the fifth round of Global Fund funding. Unfortunately, Nepal was not considered for the fifth round, and it is not known how FPAN will continue its work.

FPAN currently procures two types of tests and conducts parallel testing. Information on the types of tests was not available. The consultants were told that there has been no need for a tie-breaker to date, and no provisions have been made to procure these tests.

Other NGOs, such as Seawind, provide VCT services, but no information was obtained.

3.3 Clinical Diagnosis

3.3.1 Government

It is difficult to determine where VCT services begin or end and where clinical services begin or end. For the purpose of this mapping and forecasting exercise, only the National Public Health Laboratory was considered a government-run clinical diagnostic center. Obviously, much more information is needed to accurately map this area.

According to NPHL records, it conducted the following HIV tests:

Year	Quantity
2000	1,080
2001	3,133
2002	1,215
2003	1,756
2004	1,619

Because the NPHL is within the MOH compound including Teku Hospital, most of the HIV diagnostic testing requested by the hospital is carried out at the NPHL. Determine, Serodia, and ELISA[®] tests are used for diagnostic testing. If there are enough samples, ELISA testing will be conducted, otherwise rapid tests will be used, and the protocol is serial testing. Because of the manner in which the records were held, it was impossible to determine the number of each test utilized in a one-year period. NPHL usually obtains its tests from NCASC, but because of a shortage, procured some HIV tests with its own budget in the past year.

Diagnostic testing is carried out in the majority of hospitals in Nepal. These hospitals procure HIV tests from their own budgets and patients pay to get tested.

In addition, the NPHL is the referral laboratory for the nation and as such is expected to provide QA, as described in the *National Guidelines for Voluntary HIV/AIDS Counseling and Testing*.

In addition to rapid tests and the ELISA machine, the NPHL carries out Western blot[®] tests and is the only laboratory with a CD4 counter.

3.4 Forecast for Voluntary Counseling and Testing and Clinical Diagnosis

Following is a forecast of the total quantity of HIV tests needed to get the following number of patients on ARVs over the next three years:

2006	876 patients
2007	1,510 patients
2008	2,207 patients

The number of patients to be tested was calculated based on the following assumptions, which were discussed and approved by the Director of the NCASC:

- Target number of 876 patients on ARVs by the end of 2006.
- Subtract existing patients (163 on actual treatment and potential 137 on waiting list), therefore 576 new patients will need to be identified and initiate ART in 2006 to meet the target.
- One hundred percent of the clinically eligible people will initiate ART.
- Of the HIV positive people identified, 15 percent will be clinically eligible for ART.
- Of the total number of people tested, 15 percent will be HIV positive.

Based on these assumptions, table 7 presents the total number of people that need to be tested to reach the target number of patients on ART by the end of each year.

Table 7. Number of People to be Tested to Reach ART Targets

		2006	2007	2008
Total No. Patients on ART by end of Year		876	1,510	2,207
Existing ART Patients (includes patients on wait list 2006)		- 300	- 876	- 1,510
No. New Patients on ART (100% clinically eligible initiate ART)	100%	576	634	697
Clinically Eligible	15%	576	634	697
HIV Prevalence	15%	3,840	4,227	4,647
No. People Tested		25,600	28,178	30,978

With the targets identified, the total number of tests required was calculated based on the following assumptions:

- serial testing
- fifteen percent prevalence rate
- two percent discordance rate
- includes 5 percent wastage rate
- includes three months buffer stock.

Based on these assumptions, table 8 presents the total quantity of HIV tests required for VCT and clinical diagnosis.

Table 8. Total Quantity of HIV Tests Required for VCT and Clinical Diagnosis

	Target on ARVs	Screening tests	Confirmatory tests	Tie-breaker tests
2006	876	33,960	5,040	672
2007	1,510	36,960	5,544	740
2008	2,207	40,656	6,100	813

Since the FHI-supported NGOs have set a target of 7,000 clients tested in 2006, the forecast for these sites will be subtracted from the total. The remaining tests will be conducted by the public sector sites supported by JICA and the NGOs supported by GFATM.

The forecast for the FHI-supported sites was based on the following assumptions:

- 7,000 clients will be tested in 2006
- twenty percent increase in 2007
- twenty percent increase in 2008
- parallel testing
- two percent for tie-breaker
- five percent wastage rate
- three months buffer stock.

Based on these assumptions, table 9 presents the number of tests required by the FHI-supported NGOs.

Table 9. Tests Required by the FHI-supported NGOs

	First Screening Test (Determine)		Second Screening Test (Capillus)		Tie-breaker Test (Uni-Gold)	
	No of tests	No of kits	No of tests	No of kits	No of tests	No of kits
2006	9,189	92	9,180	922	184	10
2007	11,025	120	11,025	120	221	15
2008	13,230	133	13,230	133	265	24

Subtracting the tests used by the FHI-supported NGOs, table 10 shows the remaining tests that will be required.

Table 10. Tests Required for VCT and Clinical Diagnosis Minus FHI-supported NGO Requirements

	Screening Test	Confirmatory Test	Tie-breaker Test
2006	24,771	3,716	488
2007	25,935	3,891	519
2008	27,426	4,114	548

3.4.1 In the Pipeline

JICA plans to procure tests for the government VCT program, and GFATM will procure tests for six NGOs. Table 11 specifies which tests will be procured for which period.

