

Assessment of Antiretroviral Medicine Access and Use in Mombasa, Kenya  
and Pharmaceutical Management Capacity at Four Sites to Support the  
Introduction of Antiretroviral Therapy.  
September 2-29, 2002

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Strategic Objective 4





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## **About RPM Plus**

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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## ACRONYMS

ADR	adverse drug reaction
AFB	acid-fast bacilli
AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral [medicines]
CBC	complete blood count
CD	controlled drugs
CPGH	Coast Provincial General Hospital
CPK	creatine phosphokinase
DAART	directly administered antiretroviral therapy
DANIDA	Danish International Development Assistance
EDL	Essential Drugs List
FHI	Family Health International
GOK	Government of Kenya
HDL	high-density lipoproteins
HIV	human immunodeficiency virus
HMIS	health management information system
ICRH	International Centre for Reproductive Health
IMPACT	Implementing AIDS Prevention and Care Project [FHI]
IPT	isoniazid prevention therapy
LDL	low-density lipoproteins
LFT	liver function test
M&E	monitoring and evaluation
MEDS	Mission for Essential Drugs and Supplies
MOH	Ministry of Health [Kenya]
MSH	Management Sciences for Health
NASCOP	National AIDS and Sexually Transmitted Disease Control Program [Kenya]
NRTI	nucleoside reverse transcriptase inhibitor
NNRTI	non-nucleoside reverse transcriptase inhibitor
OI	opportunistic infection
PBMC	peripheral blood mononuclear cell
PEP	postexposure prophylaxis [for HIV]
PMIS	pharmaceutical management information system
PRDH	Port Reitz District Hospital
PSK	Pharmaceutical Society of Kenya
QA	quality assurance
QC	quality control
RDU	rational drug use
RFT	renal function test
RPM Plus	Rational Pharmaceutical Management Plus [Program]
RPR	rapid plasma reagin
RT-PCR	reverse transcriptase polymerase chain reaction

SOP	standard operating procedure
STG	standard treatment guidelines
STI	sexually transmitted infections
TAP	technical assistance partners [IMPACT/RPM Plus/Horizons]
TB	tuberculosis
TLC	total lymphocyte count
U&E	urea and electrolytes
USAID	United States Agency for International Development
VCT	voluntary counseling and testing [for HIV]
WBC	white blood count
WHO	World Health Organization

## INTRODUCTION

### Background

Management Sciences for Health's (MSH) Rational Pharmaceutical Management Plus Program (RPM Plus) is partnering with the Family Health International (FHI)/ Implementing AIDS Prevention and Care Project (IMPACT) and the Population Council/Horizons Program to implement an initiative funded by the United States Agency for International Development (USAID) for incorporating antiretroviral medicines (ARVs) into the health care system in Mombasa, Kenya as part of an existing package of care and treatment. The antiretroviral therapy (ART) program will provide valuable implementation and operations research on how to safely and effectively deliver ARVs and how to build capacity to expand access to treatment. This collaborative initiative proposes to support the Government of Kenya (GOK) to create a learning site for the safe introduction and effective use of ART in Mombasa district by strengthening the existing HIV clinic at Coast Provincial General Hospital (CPGH) and the voluntary counseling and testing (VCT) services at Port Reitz District Hospital (PRDH), Bomu (Mkomani) Clinic, a non-governmental primary health care clinic, and at Magongo Municipal Clinic, a government primary health care center. These facilities will be linked through explicit referral and follow-up systems with communities and community-based health and support organizations in Mombasa District. It is expected that this program will be part of the provincial and district health services under the guidance of the National AIDS and Sexually Transmitted Disease Control Program (NASCOP), the Ministry of Health (MOH), and the Kenya National Taskforce on ART so that the lessons learned will feed back immediately to national policymakers and stakeholders.

The specific objectives of the program are to—

- a) Improve the capacity of HIV/AIDS clinics, laboratory and pharmacy services in selected public health facilities in Mombasa to provide HIV/AIDS comprehensive care including ART.
  - i. Assess accessibility, capacity and quality of the four sites identified to provide ART and determine the needs for training, equipment and other support.
  - ii. Assess the capacity of the commodity management system at the four sites to support access to and rational use of ART and other HIV-related commodities.
  - iii. Assess the capacity of laboratory services at the four sites to support the safe and effective use of ART.
  - iv. Assess the current access to and use of ARV medicines in Mombasa
  - v. Strengthen the capacity of the four sites to provide quality ART services.
    - Train health care providers in the use of ART and clinical management of HIV.
    - Develop client referral systems.
  - vi. Strengthen the capacity of the commodity management system at the four sites to provide quality ART services.
    - Train pharmacists and pharmacy staff in the rational management and use of ARVs.
    - Develop the pharmaceutical procurement and management system.
    - Develop a secure commodity storage system.

- vii. Strengthen the capacity of the laboratory services at the four sites to provide quality ART services.
  - Train laboratory technicians in laboratory procedures for clinical management of HIV-infected patients, including monitoring of ARVs.
- viii. Strengthen data management system and analysis at the four sites.
  - Develop a monitoring and evaluation (M&E) work plan.
  - Train staff in data collection methods, analysis and reporting related to ARV management.
- b) Provide ART to 300 patients over a period of five years in accordance with eligibility criteria.
  - i. Develop a client monitoring system, including for medication adherence.
  - ii. Develop surveillance for drug resistance.
- c) Sensitize and strengthen communities and support groups in HIV/AIDS comprehensive care, including ART.
  - i. Sensitize and involve communities and support groups in comprehensive care, including ART.
  - ii. Strengthen the home-based care program.
- d) To explore selected operational research questions.
  - i. What is the effect of a modified directly observed therapy approach (DAART) on ARV adherence?
  - ii. What is the cost effectiveness of DAART upon improved ART adherence in comparison with standard adherence case management?
  - iii. What is the impact of ART upon the sexual risk behavior of HIV-infected persons taking ARVs?
  - iv. What are the changes in stigma and discrimination as perceived by HIV-infected persons taking ART?
  - v. What is the impact of ART on the household income and consumption of HIV-infected persons, including the allocation of resources within the client's household?
  - vi. What is the estimated incremental cost of adding ART to existing health services?

## **Purpose of Trip**

Ms. Helena Walkowiak, Senior Program Associate RPM Plus, Dr. Henrik Westh, Laboratory Specialist, RPM Plus consultant together with Dr. Michael Thuo, Regional Technical Advisor, RPM Plus Nairobi Office traveled to Mombasa, Kenya to join locally-hired RPM Plus consultant Dr. John Jao Majimbo, to conduct an pharmaceutical and laboratory assessment in preparation for the implementation of the ART program.

The RPM Plus team was in Mombasa for the following dates—

- Ms. Helena Walkowiak, Senior Program Associate, RPM Plus - September 5 to 29, 2002.

- Dr. Michael Thuo, Regional Technical Advisor, Nairobi Office, RPM Plus - September 2 to 26, 2002.
- Dr. Henrik Westh, Laboratory Specialist, RPM Plus Consultant - September 16 to 20, 2002.

## **Scope of Work**

Scope of work for Ms. Helena Walkowiak, Dr. Michael Thuo, and Dr. John Jao Majimbo—

- Participate in an arrival briefing and a departure debriefing for USAID/Kenya as requested.
- Conduct an assessment of the current access to and use of ARVs in Mombasa.
- Conduct formative research to inform the planning for and implementation of capacity building of the commodity management system to support introduction of ART in four learning sites in Mombasa. Collect information on the capacity of the commodity management system in Mombasa to inform planning for scaling up of the ART program.
- Meet with other key stakeholders, and local partners within the GOK, MOH, other cooperating agencies and partners to inform finalization and implementation of the ART program, as appropriate.

Scope of work for Dr. Henrik Westh—

- Participate in an arrival briefing and a departure debriefing for USAID/Kenya as requested.
- Conduct formative research to inform the planning for and implementation of capacity building of the laboratory services to support introduction of ART in four learning sites in Mombasa. Collect information on the capacity of the laboratory services in Mombasa to inform planning for scaling up of the ART program.
- Meet with other key stakeholders, and local partners within the GOK, MOH, other cooperating agencies and partners to inform finalization and implementation of the ART program, as appropriate.

## **Methodology**

The methodology for the assessment included—

1. Structured interviews with—
  - Physicians in the private sector.
  - Pharmacists at private hospitals.
  - Hospital administrators at private hospitals.
  - Private pharmacists or distributors.
  - Persons currently taking ARVs or who have taken these medicines in the past.
  - Key stakeholders.
  - Staff at the four proposed ART sites.
2. Data collection using structured data collection tools at—
  - Private pharmacies.
  - Private hospitals.

- The four proposed ART sites.
3. Simulated purchases at—
- Private pharmacies.
  - Unregistered pharmacies and drug sellers.

Activities performed by RPM Plus assessment team.

1. At the four proposed ART sites, CPGH, PRDH, Bomu (Mkomani) Clinic, and Magongo Municipal Clinic, the RPM Plus team—
  - Interviewed key administrative, clinical, and pharmacy staff.
  - Observed the systems in place to select, quantify, procure, store and dispense medicines and other commodities, including support systems of pharmaceutical management system (PMIS), financing, monitoring and evaluation.
  - Conducted 30 exit interviews and 30 pharmacy worker observations.
  - Collected information on prices paid and charges, information on stock outs and quality of inventory record keeping for a list of tracer medicines and conducted a review of prescribing.
  - Interviewed key laboratory staff and observed laboratory operations and the commodity management systems in place for reagents, kits, and supplies.
  
2. At three private hospitals current stocking and dispensing ARVs—Aga Khan Hospital, Mombasa Hospital, and Pandhya Hospital—the RPM Plus team—
  - Interviewed the hospital administrator, matron and pharmacist.
  - Observed the systems in place in the pharmacies to quantify, procure, store and dispense ARVs including record keeping and auditing systems.
  - Collected data on prices paid by patients and prices paid by the facility for ARVs and a list of tracer medicines.
  - Performed a dispensing record review of ARVs.
  - Interviewed key laboratory staff and observed the laboratory systems in place.
  