Table 11. HIV Tests in the Pipeline

	Determine			Serodia ²			Capillus			Uni-Gold		
	JICA	GFATM	Total	JICA	GFATM	Total	JICA	GFATM	Total	JICA	GFATM	Total
2006	6,000	15,000	21,000	2,000	750	2,750	1,000	7,500	8,500	1,000	n/a	1,000
2007	10,440			3,480			1,730			1,730		
2008	16,380			5,460			2,730			2,730		

Table 12 shows that there could be a very small shortage of screening tests in 2006. There is a significant overstock of confirmatory and tie-breaker tests. If there is a dramatic scale up in VCT, the figures will change accordingly. Maybe some of the Capillus could be used as screening tests to meet the shortfall. In any event, this is an area that needs constant monitoring, preferably on a monthly basis.

Table 12. Subtraction of the HIV Test Requirements (Excluding FHI-supported NGOs) and Quantities in Pipeline

	Screening Test	Confirmatory Test	Tie-breaker Test
Required	24,711	3,716	488
In pipeline	21,000	11,250	1,000
Balance	(3,711)	7,534	512

3.5 Private Voluntary Counseling and Testing and Clinical Diagnosis Testing

HIV tests are also available from the private and semi-private sectors. Large hospitals, such as Teaching Hospital and Maternity Hospital in Kathmandu, Western Regional Hospital in Pokhara,

² With the discovery that many laboratory staff members prefer other tests to Serodia, JICA may reconsider their orders for 2007 and 2008.

and others, provide HIV testing for a fee. It was not possible to determine the quantities during the visits.

3.6 Blood Safety

The Red Cross Society of Nepal is mandated to ensure blood safety. The 56 blood bank centers in Nepal administer HIV tests for all blood donations. To weed out potential risks, donors are required to fill out a questionnaire with medical but not lifestyle questions. The donation is then tested. If the sample comes out positive, the blood is re-tested with two other types of tests. If it is still positive, the blood is discarded. If the two confirmatory tests are negative, the blood bank keeps the donation. There are no provisions for the window period. To date, prevalence varies between 0.4 percent to 0.6 percent.

Each center procures its own tests with the income received for the blood transfused. Each person requiring a blood transfusion pays 600 rupees to cover the tests required to ensure blood safety. In addition, the Red Cross Society of Nepal receives support from the International Federation of Red Cross and Red Crescent Societies, as well as from other national Red Cross/Red Crescent Societies around the world.

A total of 72,000 blood donations were made in Nepal last year; 32,000 were in Kathmandu.

According to one Red Cross staff member, NCASC has reported that a total of seven people were infected by either blood or organ transplants.

3.7 Sentinel Surveillance

The *JICA Project Proposal for AIDS Control & Blood Test Equipment Supply (2005–2008)* states that there are nine governmental HIV sentinel surveillance (HSS) sites. These sites were established over all the geographic regions of the country as part of the national strategy for collection of information and evidence planning and for the monitoring and evaluation of the national response. As stated earlier, there is a question whether these sites are performing HIV testing or not because of the labor issue. Nevertheless, JICA is planning to provide HIV tests for both STI clients and ANC clients. The forecast of HIV tests required for HSS was carried out by a JICA consultant following discussions with the NCASC. It was not possible to learn the methodology despite attempts to do so.

3.7.1 HIV Sentinel Surveillance of STI Clients

Table 13 shows the quantities and types of tests that JICA plans to procure for HSS of STI clients at the nine government sites.

Table 13. Tests Procured by JICA

Test	2006	2007	2008	2009	2010
Determine	3,000	3,000	3,000	3,000	3,000
Serodia	1,000	1,000	1,000	1,000	1,000
ELISA	2,000	2,000	2,000	2,000	2,000
Capillus	300	300	300	300	300
Uni-Gold	300	300	300	300	300

3.7.2 HIV Sentinel Surveillance of ANC Clients

According to the JICA proposal, the following products will be procured in 2006 for HSS of ANC clients:

Determine	5,000
Serodia	1,000
ELISA	2,000
Capillus	500
Uni-Gold	500

Although the JICA plan is for five years, JICA does not foresee the procurement of additional tests for HSS of ANC clients beyond 2006.

4. Sexually Transmitted Infections

The global fight against the HIV/AIDS epidemic has focused much of its attention on the prevention, detection, and cure of sexually transmitted infections (STIs) due to evidence of a relationship between the spread of STIs and the transmission of the HIV virus. STI is closely linked to the HIV/AIDS epidemic.

Predictably, the detection and treatment of STIs has been adopted as one of HMGN's strategy in the fight against HIV/AIDS. As with HIV/AIDS, efforts to prevent and treat STIs require a global approach, working with all partners within and outside government, including NGOs and external development partners.

Many factors contribute to the spread of STIs, including unsafe sexual practices and the erratic use of condoms. A major problem in the prevention and treatment of STIs is the lack of information on the incidence and prevalence; when some information is available, it is usually nonspecific in terms of the various conditions. Despite the relative lack of information, there is a general consensus that the prevalence of STIs is increasing and is concentrated among female sex workers (FSW) and their clients, migrant workers, and truckers.

4.1 Service Delivery

Currently the government is the major provider of STI services through public sector health facilities, followed by NGOs, private for profit organizations, medical schools, teaching hospitals, and nursing homes. At government sites, treatment is provided free of charge.

In addition to governmental financial contributions, external development partners contribute significantly in the provision of services. JICA and GFATM are currently the major suppliers of STI drugs, both procuring through UNICEF.

According to the MOH, there are 60 recognized STI clinics in Nepal. Information was not readily available on where these sites obtain their drug supply.

Nepal has adopted the management of STIs through a syndromic approach. According to AIDS Control and Prevention Project (AIDSCAP)/FHI, syndromic approach is based on identifying a syndrome, a group of symptoms (what the patient feels or has noticed) and easily recognized signs (what the clinician finds on examination) associated with a number of well defined etiologies (the specific organisms causing the disease). Once a syndrome has been identified, treatment is provided for the majority of the organisms responsible for that syndrome. The *National STI Case Management Guidelines* provides the details on the management of STIs and was developed as a standardized protocol to be used at all levels of health care based on WHO recommended syndromic approach with adaptations to the local realities. As stated by the NCASC, the STI guidelines is an overall and comprehensive package for health care providers and includes all essential processes for the management of STIs. It also includes a flow chart for

diagnosis, proposed treatment, patient education, follow up, and referral, and highlights the importance of recording, reporting, and surveillance.

4.2 Forecasting Sexually Transmitted Infection Drug Requirements

The forecast period is intended to cover a three-year period spanning from 2006–2008.

4.2.1 Methodology

The forecasting of needs is usually based on data availability and from discussions with key informants. Specifically, the general methodology for the forecasting and quantification of drug needs entails the estimation of quantity and costs of drugs needed to support the implementation of services under a defined set of environmental factors including data availability, program goals, and cost information. In carrying out the forecast, a consideration on the methodology to use was based on the data set available on the ground. The methodology usually used for forecasting is either logistics-based or morbidity-based. In a logistics-based forecast, the consumption of the commodities in the past is used as the basis for projecting future needs, while the morbidity-based forecast uses the occurrence of a disease or condition as basis for projecting future needs. It usually takes into account the number of patients to be treated and the number of visits or treatment episodes encountered during the period of the forecast. For the morbidity method to be reliable there should be a standard treatment protocol or guideline that is adhered to by all service providers. In the absence of reliable logistics data on STI drugs used in the past, the morbidity-based method was used in forecasting the STI drug requirements.

4.2.2 Case Estimation and Data Collection

Although the morbidity-based method was adopted, obtaining the required data was problematic. As stated above, data on STI prevalence was scarce, and, where available, it was usually nonspecific. The inconsistent, or lack of, reporting by the STI clinics made the collection of reliable data an uphill task. Despite these difficulties, some reliable data was provided by the Tribhuvan University Teaching Hospital (TUTH), Nepal Fertility Care Center (NFCC), and other NGOs supported by USAID, FHI, and JICA. The case estimate was carried out by reviewing various documents and in discussions with clinicians and other service providers to come up with informed assumptions.

According to the *Nepal's National HIV/AIDS Strategy* an estimated 200,000 episodes of STIs occur annually; and while the prevalence in women is estimated at about 5 percent, the prevalence for men is not documented.

From a review of the 2004 health management information system report, about 2.3 percent of total outpatient attendance in government health facilities is due to STIs/reproductive tract infections (RTIs). Also according to the Annual HMIS report, there was a total of 18,123 cases of STIs, 34,228 cases of RTIs, and 125,058 cases of urinary tract infections (UTIs) seen in the

public sector in 2003; and 18,454 cases of STIs, 37,878 cases of RTIs, and 132,677 cases of UTIs seen in the public sector in 2004. From FHI estimates, about 12,000 episodes are treated annually in the sites they support.

For this forecast, the case estimate was made taking into consideration that although RTIs (bacteria vaginitis and fungal and yeast infections) may not be sexually transmitted, they are mostly treated as such and also some of the conditions considered under urinary tract infections (5 percent of total cases) are usually sexually transmitted or result from untreated sexually transmitted infections and are treated as such. Taking these assumptions into consideration and also in addition to the anticipated increase in case detection and treatment due to the current plans for service expansion, it is safe to assume that the number of cases will increase from the previous year for the next two years and level off or start decreasing as the strategy becomes much more effective. Thus, the number of STI episodes was estimated at 75,000 with an annual increase of 10 percent for the next two years.

Other major assumptions informing the forecast for STI drugs include—

- All patients diagnosed with STIs will be treated following the standard treatment guidelines.
- The drugs forecasted and procured will be used for the treatment of STI cases only.
- When diagnosed, treatment will be provided for the patients and their partner where available.
- After discussion with providers and information was gathered from STI sites visited, it was assumed that the breakdown of STI cases diagnosed and treated was as follows:
 - Vaginal Discharge Syndrome—21 percent
 - Urethral Discharge Syndrome—30 percent
 - Lower Abdominal Pain Syndrome—17 percent
 - Genital Ulcer Syndrome—21 percent
 - Other conditions including (Inguinal swelling (Bulbo) syndrome, Scrotal Swelling Syndrome, and Neonatal Conjunctivitis)—1 percent
- See table 14 for those cases that will be treated in the public sector facilities and other government-recognized STI treatment centers.

4.2.3 Results

Table 14. Quantities Required

S/N	Drug Products	Quantity To	Quantity To	Quantity To
		Order (2006)	Order (2007)	Order (2008)
1	Acyclovir 200 tabs	12,671	89,535	94,012
2	Acyclovir ointment	3,411	3,581	3,760
3	Azithromycin 500 mg tabs	107,338	146,599	153,929
4	Benzathine Pen. 2.4 MU	9,831	19,101	20,056
5	Cefixime 200 mg tabs	92,414	110,853	116,396