3. In the private sector, the RPM Plus team—
  - Interviewed the Chief Medical Officer and Pharmacist at Kenya Ports Authority which had previously been operating an ARV program to understand why the program had halted.
  - Interviewed eight ARV prescribers.
  - Interviewed 11 persons who are currently taking ARVs or who have taken these medicines in the past.
  - Interviewed six private pharmacies that dispense ARVs or agents/distributors of ARVs and collected information on prices paid and charged for ARVs.
  - Performed a dispensing record review of ARVs at three private pharmacies.
  - Performed an “attempted purchase” of ARVs at 23 registered and unregistered pharmacies (with International Centre of Reproductive Health – ICRH)

4. Other activities. The RPM Plus team—
- Interviewed five key informants from GOK, MOH, NASCOP, Pharmaceutical Society of Kenya (PSK), and the Kenya Medical Association.
  - Interviewed the Matron at Community Home-based Care Clinic at Bangladesh.

A list of the stakeholders interviewed and facilities visited is included as Annex 1.

This report is divided into three sections. In the first section the findings of the assessment of the current access to and use of ARVs in Mombasa and the implications for the ART program are presented. The second section reports on the initial findings of the assessment of the capacity of the pharmaceutical management systems at the four sites to support the introduction and scale up of ART together with options/recommendations for strengthening the systems. In the final section, the findings and recommendations of the assessment of laboratory capacity at the four sites to support the ART program are set out.



## ASSESSMENT OF THE CURRENT ACCESS TO AND USE OF ANTIRETROVIRAL MEDICINES IN MOMBASA

The objectives of the rapid assessment of current access to and use of ARVs in Mombasa, conducted from September 2 to 29, 2002, were to—

- Identify factors which could potentially impact the effectiveness of the GOK ART program.
- Collect information from existing and past ART programs in Mombasa on barriers encountered and successful strategies used.

The sample sizes used in this study are small, but represent the majority of the persons involved in the distribution and use of ARVs in Mombasa in September 2002. A convenient sample of physicians, pharmacists and hospital administrators from the three private hospitals that stock ARVs were interviewed and these sites were preliminarily estimated to account for approximately 90% of ART prescribing in Mombasa. A total of eight physicians known to prescribe ARVs were interviewed. In addition, a convenient sample of 11 persons living with HIV that were currently or had previously used ART was interviewed. Due to issues of confidentiality, patients were identified by their physicians and solicited to participate in this assessment. Informed consent was obtained from each person prior to the interview. The main private pharmacies and distributors that stock ARVs—six in all—were also sampled and data collected on prices paid and charged for ARVs. A dispensing record review of ARVs was performed at three private pharmacies. Finally, a simulated purchase of ARVs was performed at 23 registered and unregistered pharmacies.

### Key Considerations

The framework used to organize the data collection and report on findings of access to ARVs is presented in the following diagram.

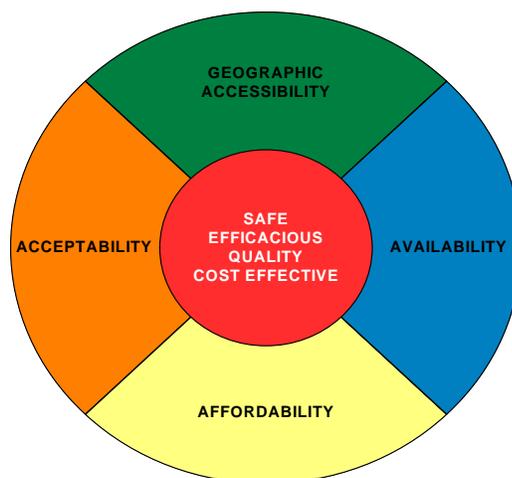


Figure 1. Dimensions of Access to Medicines

Source: Management Sciences for Health

Access, often viewed as “potential” use (freedom or ability to obtain a medicine), is a construct that encompasses various distinct dimensions—

- Availability – the relationship between demand and supply.
- Affordability – the relationship between price, cost, value and the user’s income or ability to pay for medicines or services.
- Geographical accessibility – the relationship between the location of the supply or services and the location of user.
- Cultural acceptability – the relationship between the characteristics of products and services and the user’s attitude toward, perception of, or expectations of products and services.

The variables studied in this evaluation are—

- Access to ARVs
  - Availability of ARVs
  - Affordability of ART and laboratory monitoring for ART
  - Geographical accessibility
  - Cultural acceptability
- Use of ARVs
  - Criteria for starting ART and selecting a regimen
  - Criteria for changing an ART regimen
  - Diagnostic and ongoing monitoring
  - Adherence to treatment

## **Access to ARVs in Mombasa: Key Findings**

### ***Availability of ARVs***

Since 2001, the distribution of certain ARVs under the United Nations Accelerating Access Initiative, namely products from GlaxoSmithKline, Merck Sharp and Dohme, and Bristol-Myers Squibb has been limited to the three major hospitals (Aga Khan, Mombasa and Pandya hospitals), and, for other products, to six distributors and a few private pharmacies in Mombasa. In addition, some firms, such as Phillips Pharmaceuticals, have a list of “approved” doctors and will not release ARVs, including Videx, Stocrin, Zerit and Crixivan to distributors without a prescription from one of the doctors on the list.

In September 2002, the availability of ARVs is controlled by limiting the number of pharmacies allowed to stock and dispense ARVs. Distributors and key informants identified a total of ten facilities—three private hospitals and seven private pharmacies—that supply ARVs to patients in Mombasa. “Attempted purchases” of ARVs at a sample of 23 registered and unregistered pharmacies, found that only one registered pharmacy had ARVs available for purchase. None of the unlicensed drug sellers reported that they had or were able to obtain ARVs for sale. In three cases, the vendor offered acyclovir as an alternative. Most private pharmacies (16/23) reported that they did not stock ARVs because they are too expensive and most customers cannot afford them.

An average of 11 ARV products were available at private hospitals (n=2) and seven ARVs products in private pharmacies (n=6) at the time of the visit. Three facilities sampled had only one ARV product available at the time of the visit. The pharmacists reported that ARV products are stocked according to prescription demand. Based on a review of the stocked items at these facilities, it is clear that current prescribing practices are not necessarily in line with GOK ART guidelines (February 2001). Very few of the facilities visited were able to fill a prescription for GOK-recommended ART regimens for adults, pregnant women and children (see Figure 2).

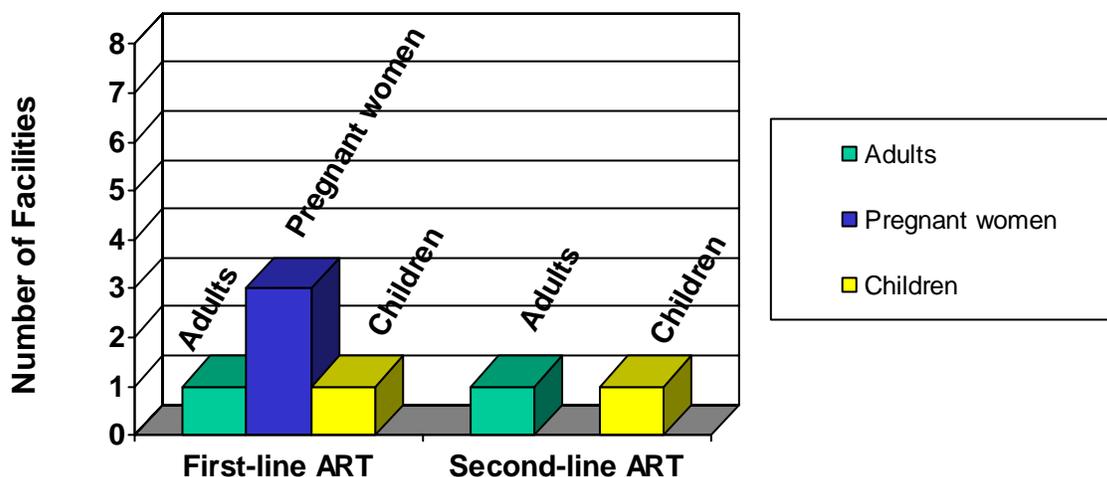


Figure 2. Number of facilities able to fill a prescription for a GOK recommended first- and second-line ART regimen

Both private pharmacies (n=6) and hospitals (n=2) that routinely keep ARVs reported that they had experienced stock outs of ARVs particularly during the start-up period when the level of demand was unknown. However, all were able to receive ARVs between 24 hours or 3 days after placing an order with distributors. Most patients interviewed who were currently taking ARVs reported that the pharmacy or clinic usually had sufficient stock to fill their prescriptions.

### **Affordability of ARVs**

Cost was mentioned by prescribers, dispensers, distributors, patients and key informants as the main barrier to providing ARV medicines to people living with HIV. None of the ARVs were available as a generic product in any facility at the time of the assessment. Interviews with physicians and key informants indicated that insurance does not cover ARV medicines or laboratory monitoring (CD4 count, viral load or ARV resistance testing) in most cases. Most patients interviewed reported that they pay for their ARV medicines, doctors' visits and laboratory monitoring out of pocket (8/11). A few patients had expenses covered through their employer (3/11). However, the sample size is small and findings cannot be generalized to the entire population of persons living with HIV in Mombasa who take ARVs. All pharmacists and physicians interviewed reported that prescriptions must currently be dispensed in full, usually a supply of 30 days, reportedly to facilitate monitoring and patient adherence. However, some pharmacists commented that purchasing a full 30 days supply can be a barrier, especially for

daily or weekly wage earners and suggested that they should be allowed to dispense 15 days supply.

The average cost of GOK-recommended first line ART regimen (February 2001) for adults and pregnant women as reported by the private pharmacies and private hospitals were compared to the salary of the lowest ranking Kenyan civil servant (Group A) per month (Ksh 3,310 which is about Ksh 2,880 net per month). As can be seen from Figure 3, a Group A Kenyan civil servant would need to work 6.8 months to purchase one month's supply of a first line GOK regimen for adults in a private pharmacy and three months to pay for one month's supply from a private hospital. To purchase one month's supply of the GOK-recommended regimen for pregnant women from a private pharmacy and private hospital, the Grade A civil servant would need to work 5.6 months and 3.4 months respectively.

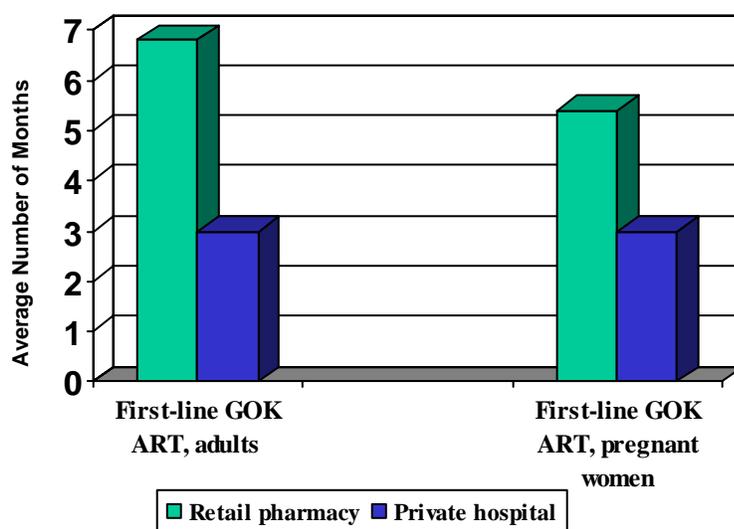


Figure 3: Average number of months a Group A GOK civil servant needs to work to pay for one month's supply of GOK-recommended ART regimen.

### ***Affordability of Laboratory Monitoring for ART***

The costs for laboratory monitoring for ART are compared to the lowest salary of a Kenyan civil servant (Group A) per week in Figure 4. Costs for CBC, U&E and LFT were obtained from three private hospitals surveyed and a private laboratory operating in Mombasa and averaged for comparison.

As can be seen from Figure 3, a Group A Kenyan civil servant would need to work 3.2 weeks to pay for a CD4 count, 11.2 weeks for a viral load assay, 1.2 weeks for CBC; 1.6 weeks for U&E, and 2 weeks for an LFT test.

So, not only the cost of the ARVs medicines, but also the costs of related laboratory monitoring tests presents a barrier to accessing GOK-recommended ART services for people living with HIV.

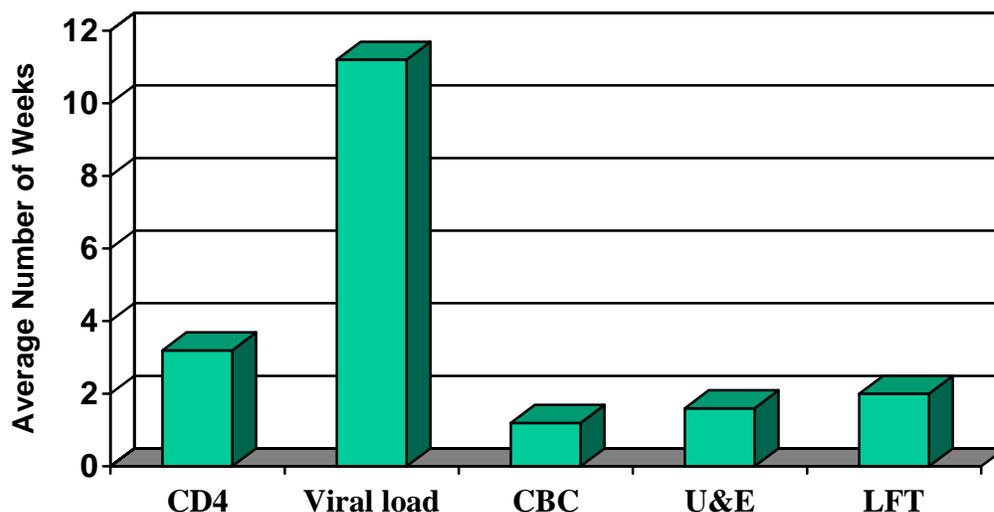


Figure 4: Average number of weeks a Group A GOK civil servant needs to work to pay for ART-related laboratory monitoring tests

### ***Geographical Accessibility***

Because the assessment was limited to Mombasa, typical indicator data for geographical accessibility, such as estimation of the population's proximity to an ARV dispensing site, were not collected.

### ***Cultural Acceptability***

From in-depth interviews with individuals who were currently taking or had taken ART in the past, confidentiality, stigma and lack of information and understanding were found to be potential constraints to participating in an ART program.

### ***Current Access to ARVs: Implications for the GOK ART Program***

- Affordability of ARV medicines and related laboratory monitoring is currently the major constraint to access to ART in Mombasa — but significant barriers also exist in availability of GOK-recommended regimens and cultural acceptability too.
- Persons who currently pay for ARVs out-of-pocket may seek to access the GOK ART Program and this can have implications for selection of regimen and entry criteria.
- With limited access to ARVs in Mombasa, the potential for leakage may be high.
- Fear of stigma and lack of confidentiality may prevent patients accessing ARVs at public facilities.

## **Use of ARVs in Mombasa: Key Findings**

Use can be viewed as “accomplished” access (“exercised” freedom or ability to utilize obtained medicine). ART-related products or services may be accessible (available, affordable, etc.) but not necessarily used rationally. The data collected on “use” was analyzed by comparing the GOK Guidelines (February 2001) with physician and patient reported practice.

Variables studied—

- Criteria for starting ART and selecting a regimen
- Criteria for changing an ART regimen
- Diagnostic and ongoing monitoring
- Adherence to treatment
- Determinants of use: key results

### ***Criteria for Starting ART and Selecting a Regimen***

#### ***GOK ART Guidelines***

##### **Criteria for Starting ART**

- Clinical state
  - Symptomatic—treat
  - Asymptomatic—CD4 and viral load
- Patient’s acceptance and readiness
- Probability of adherence

##### **Selecting a Regimen**

- Combination of three ARVs: Two nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitor (NNRTI)

#### ***Physicians’ Reported Practice***

##### **Criteria for Starting ART**

- Clinical status (4/8); CD4 count (6/8); viral load (2/8)
- Willingness or motivation of patient (3/8)
- Affordability of ART (4/8)
- Affordability of monitoring (2/8)

##### **Selecting a Regimen**

- Use (any) guidelines (7/8)
- Cost/affordability for patient (8/8)

Reported physician practice reflects adherence to the GOK clinical guidelines for starting ART. However, the affordability of the ART regimen was reported to be a critical factor for starting ART and selecting a regimen, particularly by patients.

## **Criteria for Changing an ART Regimen**

<b><i>GOK ART Guidelines</i></b>	<b><i>Physicians' Reported Practice</i></b>	<b><i>Patients' Reported Practice</i></b>
<ul style="list-style-type: none"> <li>▪ Drug toxicity or intolerance—change offending drug</li> <li>▪ Treatment failure—determine reason for failure                             <ul style="list-style-type: none"> <li>○ Clinical (patient selection)</li> <li>○ Viral (resistance)</li> <li>○ Patient (adherence)</li> </ul> </li> </ul>	<p><i>(6 physicians reported a total of 12 cases where ART regimen was changed)</i></p> <ul style="list-style-type: none"> <li>▪ Drug toxicity; intolerance; interactions; pregnancy (7/12)</li> <li>▪ Treatment failure (3/12)</li> <li>▪ Price/drug affordability (2/12)</li> </ul>	<p><i>(Patients who reported changing ART regimens sometime in their ART history)</i></p> <ul style="list-style-type: none"> <li>▪ Cost of ART (6/11)</li> <li>▪ Side effects (2/11)</li> </ul>

Again reported physician practice reflects adherence to the clinical guidelines for changing an ART regimen. The affordability of the ART regimen was reported to be a critical factor for changing an ART regimen and six of the eleven patients interviewed reported that that they had changed their ART regimen at least once to reduce costs.

## **Diagnostic and Ongoing Monitoring**

<b><i>GOK ART Guidelines</i></b>	<b><i>Physicians' Reported Practice</i></b>	<b><i>Patients' Reported Practice</i></b>
<ul style="list-style-type: none"> <li>▪ Laboratory tests for diagnostic workup—                             <ul style="list-style-type: none"> <li>○ CBC, U&amp;E, LFT, CD4, viral load</li> </ul> </li> <li>▪ CD4 count and viral load titre at—                             <ul style="list-style-type: none"> <li>○ Baseline</li> <li>○ 4 weeks after starting ART</li> <li>○ Every 3 months, thereafter + other laboratory tests (CBC, U&amp;E, LFT)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Use clinical monitoring (7/8)</li> <li>▪ Use laboratory tests to monitor (7/8)</li> <li>▪ Main challenge reported—cost of laboratory testing (6/7)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Ever had a CD4 count (10/10)                             <ul style="list-style-type: none"> <li>○ In last 6 months (5/7)</li> </ul> </li> <li>▪ Ever had viral load (5/10)                             <ul style="list-style-type: none"> <li>○ In last 6 months (2/8)</li> </ul> </li> <li>▪ Patients who pay for laboratory tests out-of-pocket (8/11)</li> </ul>

Although the physicians' reported practice on diagnostic and follow up laboratory monitoring follows GOK guidelines, the cost of the laboratory tests was reported to be a major barrier by both physicians and patients. It appears that in practice, the guidelines are not followed due to the cost of laboratory tests to patients.