6	Ceftriaxone 250 mg vial	6,726	9,835	10,326
7	Clotrimazole 100 mg pessary	(2,056)	34,381	36,101
8	Doxycycline 100 mg tabs	64,532	97,096	101,951
9	Erythromycin 500 mg tabs	356,299	643,061	675,214
10	Erythromycin 125 mg/5 ml sp	26,681	28,015	29,415
11	Fluconazole 150 mg tabs	9,020	21,966	23,064
12	Metronidazole 400 mg tabs	518,380	851,896	894,491
13	Podophyllin paint 10–25%	1,047	1,194	1,253
14	Spectinomycin 2 g vial	1,324	1,705	1,791
15	Tetracycline eye ointment	2,144	2,251	2,364
16	Tinidazole 500 mg tabs	38,227	72,583	76,212
17	Trichloroacetic acid	397	597	627

4.3 Procurement, Storage, and Distribution

Procurement of STI drugs as well as other essential drugs using government funds is done through the NCASC following the national procurement guidelines. In addition, JICA is funding the procurement of STI drugs, procuring through UNICEF. The drugs procured are usually destined for different areas of the country that are being supported by the various donor agencies. JICA is currently procuring STI drugs for 6,000 episodes each year for the next two years and this will be supplied to STI centers including some NGOs that are being supported by FHI while the GFATM is procuring STI drugs for six selected districts including Doti, Achham, Nawal Parasi, Banke, Chitwan, and Jhapa.

STI drugs are stored in the NCASC storeroom and at MASS, which also distributes the drugs to various health institutions. As stated earlier, the STI drugs will be distributed to all government, and government-approved NGO and International NGO STI treatment sites free of charge.

Similar to ARVs and HIV tests, STI drugs are not managed by a logistics management system but are managed based on NCASC and other organizations' best estimates. STI drugs will be discussed at the proposed design workshop.

5. Opportunistic Infections

The U.S. Centers for Disease Control and Prevention (CDC) defines opportunistic infections (OIs) as infections caused by bacteria, fungi, protozoa, and other infectious agents that an intact immune system can usually manage but which take advantage of the *opportunity* provided by weakened immunity—as in HIV/AIDS—to proliferate in the body.

One of the key strategies in the *Nepal's National HIV/AIDS Strategy* is to guarantee treatment, care, and support for people infected and affected by HIV. One of the priorities under this strategy is to ensure the availability of medical services for all people living with HIV/AIDS, including the treatment of opportunistic infections. To be able to achieve this objective, the following strategies were outlined:

- develop a standard treatment protocol that ensures that treatment is initiated based on the recommendation of trained health personnel following the standard treatment guidelines
- include drugs to treat opportunistic infections in the essential drugs list
- ensure drug availability

At the time of this forecast, the standard treatment guidelines for the management of OIs were still to be developed.

Another strategy to achieve the above objective is to establish centers at locations that provide equitable access for all and provide diagnosis, treatment, and care for HIV/AIDS-related illnesses including OIs. Currently treatment for OIs is provided through general health services. At these levels of treatment, there is usually the absence of appropriate means for diagnosis, and treatment is thus based on symptoms. In addition, all health personnel have not received training to properly recognize the signs and symptoms of OIs and treat accordingly.

5.1 Some Clinical Signs of Opportunistic Infections

In addition to the clinical signs of OIs presented in table 15, patients could experience fever, weight loss, and other systemic symptoms. Weakness may accompany all infections.

Table 15. Clinical Signs of Opportunistic Infections

Organisms	Clinical Features
	Lungs
Pneumocystis carinii, mycobacterium tuberculosis	Cough, shortness of breath, chest pain
	Gastrointestinal tract

Candida, salmonella species (non-typhi), cryptosporidium, isospora, mycobacterium tuberculosis, atypical mycobacteria, cytomegalovirus, strongyloides	Difficulty swallowing, nausea, vomiting, abdominal pain, severe weight loss (malabsorption), chronic severe diarrhea
	Brain
Toxoplasma gondii, cryptococcus, HIV (causing encephalopathy)	Headache, impaired mental function, coma, fits, peripheral and central paralysis, inco-ordination
Cytomegalovirus	Visual defects
	Skin/Mucocutaneous
Herpes simplex	Perioral and oral ulceration, genital and perianal ulceration

Courtesy: AIDS action: April 1990, Issue 10.

5.2 Forecast

5.2.1 Forecast Methodology

In the absence of reliable logistic data on past consumption of drugs for treating opportunistic infections, the forecast was based mainly on informed assumptions provided by a number of service providers involved in OI management. The morbidity-based method of forecasting was thus adopted. As previously discussed, the morbidity-based method considers the number of patients to be treated, and the number of expected treatment episodes during the forecast period.

Also equally important is the availability of standard treatment guidelines. As earlier mentioned, at the time of this forecast exercise, the standard treatment guidelines for the management of OIs were in development. Following discussions with clinicians who have treated patients with OIs, it was agreed that the forecast should be based on other international guidelines including WHO guidelines for OI management. According to WHO, a syndromic approach to diagnosis and treatment of OIs, as elaborated in the WHO acute care module of Integrated Management of Adolescent and Adult Illness, is critical in assessing HIV-infected patients in peripheral health centers with limited or no laboratory diagnostics.

5.2.2 Case Estimation and Data Collection

By UNAIDS estimates, approximately 62,000 people are living with HIV/AIDS in Nepal, while the NCASC reports that on October 31, 2005, there were 5,564 officially diagnosed HIV positive cases, with 929 full blown AIDS cases. The number of cases to be forecasted for was based on the number of HIV positive cases reported by the NCASC, because most cases that are detected come to the hospital already in an advanced stage of the disease. These conclusions and

assumptions used in the forecast were arrived at after discussions with service providers. There was very limited data on prevalence, proportions, or patterns of opportunistic infections among the HIV-positive patients.

After discussions with service providers, the following assumptions were used for the forecast:

- Most patients will manifest more than one condition at a time.
- The number of people on ART is limited.
- With increased availability and accessibility to ART, the number of OI cases will eventually come down, because antiretroviral therapy is believed to be the most potent preventive regimen available against opportunistic infections.
- Service providers will adhere to WHO guidelines for the management of OIs.
- Fifty percent of all OIs will be treated by public sector providers.

Table 16 shows disease prevalence as specified by service providers.

Table 16. Prevalence of Different Opportunistic Infections

Opportunistic Infections and Symptoms	Prevalence
Cryptococcal meningitis	0.5%
Pneumocystis <i>jiroveci</i> pneumonia (PCP)	20%
Toxoplasmosis	0.5%
Oral candidiasis	50%
Herpes simplex	15%
Herpes zoster	30%
Weight loss	100%
Skin rash	60%
Fever of unknown origin	50%
Recurrent diarrhea	50%
Cytomegalovirus (CMV)	1%
Bacterial pneumonia	20%
Scabies	5%
Psoriasis	3%
Worm infestations	10%
Mycobacterium Avium Complex (MAC)	5%
Salmonellosis	5%
Other AIDS related diarrhea	20%

5.2.3 Forecast Results

Table 17. Drugs Required to Treat Opportunistic Infections

S/N	Drug Products	Quantity To	Quantity To	Quantity To
		Order (2006)	Order (2007)	Order (2008)
1	Acetyl salicylic acid 300 mg tablet	240,991	253,040	265,692
2	Acyclovir 200 mg tablet	536,239	571,871	600,465
3	Acyclovir 500 mg vial	25,304	26,569	27,898
4	Albendazole 400 mg tablet	8,890	10,122	10,628
5	Amoxicillin-clavulanic acid 625 mg tablets	67,477	70,851	74,394
6	Amphotericin B 50 mg vial	422	590	620
7	Benzyl benzoate lotion 25%	201	211	221
8	Calamine lotion	1,928	2,024	2,126
9	Ceftriaxone injectable 1 g vial	22,492	23,617	24,798
10	Chlorpheniramine 4 mg tablet	57,838	60,730	63,766
11	Ciprofloxacin 500 mg tablet	30,239	35,426	37,197
12	Clarithromycin 500 mg tablet	5,783	8,435	8,856
13	Clotrimazole troches 10 mg	562,312	590,427	619,949
14	Cotrimoxazole DS 960 mg tablet	(173,627)	281,718	295,804
15	Ethambutol 400 mg tablet	7,633	8,435	8,856
16	Famciclovir 500 mg tablet	36,149	37,956	39,854
17	Fluconazole 100 mg tablet	142,632	152,415	160,035
18	Ganciclovir inj 500 mg vial	705	1,181	1,240
19	Leucovorin 10 mg tablet	8,194	8,603	9,034
20	Lindane cream 1% tube	201	211	221
21	Loperamide 2 mg capsule	88,363	92,781	97,421
22	Metronidazole 400 mg tablet	19,867	23,617	24,798
23	Multivitamin tablet	1,445,945	1,518,242	1,594,154
24	Oral rehydration solution (ORS)	80,330	84,347	88,564
25	Paracetamol 500 mg tablet	240,991	253,040	265,692
26	Pyrimethamine 25 mg tablet	8,676	9,109	9,565
27	Sulfadiazine 500 mg tablet	32,775	34,413	36,134
28	Valganciclovir 450 mg tablet	1,125	1,181	1,240
29	Vitamin B complex tablet	722,972	759,121	797,077

It should be noted that in the absence of standard treatment guidelines for the management of OIs in Nepal, the estimated drug requirement is based on the WHO- and CDC-recommended treatment guidelines for opportunistic infections. This estimate should be used for strategic planning only. After Nepal's standard treatment guidelines are approved, the forecast should be reviewed to ensure that it follows the standard treatment guidelines and, thus, provides for the drugs that will be used to manage OIs.

6. Regulatory Process and Quality Assurance

The Department of Drug Administration (DDA) is the government body that controls the entry of pharmaceuticals into Nepal. The DDA has a set of requirements that companies must follow in order to register their drugs, but because of lack of personnel, companies that export to Canada, the United States of America (U.S.), the European Union (EU), New Zealand, etc., do not go through the same rigorous examination as those companies that do not export to these countries. This is due to the strict import regulations practiced by those countries. Also, when the DDA prepares a dossier for a specific company, it does not necessarily look at the company's manufacturing site, but only the name of the product. This does not ensure that the drug is the same quality as the drug imported by North American and EU countries.

The companies that want to export drugs to Nepal first have to register as a company, pay a fee, and go through a review. After they are registered, the companies register each drug individually, with an average fee of U.S.\$30 per registered product.

Because ARVs are not on the Essential Drugs List, and because of the frequent updates in care and treatment of HIV/AIDS patients, the DDA will, on an exceptional basis, approve the import of drugs that are part of the ART program if the National ARV protocol has been adjusted to include this new therapy and it is on the WHO list of accepted ARVs. None of the ARVs entering Nepal need to be on the WHO prequalified list.

In the area of Expanded Programme on Immunization (EPI), however, the donor community has worked with the government to ensure that all vaccines coming into Nepal are on the WHO prequalified list.

6.1 Quality Assurance

The consultants noticed that most of the people working in HIV/AIDS are working extremely hard and are very committed, but they are working in resource-poor environments that impact the quality of their work. This was noticed mainly in laboratories. Although the *National Guidelines for Voluntary HIV/AIDS Counseling and Testing* have procedures for QA, the consultants could not determine whether they were followed rigorously by all laboratories. In addition, the consultants were not aware of any formal strategy that deals with site performance and training.