## **Adherence to Treatment**

### ***GOK ART Guidelines***

- Before starting, consider factors that may affect patient's adherence.
  - Motivation of patient
  - Impact of ART on lifestyle
- Adherence failure can lead to ARV failure

### ***Physicians' Reported Practice***

- Physicians who estimate that the time of the interview, all of their patients were achieving greater than 95% adherence levels (6/8)
- Main barrier reported—cost (6/7)

### ***Patients' Reported Practice***

- Ever stopped ART for one week or more week (8/11)
  - Stopped ART for at least 1 week in the past 3 months (4/8)
- Ever stopped because unable to afford ARVs (5/8)
- Ever stopped because felt well and failed to understand the need to continue ART (2/8)
- Ever stopped due to side effects (1/8)

Although six out of eight physicians estimated that all of their patients were achieving adherence rates of greater than 95%, the patients' reported practice indicates that this may be an overestimate. Eight of the eleven patients interviewed reported ever stopping ART for one week or longer and four of the eleven patients had stopped ART for a week or longer in the last 3 months. Again, cost of ARV medicines is reported to be the main determinant of adherence.

### ***Determinants of Use: Key Results***

Educating and updating health care providers together with educating and providing access to information on ART to people living with HIV and the community is reported to be a key determinant of promoting the rational use of ART. However, both providers and patients need an enabling environment – patients need to be able to access ARV medicines and important laboratory monitoring in order to do “the right thing” not only when they start ART but also in the long term. ARVs and laboratory monitoring need to be available and affordable.

In addition, removing disincentives and providing incentives can encourage both providers and patients to use ART rationally. For example, having a financial package of care that includes both ARV medicines and laboratory monitoring can act as a disincentive for patients to choose to pay for only part of the total treatment package (medicines and not the laboratory tests).

## **ASSESSMENT OF THE CAPACITY OF THE PHARMACEUTICAL MANAGEMENT SYSTEMS TO SUPPORT ART INTRODUCTION AND SCALE UP AT FOUR SITES**

The objective of the assessment conducted from September 2 to 29, 2002 was to assess the capacity of the pharmaceutical management system at four sites—CPGH, PRDH, Magongo Municipal Clinic and Bomu (Mkomani) Clinic—to support access to and rational use of ART and other HIV-related commodities.

The initial findings and initial recommendations of the assessment are presented in three tables. The findings of the capacity of the pharmaceutical management system at four sites to support the introduction of ART are presented in Table 1. Table 2 outlines possible options and recommendations to strengthen the capacity of the four sites to support the introduction of the program. Finally, some initial observations on the capacity of the pharmaceutical management system to support the future scale up the ART program are presented in Table 3. The tables are organized as follows—

Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART

- Section A: Overarching issues for all four sites
- Section B: CPGH
- Section C: PRDH
- Section D: Magongo Municipal Clinic
- Section E: Bomu Clinic

Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up

- Section A: Overarching issues for all four sites
- Section B: Issues common to all four sites
- Section C: CPGH
- Section D: PRDH
- Section E: Magongo Municipal Clinic
- Section F: Bomu Clinic

Table 3: Capacity of the Pharmaceutical Management System to Support ART Program Scale Up

- Section A: Overarching issues for all four sites
- Section B: CPGH
- Section C: PRDH
- Section D: Magongo Municipal Clinic
- Section E: Bomu Clinic

These initial findings and options/recommendations are presented as *drafts for comment* and are to be reviewed at the Stakeholders Meeting for Dissemination of Assessment Results in November 2002.

## **Key Considerations**

The key considerations reported on in this evaluation are—

- Normative (standards) – policies, standard operating procedures (SOPs), and standard treatment guidelines (STGs)
- Capacity
  - Infrastructure – structural and equipment
  - Human resources – staffing levels and training
  - Systemic – how well the pharmaceutical management system is functioning and capacity to support ART program
- Variables reported on—
  - Availability of guidelines in pharmacy
  - Availability of a set of tracer medicines
  - Time out of stock for a set of tracer medicines
  - Existence of inventory records and quality of record keeping
  - Number of encounters where antibiotic medicines were prescribed
  - Quality of counseling by pharmacy staff
  - Patient retention of information given about their medicines

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART  
Section A: Overarching Issues for All Four Sites – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
<p><b>POLICIES, LEGISLATION, REGULATION</b></p> <ul style="list-style-type: none"> <li>• National STGs for ART and for monitoring of ARVs exist.</li> <li>• At least one brand of all ARV preparations on national ART guidelines is registered.</li> <li>• National VCT guidelines exist.</li> <li>• Directive from the Director of Medical Services to set up ART centers in each province issued September 2002.</li> <li>• Drug inspector based at PRDH could function as the external auditor for the program for 4 sites (responsibilities currently include auditing of controlled drugs (CDs).</li> </ul>	<p><b>POLICIES, LEGISLATION, REGULATION</b></p> <ul style="list-style-type: none"> <li>• National policies on dispensing/prescribing ARVs do not exist.</li> <li>• National/local STGs for opportunistic infections (OIs) and palliative care do not exist.</li> <li>• ARVs and many medicines for prophylaxis/treatment of OIs not on Essential Drug List (EDL).</li> </ul> <p><b>DRUG INFORMATION</b></p> <ul style="list-style-type: none"> <li>• National Drug Information Centre reported to exist but not yet functional.</li> <li>• No local network exists.</li> </ul> <p><b>ADR MONITORING</b></p> <ul style="list-style-type: none"> <li>• National system to monitor and report on adverse drug reactions (ADRs) reported to exist but not yet functional.</li> <li>• Regional/local system to monitor and report on ADRs not functional.</li> </ul> <p><b>HEALTH MANAGEMENT INFORMATION SYSTEM (HMIS)</b></p> <ul style="list-style-type: none"> <li>• National system to monitor resistance to ARVs does not exist.</li> </ul> <p><b>AVAILABILITY</b></p> <ul style="list-style-type: none"> <li>• Fluconazole not yet available through the Axios donation program.</li> </ul> <p><b>TRAINING OF PHARMACY STAFF</b></p> <ul style="list-style-type: none"> <li>• Staff have received limited pre-service training of pharmacy staff in relevant clinical management of HIV/AIDS.</li> <li>• Staff have received limited pre-service training of pharmacy staff in pharmaceutical management.</li> <li>• Pharmaceutical technologists and pharmacists belong to different professional organizations – pharmaceutical technologists do not have access to PSK training.</li> <li>• Lack of agreement over roles and responsibilities of pharmacy staff and prescribers constrain collaboration on training/keeping updated.</li> </ul> <p><b>COST RECOVERY</b></p> <ul style="list-style-type: none"> <li>• Fees, exemptions, systems, retention of cost sharing fees vary across 4 facilities.</li> <li>• Proposed bill to abolish cost-sharing is pending approval.</li> </ul>	

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART**  
**Section B: Coast Provincial General Hospital (CPGH) – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
<p><b>POLICIES and STANDARDS</b></p> <ul style="list-style-type: none"> <li>National ART guidelines available in pharmacy office (not pharmacy). Also copies of Kenya HIV/AIDS strategic plan and key World Health Organization (WHO) documents. Guidelines need to be made available in pharmacy. <i>Indicator:</i> <i>National ART guidelines reported to be available and seen in pharmacy at site= YES</i></li> </ul> <p><b>INFRASTRUCTURE/ EQUIPMENT</b></p> <ul style="list-style-type: none"> <li>Overall adequate to support introduction of ART – improvements needed are feasible and low cost and probably can be funded by site. Requirements: <ul style="list-style-type: none"> <li>➢ Indented counseling window for privacy.</li> <li>➢ Secured cupboard next to CD cupboard in secured area to stock bulk stock.</li> <li>➢ Lockable, small refrigerator in secured area.</li> <li>➢ Secured cupboard in dispensary for working stock.</li> <li>➢ Bars on window to pharmacy office and strengthening of doors. Lock on back door which can allow access to dispensary staff needed.</li> <li>➢ Poor ventilation – needs to be improved.</li> <li>➢ General maintenance needed – e.g. replace non-functioning fluorescent lights.</li> <li>➢ Procedure to monitor refrigerators needed.</li> <li>➢ Stand alone computers available but need to be upgraded, linked to a network and software.</li> </ul> </li> </ul>	<p><b>POLICIES AND STANDARDS</b></p> <ul style="list-style-type: none"> <li>Limited availability of SOPs - SOPs for ART program will need to be prepared.</li> </ul> <p><b>HUMAN RESOURCES - TRAINING</b></p> <ul style="list-style-type: none"> <li>One pharmacist needs HIV/AIDS training to be key resource for program.</li> <li>Also two pharmacists and six pharmaceutical technologists need HIV/AIDS training.</li> <li>Three pharmacists and six pharmaceutical technologists and three pharmacy assistants need pharmaceutical management training.</li> <li>Three pharmacists and undetermined number of doctors need rational drug use (RDU) training.</li> <li>System is needed to provide ongoing updates/training of existing/new staff in HIV/AIDS.</li> <li>Can be difficult to release staff from site for training.</li> </ul> <p><b>PHARMACEUTICAL MANAGEMENT - AVAILABILITY</b></p> <ul style="list-style-type: none"> <li>Some problems with availability of HIV-related essential medicines seen. <i>Indicator:</i> <i>Average percent of time out of stock for a set of tracer medicines in storage and health facilities = 9.21% (n=16)</i></li> </ul> <p><b>QUANTIFICATION</b></p> <ul style="list-style-type: none"> <li>Lack of experience/training for complex quantification.</li> <li>Lack of computerized HMIS for quantification and monitoring scale up of ART program.</li> </ul>	

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART  
Section B: Coast Provincial General Hospital (CPGH) – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
<p><b>HUMAN RESOURCES – STAFFING LEVELS</b></p> <ul style="list-style-type: none"> <li>• Highly motivated, recently qualified pharmacist who could act as a technical resource for the project available.</li> <li>• Facility still needs three more pharmaceutical technologists (posts are reported to be vacant due to hiring freeze).</li> <li>• Anecdotal reports of high pharmacist turnover due to low salaries relative to private sector.</li> <li>• However, staffing levels are adequate to support start up of ART project if ARVs are provided from main pharmacy.</li> </ul> <p><b>M&amp;E</b></p> <ul style="list-style-type: none"> <li>• A quality committee/group exists and is interested in incorporating pharmaceutical management indicators as part of monitoring.</li> <li>• Lack of availability of data for monitoring is a limitation.</li> </ul> <p><b>OTHER</b></p> <ul style="list-style-type: none"> <li>• CPGH ready to start amenity pharmacy to provide ARVs to company employees to complement GOK ART program. Will use same pharmaceutical management system as for GOK ART program.</li> <li>• ARVs may soon be available through GOK/MOH.</li> </ul>	<p><b>DISTRIBUTION – INVENTORY MANAGEMENT</b></p> <ul style="list-style-type: none"> <li>• Some problems with inventory management seen. <i>Indicators:</i> <ul style="list-style-type: none"> <li>➢ <i>Inventory stock records exist and available = Yes</i></li> <li>➢ <i>Average percent of stock records that correspond with physical counts for a set of tracer medicines in storage and health facilities = 47.1% (n=17)</i></li> </ul> </li> <li>• Internal auditing system in place for CDs could be used as model for ARVs.</li> <li>• External audit would need to be set up – Chief Pharmacist agreeable.</li> </ul> <p><b>DISTRIBUTION – TRANSPORTATION</b></p> <ul style="list-style-type: none"> <li>• Pharmacy does not have own vehicle for pick up.</li> </ul> <p><b>USE - PRESCRIBING</b></p> <ul style="list-style-type: none"> <li>• No RDU monitoring.</li> <li>• Lack of medical records makes it difficult to monitor RDU.</li> <li>• Some evidence of irrational prescribing seen. <i>Indicator</i> <ul style="list-style-type: none"> <li>➢ <i>Percentage of encounters with antibiotics dispensed at home-based care clinic =72% (n=32)</i></li> </ul> </li> <li>• Availability of STGs for prescribers in clinics variable. <i>Indicators</i> <ul style="list-style-type: none"> <li>➢ <i>National ART guidelines reported to be available and seen in clinics at site= YES</i></li> <li>➢ <i>National Tuberculosis (TB) guidelines reported to be available and seen in clinics at site= YES</i></li> <li>➢ <i>National Sexually Transmitted Infections (STI) guidelines reported to be available and seen in clinics at site= NO (but chart of syndromic treatment seen on wall)</i></li> </ul> </li> <li>• Lack of drug information reference books for prescribers in clinics.</li> <li>• Lack RDU training reported.</li> <li>• ADR reporting forms and system exists but do not appear to be used.</li> </ul>	

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART**  
**Section B: Coast Provincial General Hospital (CPGH) – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
	<p><b>USE – DISPENSING</b></p> <p>Dispensing practices needs to be strengthened.</p> <ul style="list-style-type: none"> <li>• Inefficient system at pharmacy windows.</li> <li>• Space/arrangement not conducive to confidential counseling.</li> <li>• Tablet counters available but staff count in hands.</li> <li>• Medicines are dispensed in paper envelopes.</li> <li>• No glass bottles available – patients bring own.</li> <li>• Prepacking – done but quality assurance (QA) procedures and record keeping are inadequate.</li> <li>• No system exists to monitor adherence in pharmacy.</li> <li>• No patient information leaflets reported to be available.</li> <li>• No reference books/sources reported to be available.</li> <li>• Need registers and eventually software to monitor rational use.</li> </ul> <p>Counseling practices needs to be strengthened.</p> <p><i>Indicators</i></p> <ul style="list-style-type: none"> <li>➤ Average length of counseling session = 15 sec (n=23)</li> <li>➤ Percentage of pharmacy workers who gave the name of medicine =6.7% (n=30)</li> <li>➤ Percentage of pharmacy workers that gave one or more instructions on how to take medicine = 100% (n=30)</li> <li>➤ Percentage of pharmacy workers who explained what the medicine was for = 13% (n=30)</li> <li>➤ Percentage of pharmacy workers that explained frequency = 100% (n=30)</li> <li>➤ Percentage of pharmacy workers that explained how long to take the medicine for = 100% (n=30)</li> <li>➤ Percentage of pharmacy workers that asked patient/caregiver to repeat instructions = 10% (n=30)</li> </ul>	

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART**  
**Section B: Coast Provincial General Hospital (CPGH) – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
	<p><b>USE – PATIENT RETENTION OF INFORMATION</b></p> <ul style="list-style-type: none"> <li>• Exit interviews indicate that information received and/or retained by patient is inadequate</li> </ul> <p><i>Indicators</i></p> <ul style="list-style-type: none"> <li>➢ Percentage of patients/caregivers who could recall name of medicine = 63% (n=30)</li> <li>➢ Percentage of patients/caregivers who could recall what the medicine was for = 60% (n=30)</li> <li>➢ Percentage of patients/caregivers who could recall the dose of the medicines = 69% (n=30)</li> <li>➢ Percentage of patients/caregivers who could recall how long to take the medicines for = 33% (n=30)</li> <li>➢ Percentage of patients/caregivers who could recall other information about how to take their medicines = 3% (n=30)</li> </ul> <p>Exit interviews indicate that the doctor and pharmacy staff are main providers of information to patient. None of patients reported getting any information from the nurse.</p> <p><i>Indicators</i></p> <p>Patients reported getting following information mainly from doctors:</p> <ul style="list-style-type: none"> <li>➢ Name of medicine: doctor 31% pharmacy 0% nurse 0% no one 0%</li> <li>➢ What the medicine was for : doctor 45% pharmacy 0% nurse 0% no one 12%</li> </ul> <p>Patients reported getting following information mainly from dispensers</p> <ul style="list-style-type: none"> <li>➢ Dose: pharmacy 64% doctor 1% nurse 0% no one 0%</li> <li>➢ Duration of course: pharmacy 5% doctor 3% nurse 0% no one 19%</li> <li>➢ Other instructions: pharmacy 3% doctor 0% nurse 0% no one 0%</li> </ul> <p><b>PMIS</b></p> <ul style="list-style-type: none"> <li>• Inventory management, record keeping, medical records, RDU monitoring, ADR monitoring – all systems need strengthening.</li> <li>• Stand alone computers available but need to be upgraded, linked to a network and software.</li> </ul>	

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART**  
**Section C: Port Reitz District Hospital (PRDH) – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
<p><b>OTHER</b></p> <ul style="list-style-type: none"> <li>• The facility is an integral part of referral system for GOK HIV program.</li> <li>• Facility is currently undergoing major renovations.</li> <li>• ARVs may soon be available through GOK/MOH</li> </ul>	<p><b>POLICIES AND STANDARDS</b></p> <ul style="list-style-type: none"> <li>• Poor availability of national guidelines, STGs, EDL e.g. national ART guidelines at the pharmacy. <i>Indicator</i> <i>National ART guidelines reported to be available and seen in pharmacy at site= NO</i></li> <li>• Limited availability of SOPs - SOPs for ART program will need to be prepared</li> </ul> <p><b>HUMAN RESOURCES - TRAINING</b></p> <ul style="list-style-type: none"> <li>• One pharmaceutical technologist, one pharmacy assistant and one drug inspector need HIV/AIDS training</li> <li>• One pharmacist and one pharmaceutical technologist and yet to be decided number of storekeeping staff need pharmaceutical management training.</li> <li>• One pharmaceutical technologist and undetermined number of doctors need RDU training.</li> <li>• System is needed to provide ongoing updates/training of existing/new staff in HIV/AIDS.</li> <li>• Can be difficult to release staff from site for training.</li> </ul> <p><b>PHARMACEUTICAL MANAGEMENT - AVAILABILITY</b> Problems with availability of HIV-related essential medicines perceived but unable to quantify as record cards unavailable. <i>Indicator:</i> ➤ <i>Average percent of time out of stock for a set of tracer medicines in storage and health facilities = record cards not available</i></p> <p><b>DISTRIBUTION – TRANSPORTATION</b></p> <ul style="list-style-type: none"> <li>• Pharmacy does not have own vehicle for pick up.</li> <li>• Hospital transportation hampered by lack of fuel and shortage of drivers.</li> </ul>	<p><b>INFRASTRUCTURE/ EQUIPMENT</b></p> <ul style="list-style-type: none"> <li>• Major renovations currently underway funded by Danish International Development Assistance (DANIDA) but pharmacy is not scheduled for renovations until next year. Pharmacy is in some disrepair and would require renovations/ alterations (e.g. secured cupboards) that could be done as part of the major refit.</li> <li>• Poor ventilation in pharmacy – cooling system inadequate.</li> <li>• Secured cupboards needed for bulk stock and working stock. Shelving/storage space needs to be improved.</li> <li>• Lockable refrigerator needed – current refrigeration inadequate. No procedure to monitor refrigerators.</li> <li>• Pharmacy window does not allow for confidential counseling – would need to be rebuilt/ or counseling area nearby to be identified.</li> <li>• Obsolete equipment needs to be removed and outdated equipment replaced</li> <li>• Transitional pharmacy storeroom inadequate, not secure, very hot, poor ventilation, no electricity, roof leaks, and record keeping poor. The storeroom is to be relocated as part of refit and put under new management shortly – will need to be reassessed after refit/move.</li> <li>• Very bad access road – especially in rainy season. Limited public transport</li> </ul>