The Quality Control Division of the DDA is currently understaffed, but with British Department for International Development (DFID) funding, an additional 12 pharmacists are being hired and additional equipment is being procured. The DDA expects to examine 1,200 drug samples and inspect 3,000 pharmacies with these additional resources in a one-year period.

The DDA has adopted the WHO adverse drug reaction regulations and has developed a reporting format. None of the prescribing physicians with whom the consultants met mentioned this report. The consultants do not know whether this form is utilized in Nepal or not.

HIV tests are not regulated by the DDA but the reagents are. Because of the limited staffing at the DDA, they have not been able to regulate reagents.

7. Supply Chain Analysis

To date, the HIV/AIDS program commodities have been managed without the benefit of a formal logistics system. Decisions on procurement and distribution are not made based on logistics data but on individuals' best estimates. All personnel should be congratulated for their dedication and hard work. As programs scale up, the need for a logistics system cannot be overstated. Since this system should cover various programs run by both government and NGOs, a design workshop, including all stakeholders in the program areas, needs to take place. The intent of this workshop is to get stakeholders to come to an agreement on logistics functions, and it will include LMIS, inventory control, and storage and distribution. The workshop will also address finance, procurement, and any other element that can impact the logistics system. Because most of the programs are new and the quantities limited, products in this program were successfully managed.

A positive development is that the NCASC has hired a logistician. This is a key position that will support the functioning of the national logistics system.

What follows is an analysis of the HIV/AIDS commodity supply chain, some elements of which may be useful during the design workshop.

7.1 Financing

7.1.1 Antiretroviral Drugs

To date, GFATM is the only donor funding the procurement of ARVs, with a DFID allocation to GFATM of U.S.\$750,000 for adult and pediatric care and support. Although the government procured ARVs in the past, it is not planning to procure ARVs in the near future. As stated earlier, GFATM committed to procure enough ARVs for 750 patients for a one-year period. Whether GFATM funding will extend for another three years is uncertain, and the final decision will be made in March or April 2006, when GFATM carries out a project implementation assessment. The criteria which will be used for the assessment is an 80% implementation rate by the end of March 2006. There are 163 patients currently on ARVs, but the lack of drugs has prevented at least an additional 64 patients, who have qualified for treatment, to access ARVs within the government program. Additional funding has not yet been identified for future years or for additional patients.

7.1.2 HIV Tests

JICA has committed to fund some HIV tests until 2010. GFATM will procure tests for the year 2006 and, as stated above, depending on the assessment results, could procure tests for an additional three years. UNICEF will continue to cover the test requirements for the PMTCT

program. Although FHI's current funding ends in June 2006, USAID will continue to fund either FHI or another organization in supporting some NGOs. In the case of other NGOs, such as FPAN, which has a tremendous potential for growth, no funding has been identified to date, and it is unknown whether their program can continue at the current rate, let alone expand, without outside funding.

7.2 Forecasting

7.2.1 Antiretroviral Drugs

When the ART program started in February 2004, NCASC did not have consumption data to inform the forecast. The methodology utilized by NCASC is not known, but the drugs procured have been sufficient to cover a specific number of patients for a specific period. Nevertheless, this seems like an area where NCASC could benefit from some capacity building. As stated previously, in September, the Director of the NCASC was under the impression that he had sufficient drugs for 250 patients for five months, while in reality, there were enough drugs for 119 patients for six months. The forecast prepared by GFATM, with the assistance of NCASC and practitioners, was overall well executed but did not take into account the phasing-in of patients and buffer stock. Well-trained NCASC staff members would be in a position to work with GFATM and other potential donors to provide a forecast rooted in good forecasting principles.

7.2.2 HIV Tests

One of the most challenging elements in forecasting for governmental sites is the lack of data, and another is the lack of an expansion plan with targets. As stated, it would be beneficial for NCASC staff to become familiar with forecasting methodology for HIV tests so they could work with JICA, GFATM, and UNICEF to determine each of the programs' needs. Data does exist for the FHI-supported VCT program, but FHI could also benefit from some assistance in forecasting methodology.

7.3 Procurement

7.3.1 Antiretroviral Drugs

The government has procured some ARVs with its own funds in the past. It is uncertain whether the WHO prequalification list of ARV drugs guided the process of tendering and procurement, or whether the selection criteria was based on price and availability of drugs only. Most of the drugs procured came from Cipla, in India. What is uncertain is whether they came from the WHO prequalified manufacturing sites or other sites. All procurement with GFATM or UNICEF for PMTCT drugs will utilize UNICEF as the procurement agent ensuring that the drugs will be

procured from WHO prequalified manufacturing sites. It is very important for the patients to have access to quality products for their own safety and to prevent treatment failure.

In the case of the GFATM procurement for 750 patients, it would be best if the procurements could be broken into three or four individual procurements to allow for adjustment in quantities if reality shows that the quantities forecasted for the various regimens do not correspond to the actual need.

7.3.2 HIV Tests

JICA, GFATM, and UNICEF will order their tests from UNICEF. FHI will procure their tests through their headquarters in the U.S. Since there is little data on the use of HIV tests in sites other than FHI-supported NGOs, this area needs to be closely monitored and procurement plans adjusted if needed.