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART**  
**Section C: Port Reitz District Hospital (PRDH) – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
	<p><b>USE - PRESCRIBING</b></p> <ul style="list-style-type: none"> <li>• No RDU monitoring.</li> <li>• Lack of medical records makes it difficult to monitor RDU.</li> <li>• Some evidence of irrational prescribing seen.</li> </ul> <p><i>Indicator</i> <i>Percentage of encounters with antibiotics prescribed in outpatient clinics = 87.1% (n=31)</i></p> <ul style="list-style-type: none"> <li>• Availability of STGs for prescribers in clinics – poor</li> </ul> <p><i>Indicators</i></p> <ul style="list-style-type: none"> <li>➢ <i>National ART guidelines reported to be available and seen in clinics at site= NO</i></li> <li>➢ <i>National TB guidelines reported to be available and seen in clinics at site= YES</i></li> <li>➢ <i>National STI guidelines reported to be available and seen in clinics at site= NO</i></li> </ul> <ul style="list-style-type: none"> <li>• Lack of drug information reference books for prescribers in clinics.</li> <li>• No functioning ADR system.</li> <li>• Lack RDU training reported.</li> </ul> <p><b>USE – DISPENSING</b></p> <p>Dispensing practice needs to be strengthened</p> <ul style="list-style-type: none"> <li>• Space/arrangement not conducive to confidential counseling.</li> <li>• Tablet counters available but staff count in hands.</li> <li>• Medicines are dispensed in paper envelopes.</li> <li>• No glass bottles available – patients bring own.</li> <li>• Prepacking – done but QA procedures/record keeping are inadequate.</li> <li>• No system exists to monitor adherence at the pharmacy.</li> <li>• No patient information leaflets reported to be available.</li> <li>• No reference books/sources available.</li> <li>• Need registers and eventually software to monitor use.</li> </ul>	<p><b>HUMAN RESOURCES – STAFFING LEVELS</b></p> <ul style="list-style-type: none"> <li>• Currently have one pharmaceutical technologist and one pharmacy assistant due to hiring freeze. Staffing is inadequate to support start up of ART program.</li> <li>• Pharmaceutical technologist is overworked and disheartened by long term staff shortages, inadequate salary, poor working environment.</li> </ul> <p><b>QUANTIFICATION</b></p> <ul style="list-style-type: none"> <li>• Lack of stock records for quantification and monitoring scale up of ART program.</li> <li>• Pharmacy staff not involved in quantification of medicines currently.</li> <li>• Lack of experience/training for complex quantification.</li> <li>• Lack of computerized HMIS for quantification and monitoring scale up of ART program</li> </ul> <p><b>DISTRIBUTION – INVENTORY MANAGEMENT</b></p> <ul style="list-style-type: none"> <li>• Poor inventory management of storeroom. Unable to locate stock records and stock is piled up on floor waiting to be unpacked and entered. Impossible to carry out any kind of record review in storeroom.</li> </ul> <p><i>Indicators:</i></p> <ul style="list-style-type: none"> <li>➢ <i>Inventory stock records exist and available = NO</i></li> <li>➢ <i>Average percent of stock records that correspond with physical counts for a set of tracer medicines in storage and health facilities = unable to calculate as no records were available</i></li> </ul> <ul style="list-style-type: none"> <li>• No regular internal or external auditing</li> </ul>

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART**  
**Section C: Port Reitz District Hospital (PRDH) – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
	<p><b>USE – DISPENSING (continued)</b></p> <ul style="list-style-type: none"> <li>• Counseling observed to be inadequate due to staff shortages</li> </ul> <p><i>Indicators</i></p> <ul style="list-style-type: none"> <li>➤ Average length of counseling session = 22 sec (n=26)</li> <li>➤ Percentage of pharmacy workers who gave the name of medicine = 6.7% (n=30)</li> <li>➤ Percentage of pharmacy workers that gave one or more instructions on how to take medicine = 97% (n=30)</li> <li>➤ Percentage of pharmacy workers who explained what the medicine was for = 37% (n=30)</li> <li>➤ Percentage of pharmacy workers that explained frequency = 97% (n=30)</li> <li>➤ Percentage of pharmacy workers that explained how long to take the medicine for = 87% (n=30)</li> <li>➤ Percentage of pharmacy workers that asked patient/caregiver to repeat instructions = 20% (n=30)</li> </ul> <p><b>USE – PATIENT RETENTION OF INFORMATION</b></p> <ul style="list-style-type: none"> <li>• Exit interviews indicate that information received and/or retained by patient is inadequate.</li> </ul> <p><i>Indicators</i></p> <ul style="list-style-type: none"> <li>➤ Percentage of patients/caregivers who could recall name of the medicine = 66% (n=30)</li> <li>➤ Percentage of patients/caregivers who could recall what the medicine was for = 68% (n=30)</li> <li>➤ Percentage of patients/caregivers who could recall the dose of the medicines = 80% (n=30)</li> <li>➤ Percentage of patients/caregivers who could recall how long to take the medicines = 35% (n=30)</li> <li>➤ Percentage of patients/caregivers who could recall other information about how to take their medicines = 14% (n=30)</li> </ul>	

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART**  
**Section C: Port Reitz District Hospital (PRDH) – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
	<p><b>USE – PATIENT RETENTION OF INFORMATION (continued)</b> Exit interviews indicate that the doctor and pharmacy staff are main providers of information to patient. None of patients reported getting any information from the nurse. <i>Indicators</i> <i>Patients reported getting following information mainly from doctors:</i></p> <ul style="list-style-type: none"> <li>➤ <i>Name of medicine: doctor 46% pharmacy 0% nurse 0% no one 0%</i></li> <li>➤ <i>What the medicine was for: doctor 49% pharmacy 0% nurse 0% no one 18%</i></li> </ul> <p><i>Patients reported getting following information mainly from dispensers</i></p> <ul style="list-style-type: none"> <li>➤ <i>Dose: pharmacy 77% doctor 0% nurse 0% no one 0%</i></li> <li>➤ <i>Duration of course: pharmacy 8% doctor 3% nurse 0% no one 22%</i></li> <li>➤ <i>Other instructions: pharmacy 54% doctor 2% nurse 0% no one 0%</i></li> </ul> <p><b>PMIS</b></p> <ul style="list-style-type: none"> <li>• Inventory management, record keeping, medical records, RDU monitoring, ADR monitoring – all systems need strengthening.</li> </ul> <p><b>M&amp;E</b></p> <ul style="list-style-type: none"> <li>• A quality committee/group exists but is irregular in monitoring and enforcement is limited.</li> <li>• Lack of availability of data constraints monitoring.</li> </ul>	

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART  
Section D: Magongo Municipal Clinic – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
<p><b>OTHER</b></p> <ul style="list-style-type: none"> <li>• TB Isoniazid Preventative Therapy (IPT) Program is operating at Magongo.</li> <li>• Operational VCT.</li> <li>• Highly motivated Matron.</li> <li>• Anecdotal reports that majority of clients seek health care at municipal clinics rather than hospitals.</li> <li>• Geographical accessibility of municipal clinics can facilitate scale up of program in long term.</li> </ul>	<p><b>POLICIES AND STANDARDS</b></p> <ul style="list-style-type: none"> <li>• Poor availability of national guidelines, STGs, EDL e.g. national ART guidelines in pharmacy. <i>Indicator</i> <i>National ART guidelines reported to be available and seen in pharmacy at site= NO</i></li> <li>• Limited availability of SOPs - SOPs for ART program will need to be prepared.</li> </ul> <p><b>HUMAN RESOURCES - TRAINING</b></p> <ul style="list-style-type: none"> <li>• One enrolled nurse/dispenser needs HIV/AIDS training.</li> <li>• One nurse/dispenser and one matron needs pharmaceutical management training.</li> <li>• One nurse/dispenser, one matron and an undetermined number of clinical officers need RDU training.</li> <li>• System is needed to provide ongoing updates/training of existing/new staff in HIV/AIDS.</li> <li>• Can be difficult to release staff from site for training.</li> </ul> <p><b>DISTRIBUTION – INVENTORY MANAGEMENT</b></p> <ul style="list-style-type: none"> <li>• Poor inventory management practices seen. <i>Indicators:</i> <ul style="list-style-type: none"> <li>➢ <i>Inventory stock records exist and available = Yes</i></li> <li>➢ <i>Average percent of stock records that correspond with physical counts for a set of tracer medicines in storage and health facilities = 37.5% (n=8)</i></li> </ul> </li> <li>• No regular internal or external auditing – matron agreeable to establish a system.</li> </ul> <p><b>DISTRIBUTION – TRANSPORTATION</b></p> <ul style="list-style-type: none"> <li>• Facility does not have own vehicle for pick up.</li> </ul>	<p><b>INFRASTRUCTURE/ EQUIPMENT</b></p> <ul style="list-style-type: none"> <li>• Clinic is in a general state of disrepair – maintenance is poor/non-existent with staff using own funds for repair of lock on front door. Would be difficult to assure on-going security. No grills on windows except pharmacy.</li> <li>• No fans are working. No plug for refrigerator. No water – has been disconnected due to non-payment of bills.</li> <li>• Inadequate storage space in bulk store (if clinic was fully stocked as required). Secured cupboards needed for ARV bulk stock and working stock.</li> <li>• Pharmacy window does not allow for confidential counseling – would need to be rebuilt/ or counseling area nearby to be identified.</li> </ul> <p><b>HUMAN RESOURCES – STAFFING LEVELS</b></p> <ul style="list-style-type: none"> <li>• Enrolled nurse/dispenser disheartened by poor working conditions, delays in receiving salary.</li> <li>• General reluctance of staff to take on additional duties without increase in pay.</li> <li>• Staffing may be inadequate – depending on work load for ART program.</li> <li>• Difficult to recruit staff.</li> <li>• City council is retrenching staff.</li> </ul>