7.4 Distribution

7.4.1 Logistics Management Information System

Although all programs visited had some form of recording mechanism, many were client-based and some facilities had ledgers capturing receipts and dispensed data. In short, there is no logistics management information system, where logistics data is collected, reported, and used for decision-making. In some instances, the consultants had great difficulty in obtaining information, and in some specific cases, getting the information would have been too onerous. For instance, in one site, records for ARVs are kept in two separate files. A one-line transaction appears in a ledger book with a reference to another document containing the details, which is kept in a file folder with hundreds of other pieces of paper not kept in any order. It would have taken hours, if not days to get the data. Some sites, for example those supported by FHI, report regularly, but for the most part, provide service data.

In addition to the disparate record keeping, none of the organizations utilized similar forms, making data gathering a real challenge.

The Ministry of Health uses an LMIS for what they call *program products* (i.e., full-supply products including contraceptives) and essential drugs. The development of the LMIS has been supported by DELIVER and is a genuine success in Nepal. The forms are common for all 4,000 service delivery points, and reporting is over 80 percent. Some of the elements of this LMIS could prove useful for the management of ARVs, HIV tests, and drugs intended for OI and STI programs, but will require extensive modification to capture the complexities of these products.

7.4.2 Inventory Control

Everyone involved in the management of HIV/AIDS program commodities is doing their best to avoid stock outs and expiries, but, as mentioned earlier, there is no logistics system, therefore no established inventory control system: many of the sites visited did not have an established max-min system, order interval, or emergency order point. Products are sent from NCASC to the service delivery sites on the recommendation of the NCASC director or other authorized NCASC personnel not based on past consumption, but based on best estimates.

Those FHI-supported NGOs visited had established their own max-min and order point. Most ordered a one month supply when they had two weeks stock on hand. Since they would get resupplied within a day or two, this system worked well. With FHI now providing all tests, a new max-min and order point will have to be established.

7.4.3 Warehouse and Storage

NCASC is the recipient of all HIV/AIDS program products, and as such, decides where products are stored. At times, NCASC will determine that some or all of the products (ARVs and STI and OI drugs) will be kept in their small room and, whenever they run out of space, some will be sent to MASS for storage. In other cases, such as PMTCT products, NCASC will ask MASS to store the total shipment. The NCASC room is very small and there is no order. Boxes are stacked one on top of the other in the middle of the room. Shelves are placed along the walls, and these are also stacked with product, without identification labels. At times, the same product is placed on different shelves, making it difficult to assess the quantities. The staff member responsible for the management of the products is very knowledgeable, but he is also responsible for following orders, receiving shipments, and tracking back orders, this in addition to other duties.

MASS, on the other hand, is doing a great job. Initially, MASS was contracted by FHI to store and distribute products for the FHI/USAID-supported VCT-STI program, including products donated by JICA. They have clean, orderly storerooms, and they keep computerized records of all transactions. Because of this success, UNICEF and GFATM have requested that their products be stored at MASS, but MASS's storage space is already utilized at maximum capacity.

Because stock is stored in two separate locations, and there is no common or shared record keeping, it becomes difficult to determine stock on hand. Also, the small room at NCASC is not equipped to play the role of central storage space. Finally, the transfer of product from NCASC to MASS is cumbersome and occupies NCASC staff time. The consultants made the recommendation that products should not be stored at NCASC at all. NCASC will remain the recipient of the products, and an authorized NCASC signature will be required for MASS to release products to program recipients, but all products should be stored at MASS immediately upon arrival in country (following customs clearance, etc.).

The donor community, along with FHI, agreed with the recommendation and will work with NCASC and MASS on the details.

The consultants had the opportunity to visit the Logistics Management Division of the Ministry of Health. Program products, including contraceptives, are stored at the LMD warehouses. Storage capacity and quality was impressive, including the fridges for the products requiring cold storage. A couple of generators were at the ready in case of power outage.

With programs expanding, thought has to be put on warehousing needs for the short, medium and long term.

One option is to expand MASS's capacity. The consultants were told that FHI has agreed to support additional storage space for MASS. The question of additional equipment such as fridges, with outside thermostats and generators needs to be addressed. Although the staff is doing a good job in managing the products and information, they should receive additional training on warehousing principles and their computerized system should to be part of the LMIS driving decision-making.

Another option would be to store the HIV/AIDS program products at the LMD. This would ensure sustainability as well as get the government of Nepal to commit to this program area. In discussions with the director general of the Department of Health Services, under which LMD sits, it was recommended that this be considered as an option for the medium to long term, with a transition plan.

Storage, particularly the need for cold storage, at other levels of the supply chain will have to be assessed. Storage facilities appeared to be adequate in the hospitals and clinics visited, and good storage practices were followed.

7.4.4 Transport

From information received from the various organizations, transport is not problematic for the current level of program implementation.

Teku Hospital is in Kathmandu and has no problems accessing ARVs. Because of the distance, shipping to Bheri Zonal Hospital is more problematic. The director of the NCASC brings ARVs to BZH when he travels in that area. The same situation exists for the PMTCT program: Maternity Hospital in Kathmandu and BPKIHS in Dharan pick up their supplies from MASS, but UNICEF covers the shipping to BZH. As programs expand and new sites provide services, transport will become a major consideration for reasons of topography and distances to cover. This needs to be discussed in detail during the design workshop.

7.5 Funding of Logistics Functions

A few of the people interviewed brought to the consultants' attention the fact that when donors procure program commodities, they do not always include funds for their management, such as LMIS, storage, transport, etc. Nepal's government does not seem to have the budget to cover these important functions. Donors need to be made aware that funding is needed for the good

functioning of a logistics system. It is not possible at the present time to assess the amount, but 10 percent of the cost of the goods seems to be a good rule of thumb. A costing exercise could take place, assessing the cost of transport and storage at all levels of the supply chain.