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART**  
**Section D: Magongo Municipal Clinic – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
	<p><b>USE - PRESCRIBING</b></p> <ul style="list-style-type: none"> <li>• No RDU monitoring.</li> <li>• Lack of medical records makes it difficult to monitor RDU.</li> <li>• Availability of STGs for prescribers in clinics – poor</li> </ul> <p><i>Indicators</i></p> <ul style="list-style-type: none"> <li>➢ <i>National ART guidelines reported to be available and seen in clinics at site= NO</i></li> <li>➢ <i>National TB guidelines reported to be available and seen in clinics at site= NO</i></li> <li>➢ <i>National STI guidelines reported to be available and seen in clinics at site= NO</i></li> </ul> <ul style="list-style-type: none"> <li>• Lack of drug information reference books for prescribers in clinics</li> <li>• No functioning ADR system.</li> <li>• Lack RDU training reported.</li> </ul> <p><b>USE – DISPENSING</b></p> <p>Poor dispensing practices observed.</p> <ul style="list-style-type: none"> <li>• Space/arrangement not conducive to confidential counseling.</li> <li>• Staff count in hands.</li> <li>• No tablet envelopes available – staff make own from recycled paper.</li> <li>• No glass bottles available – patients bring own.</li> <li>• No system exists to monitor adherence in pharmacy.</li> <li>• No patient information leaflets seen to be available.</li> <li>• Counseling practices observed to be inadequate.</li> </ul> <p><i>Indicators</i></p> <ul style="list-style-type: none"> <li>➢ <i>Average length of counseling session = 19 sec (n=25)</i></li> <li>➢ <i>Percentage of pharmacy workers who gave the name of medicine =0% (n=23)</i></li> <li>➢ <i>Percentage of pharmacy workers that gave one or more instructions on how to take medicine = 91% (n=23)</i></li> <li>➢ <i>Percentage of pharmacy workers who explained what the drug was for = 57% (n=23)</i></li> <li>➢ <i>Percentage of pharmacy workers that explained frequency = 87% (n=23)</i></li> </ul>	<p><b>PHARMACEUTICAL MANAGEMENT - AVAILABILITY</b></p> <ul style="list-style-type: none"> <li>• Poor availability of HIV-related essential medicines at time of visit</li> </ul> <p><i>Indicator:</i></p> <ul style="list-style-type: none"> <li>➢ <i>Average percent of time out of stock for a set of tracer medicines in storage and health facilities = 74.2% (n=6)</i></li> </ul> <p><b>QUANTIFICATION</b></p> <ul style="list-style-type: none"> <li>• Lack of experience/training for complex quantification.</li> <li>• Lack of computerized HMIS for quantification and monitoring scale up of ART program.</li> </ul> <p><b>COST SHARING</b></p> <ul style="list-style-type: none"> <li>• No cost sharing fees are retained by clinic.</li> </ul>

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART**  
**Section D: Magongo Municipal Clinic – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
	<p><b>USE – DISPENSING (continued)</b></p> <ul style="list-style-type: none"> <li>➤ Percentage of pharmacy workers that explained how long to take the medicine for = 35% (n=23)</li> <li>➤ Percentage of pharmacy workers that asked patient/caregiver to repeat instructions = 4% (n=23)</li> <li>• No reference books/sources available.</li> <li>• Need registers and eventually software to monitor use.</li> </ul> <p><b>USE – PATIENT RETENTION OF INFORMATION</b></p> <ul style="list-style-type: none"> <li>• Exit interviews indicate that information received and/or retained by patient is inadequate.</li> </ul> <p>Indicators</p> <ul style="list-style-type: none"> <li>➤ Percentage of patients/caregivers who could recall name of medicine = 58% (n=30)</li> <li>➤ Percentage of patients/caregivers who could recall what the medicine was for = 56% (n=30)</li> <li>➤ Percentage of patients/caregivers who could recall the dose of the medicines = 60% (n=30)</li> <li>➤ Percentage of patients/caregivers who could recall how long to take the medicines = 38% (n=30)</li> <li>➤ Percentage of patients/caregivers who could recall other information about how to take their medicines = 23% (n=30)</li> </ul> <p>Exit interviews indicate that the doctor and pharmacy staff are main providers of information to patient. None of patients reported getting any information from the nurse.</p> <p>Indicators</p> <p>Patients reported getting following information mainly from doctors:</p> <ul style="list-style-type: none"> <li>➤ Name of medicine: doctor 33% pharmacy 0% nurse 0% no one 0%</li> <li>➤ What the medicine was for: doctor 49% pharmacy 0% nurse 0% no one 5%</li> </ul> <p>Patients reported getting following information mainly from dispensers</p> <ul style="list-style-type: none"> <li>➤ Dose: pharmacy 53% doctor 5% nurse 0% no one 0%</li> <li>➤ Duration of course: pharmacy 14% doctor 5% nurse 0% no one 11%</li> <li>➤ Other instructions: pharmacy 12% doctor 11% nurse 0% no one 0%</li> </ul>	

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART  
Section D: Magongo Municipal Clinic – Initial Findings for Comment**

<b>Strengths/Opportunities</b>	<b>Limitations</b>	<b>Major Constraints</b>
	<p><b>MIS</b></p> <ul style="list-style-type: none"> <li>• Inventory management, record keeping, medical records, RDU monitoring, ADR monitoring – all systems need strengthening.</li> </ul> <p><b>M&amp;E</b></p> <ul style="list-style-type: none"> <li>• No quality committee/group reported to exist.</li> <li>• Lack of availability of data is a major constraint to monitoring.</li> </ul>	

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART**  
**Section E: Bomu Clinic – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
<p><b>INFRASTRUCTURE/ EQUIPMENT</b></p> <ul style="list-style-type: none"> <li>• Overall adequate to support introduction of ART – improvements needed are feasible and low cost and probably can be funded by site. Very secure with burglar alarms and monitors in pharmacy. Good ventilation and cooling system. Networked, relatively sophisticated computer system available.</li> <li>Requirements: <ul style="list-style-type: none"> <li>➢ Secured cupboard in secured area.</li> <li>➢ Lockable, small refrigerator in secured area.</li> <li>➢ Secured cupboard in dispensary for working stock.</li> <li>➢ Setting up of a private counseling area – area has been identified.</li> <li>➢ Small office space for pharmacy-in-charge.</li> <li>➢ Add capacity for real-time management of pharmacy inventory stock to existing software.</li> </ul> </li> </ul> <p><b>DISTRIBUTION – INVENTORY MANAGEMENT</b></p> <ul style="list-style-type: none"> <li>• Excellent inventory management practices.</li> <li><i>Indicators:</i> <ul style="list-style-type: none"> <li>➢ <i>Inventory stock records exist and available = Yes</i></li> <li>➢ <i>Average percent of stock records that correspond with physical counts for a set of tracer medicines in storage and health facilities = 92.3% (n=13)</i></li> </ul> </li> <li>• Procedure to monitor refrigerators needed.</li> <li>• Internal auditing system in place for CDs can be adapted for ARVs.</li> <li>• External audit would need to be set up – Administrator agreeable.</li> </ul>	<p><b>POLICIES AND STANDARDS</b></p> <ul style="list-style-type: none"> <li>• Poor availability of national guidelines, STGs, EDL e.g. national ART guidelines in pharmacy.</li> <li><i>Indicator:</i> <i>National ART guidelines reported to be available and seen in pharmacy at site= NO</i></li> <li>• Limited availability of SOPs - SOPs for ART program will need to be prepared.</li> </ul> <p><b>HUMAN RESOURCES - TRAINING</b></p> <ul style="list-style-type: none"> <li>• One pharmaceutical technologist and one pharmacy assistant need HIV/AIDS training.</li> <li>• One pharmaceutical technologist and one pharmacy assistant and one storekeeper need pharmaceutical management training.</li> <li>• One pharmaceutical technologist and one pharmacy assistant and two doctors need RDU training.</li> <li>• System is needed to provide ongoing HIV/AIDS updates/training of existing/new staff.</li> <li>• Can be difficult to release staff from site for training.</li> </ul> <p><b>PHARMACEUTICAL MANAGEMENT - AVAILABILITY</b></p> <ul style="list-style-type: none"> <li>• Some problems with availability of HIV-related essential medicines</li> <li><i>Indicator:</i> <ul style="list-style-type: none"> <li>➢ <i>Average percent of time out of stock for a set of tracer medicines in storage and health facilities = 19.16% (n=14)</i></li> </ul> </li> </ul> <p><b>QUANTIFICATION</b></p> <ul style="list-style-type: none"> <li>• Lack of experience/training for complex quantification.</li> <li>• Lack of computerized HMIS for quantification and monitoring scale up of ART program</li> </ul>	