8. Conclusion and Recommendations

HIV/AIDS programming is relatively new in Nepal, with the provision of ARVs beginning in February 2004. Prior to this time, few services were available for HIV positive people. Stigma surrounding AIDS prevented, and continues to prevent, many people from being tested. Much effort has gone into the scaling up of not only ART but also testing for HIV, a prerequisite for running an ART program.

Although much has been accomplished in a short period of time, much more needs to be done to address the needs of the Nepalese people. With the tremendous scale up effort that is planned by His Majesty's Government of Nepal and the NGO community, with the support of the donor community, more attention needs to be given to the supply side of programming, otherwise, these programs will fail miserably. Forecasting the quantities of ARV, HIV tests, and STI and OI drugs required for scale-up is a crucial part of program expansion, but it is imperative that a continuous supply of ARVs be planned for, funded, procured, and made available to those patients who are currently on ART. A well-functioning logistics system will assist in ensuring that programs meet their goals.

Recommendations

1. In order to ensure a continuous supply of required products for the Nepal HIV/AIDS program, a design workshop should take place to determine the specifications of a logistics system for those products, including LMIS, inventory control, storage, and distribution, including decisions on finance, forecasting, and procurement.
2. Once the logistics system is designed, curriculum development and training should take place so that the appropriate staff can manage the logistics system to support the HIV/AIDS program.
3. Donors should include funds to support the logistics management of HIV/AIDS program commodities.
4. In the meantime, and depending on the individual's skill set and knowledge, the newly-hired NCASC logistician and the FHI logistics consultant should get some training either in logistics management and/or in HIV/AIDS programming.
5. NCASC should organize a quarterly forecasting forum, including donors, clinicians, and experienced logisticians, to review ARV, HIV tests, and STI and OI drugs forecast and come up with an adjusted forecast that is as accurate as possible and reflects the current reality.
6. A sub-committee of the Commodity Security Committee should be established to monitor and ensure product availability of all HIV/AIDS Program products.

7. A clearly defined national expansion strategy for VCT should be developed, which would include the number of sites planned and targets of clients to be tested on a yearly basis.
8. In the short term, and until a logistics system is in place, ART sites should collect consumption data on ARVs and OI drugs given to the patients.
9. In the short term, and until a logistics system is in place, all government and NGO testing laboratories should collect consumption or use data on the different tests used by category of test (screening, confirmatory, and tie-breaker) to facilitate forecasting.
10. In the short term, and until a logistics system is in place, all government-approved STI clinics should collect consumption data on STI drugs.
11. In the short term, and until a logistics system is in place, MASS staff should get some training in warehouse management and consider organizing their computer system to generate a variety of reports which will be required for decision-making.
12. Since program implementation depends on quality testing, attention should be paid to the laboratories throughout the country, ensuring that testing protocols are followed and establishing quality control mechanisms. Training or re-training of laboratory technicians should be considered.
13. ARV drug procurement should be compliant with the WHO list of prequalified drugs to ensure that patients obtain quality products and prevent treatment failure.
14. Standard treatment guidelines for the management of opportunistic infections should be completed as soon as possible so that quantification can be reviewed using these guidelines.
15. The HIV testing expansion plan should go hand in hand with the development of referral services that provide HIV care and support and include but are not limited to ART provision. Plans for development of these services should be as detailed as possible to assist in forecasting the required supplies over the years.
16. Standard treatment guidelines for pediatric ARV drugs should be completed as soon as possible, and pediatric ARV drugs and formulations should be made part of the procurement list.

Appendix—Organizations visited

Kathmandu

His Majesty's Government of Nepal

- Ministry of Health and Population
- National Center for AIDS and STD Control
- Department of Health Services
- Logistics Management Division
- Department of Drug Administration
- National Public Health Laboratory
- Primary Health Care Center, Lalitpur

Hospitals

- Sukraraj Tropical and Infectious Disease Hospital (Teku)
- Bir Hospital
- Maternity Hospital
- Tribhuvan University Teaching Hospital

NGOs

- Novo Kiran
- Maiti Nepal
- Family Planning Association of Nepal
- STD/AIDS Counselling & Training Services
- Red Cross Society of Nepal, Blood Bank
- Youth Vision
- Nepal Fertility Care Centre

International Organizations

- USAID
- DFID
- UNAIDS
- GFATM
- World Bank
- UNICEF
- JICA
- WHO
- UNFPA

Other

- Nepal Family Health Program
- Management Support Services (P) Ltd.

- FHI
- PSI
- Nepal CRS Company (P) Ltd.
- Consultants for Health and Development

Nepalgunj

Ministry of Health and Population

- Regional Medical Store
- District National Health Administration
- District Public Health Center
- Health Post
- Sub-Health Post

Hospitals

- Bheri Zonal Hospital

NGOs

- Nepal STD & AIDS Research Centre

Pokhara

Ministry of Health and Population

- Western Regional Hospital

NGOs

- International Nepal Fellowship/Paluwa
- Naulo Ghumti
- Friends of Hope
- Community Support Group
- Siddartha Club

Private Hospitals

- Fishtail Hospital and Research Centre (P.) Ltd

For more information, please visit <http://www.deliver.jsi.com>.

DELIVER

John Snow, Inc.

1616 North Ft. Myer Drive, 11th Floor

Arlington, VA 22209 USA

Tel: 703-528-7474

Fax: 703-528-7480

www.deliver.jsi.com