<b>Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART</b>		
<b>Section E: Bomu Clinic – Initial Findings for Comment</b>		
<b>Strengths/Opportunities</b>	<b>Limitations</b>	<b>Major Constraints</b>
<p><b>HUMAN RESOURCES – STAFFING LEVELS</b></p> <ul style="list-style-type: none"> <li>• Highly motivated, pharmaceutical technologist (recently qualified) and pharmacy assistant on staff.</li> <li>• Staffing levels adequate to support start up of ART program from pharmacy.</li> </ul> <p><b>M&amp;E</b></p> <ul style="list-style-type: none"> <li>• Quality committee exists and interested in incorporating pharmaceutical management indicators as part of monitoring.</li> <li>• Availability of data is a limitation.</li> </ul> <p><b>OTHER</b></p> <ul style="list-style-type: none"> <li>• Have TB IPT unit – if clients finish six months of treatment and come with buddy – they are eligible for ARVs.</li> <li>• Active peer education program to educate community on ART underway.</li> <li>• Active VCT.</li> </ul>	<p><b>USE - PRESCRIBING</b></p> <ul style="list-style-type: none"> <li>• No RDU monitoring</li> <li>• Some evidence of irrational prescribing: <i>Indicator</i> <i>Percentage of encounters with antibiotics prescribed in outpatient clinics = 80% (n=35)</i></li> <li>• Availability of STGs for prescribers in clinics – poor <i>Indicators</i> <ul style="list-style-type: none"> <li>➢ <i>National ART guidelines reported to be available and seen in clinics at site= NO</i></li> <li>➢ <i>National TB guidelines reported to be available and seen in clinics at site= YES</i></li> <li>➢ <i>National STI guidelines reported to be available and seen in clinics at site= NO (but syndromic chart seen)</i></li> </ul> </li> <li>• Lack of drug information reference books for prescribers in clinics.</li> <li>• No functioning ADR system.</li> <li>• Lack RDU training reported.</li> </ul> <p><b>USE - DISPENSING</b></p> <p>Dispensing practice inadequate:</p> <ul style="list-style-type: none"> <li>• Space/arrangement not conducive to confidential counseling.</li> <li>• Tablet counters available but staff observed to count in hands.</li> <li>• Medicines are dispensed in paper envelopes.</li> <li>• Glass bottles can be made available.</li> <li>• Prepacking – done but QA procedures/record keeping are inadequate.</li> <li>• No system exists to monitor adherence in pharmacy.</li> <li>• No patient information leaflets seen to be available.</li> <li>• Counseling inadequate due to staff shortages. <i>Indicators</i> <ul style="list-style-type: none"> <li>➢ <i>Average length of counseling session = 84 sec (n=23)</i></li> <li>➢ <i>Percentage of pharmacy workers that gave one or more instructions on how to take medicine = 90% (n=30)</i></li> </ul> </li> </ul>	

**Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART**  
**Section E: Bomu Clinic – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
	<p><b>USE – DISPENSING (continued)</b></p> <ul style="list-style-type: none"> <li>➤ Percentage of pharmacy workers who gave the name of medicine = 3.3% (n=30)</li> <li>➤ Percentage of pharmacy workers who explained what the medicine was for = 17% (n=30)</li> <li>➤ Percentage of pharmacy workers that explained frequency = 90% (n=30)</li> <li>➤ Percentage of pharmacy workers that explained how long to take the medicine for = 90% (n=30)</li> <li>➤ Percentage of pharmacy workers that asked patient/caregiver to repeat instructions = 40% (n=30)</li> </ul> <ul style="list-style-type: none"> <li>• No reference books/sources available.</li> <li>• Need registers and eventually software to monitor use.</li> </ul> <p><b>USE – PATIENT RETENTION OF INFORMATION</b></p> <ul style="list-style-type: none"> <li>• Exit interviews indicate that information received and/or retained by patient is inadequate</li> </ul> <p><i>Indicators</i></p> <ul style="list-style-type: none"> <li>➤ Percentage of patients/caregivers who could recall name of medicine = 63% (n=30)</li> <li>➤ Percentage of patients/caregivers who could recall what the medicine was for = 79% (n=30)</li> <li>➤ Percentage of patients/caregivers who could recall the dose of the medicines = 99% (n=30)</li> <li>➤ Percentage of patients/caregivers who could recall how long to take the medicines for = 61% (n=30)</li> <li>➤ Percentage of patients/caregivers who could recall other information about how to take their medicines = 4% (n=30)</li> </ul>	

Table 1: Capacity of the Pharmaceutical Management System to Support the Introduction of ART		
Section E: Bomu Clinic – Initial Findings for Comment		
Strengths/Opportunities	Limitations	Major Constraints
	<p><b>USE – PATIENT RETENTION OF INFORMATION (continued)</b></p> <ul style="list-style-type: none"> <li>Exit interviews indicate that the doctor and pharmacy staff are main providers of information to patient.</li> </ul> <p><i>Indicators</i></p> <p><i>Patients reported getting following information mainly from doctors:</i></p> <ul style="list-style-type: none"> <li>➤ Name of medicine: doctor 54% pharmacy 0% nurse 0% no one 6%</li> <li>➤ What the medicine was for : doctor 69% pharmacy 0% nurse 0% no one 13%</li> </ul> <p><i>Patients reported getting following information mainly from dispensers</i></p> <ul style="list-style-type: none"> <li>➤ Dose: pharmacy 90% doctor 0% nurse 0% no one 0%</li> <li>➤ Duration of course: pharmacy 25% doctor 6% nurse 1% no one 25%</li> <li>➤ Other instructions: pharmacy 3% doctor 0% nurse 0% no one 0%</li> </ul> <p>Only one patient reported getting any information from the nurse.</p> <p><b>PMIS</b></p> <ul style="list-style-type: none"> <li>Inventory management, record keeping, medical records, RDU monitoring, ADR monitoring – all systems need support.</li> <li>Networked, relatively sophisticated computer system available. Add capacity for real-time management of pharmacy inventory stock to existing software.</li> </ul> <p><b>OTHER</b></p> <p>Problems with referral of patients to public sector.</p>	

**Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up  
Section A: Overarching Issues for All Four Sites**

<b>Component</b>	<b>Limitations</b>	<b>Options/Recommendations</b>
<b>Policies, Legislation, Regulation</b>	National policies on dispensing/prescribing ARVs do not exist.	<ul style="list-style-type: none"> <li>• Facility/program level SOPs need to be developed to guide program implementation in the four sites.</li> <li>• In the long term, GOK to develop STGs/guidelines - USAID technical assistance partners (TAP) that is IMPACT, RPM Plus and Horizons could support the process.</li> </ul>
	National/local STGs for OIs and palliative care do not exist.	
	ARVs and many medicines for prophylaxis/treatment of OIs not on EDL.	<ul style="list-style-type: none"> <li>• Supplementary list to EDL may need to be developed or facility-level list/formulary amended for the four sites to guide procurement of HIV/AIDS-related essential medicines not currently included.</li> <li>• In the long term, EDL to be updated - USAID/TAP could support the process.</li> </ul>
<b>Drug Information</b>	National Drug Information Centre reported to exist but not yet functional.	<ul style="list-style-type: none"> <li>• Resource centre for ART program to be established at one of the sites using existing staff resources. USAID/TAP could support the training of key resource person and identifying books/resources for centre.</li> <li>• Sustainability of the resource centre will need to be considered – staffing; ongoing training, funding of updated books/resources.</li> <li>• Setting up of the resource centre should include a plan for integrating the centre into the national system in the long term.</li> </ul>
	No local network exists.	
<b>ADR Monitoring and Reporting</b>	National system to monitor and report on ADRs reported to exist but not yet functional.	<ul style="list-style-type: none"> <li>• ADR monitoring and reporting system to be incorporated as part of program implementation in line with national efforts.</li> <li>• USAID/TAP could support training, development of forms and SOPs for ADR monitoring and reporting. Build on existing components of system at CPGH.</li> <li>• Setting up of the ADR monitoring and reporting system should include a plan for integration into the national system in the long term.</li> </ul>
	Regional/local system to monitor and report on ADRs not functional.	
<b>HMIS</b>	National system to monitor resistance to ARVs does not exist.	<ul style="list-style-type: none"> <li>• Scientific Committee to develop criteria/plan for monitoring resistance to ARVs for ART program based on feasibility and available options in collaboration with national efforts.</li> <li>• Scientific/Steering Committee to liaise with organization/body responsible at national level to develop a plan for integration into the national system in the long term.</li> </ul>

**Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up  
Section A: Overarching Issues for All Four Sites**

<b>Component</b>	<b>Limitations</b>	<b>Options/Recommendations</b>
<b>Availability of HIV-Related Medicines</b>	Fluconazole not yet available through Axios donation program	<ul style="list-style-type: none"> <li>• USAID/TAP and ART program implementers to provide support to GOK in finalizing the application.</li> </ul>
<b>Training of Pharmacy Staff</b>	Limited pre-service training of pharmacy staff in relevant clinical management of HIV/AIDS.	<ul style="list-style-type: none"> <li>• Relevant training in HIV/AIDS clinical management and in pharmaceutical management will need to be incorporated/provided through an ongoing in-service training program for all pharmacy staff at the four sites.</li> </ul>
	Limited pre-service training of pharmacy staff in pharmaceutical management.	
	Pharmaceutical technologists and pharmacists belong to different professional organizations – pharmaceutical technologists do not have access to PSK training.	<ul style="list-style-type: none"> <li>• Pharmaceutical professional organizations to look at options for encouraging and increasing collaboration between the two cadres of pharmacy staff.</li> </ul>
	Lack of agreement over roles and responsibilities of pharmacy staff and prescribers constrain collaboration on training and keeping staff updated.	<ul style="list-style-type: none"> <li>• Professional organizations have a critical role to play to look at options for encouraging and increasing collaboration between the two profession groups.</li> </ul>
<b>Cost Recovery</b>	Fees, exemptions, systems, retention of cost sharing fees vary across the four facilities – no consensus.	<ul style="list-style-type: none"> <li>• Scientific Committee will need to look at cost recovery systems in place at all four sites – e.g. objectives, retention of fees by facility; exemptions and reach consensus on cost sharing for the ART program.</li> </ul>
	Proposed bill to abolish cost-sharing pending approval.	<ul style="list-style-type: none"> <li>• Implications of the proposed bill will need to be considered by the Scientific Committee.</li> </ul>

<b>Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up</b>		
<b>Section B: Issues Common to All Four Sites</b>		
<b>Component</b>	<b>Limitations</b>	<b>Options/Recommendations</b>
<b>Policies, Legislation, Regulation</b>	National ART guidelines seen at the pharmacy of only one of four sites. Poor availability of STGs, EDL and other key document in pharmacy.	<ul style="list-style-type: none"> <li>Guidelines and other key documents need to be made available at the pharmacy such that they are accessible to all pharmacy staff.</li> <li>TAP to assist facility staff to identify key documents that should be available at the pharmacy at all four sites.</li> </ul>
	Limited availability of SOPs - SOPs for ART program will need to be prepared	<ul style="list-style-type: none"> <li>SOPs to be developed for all four sites.</li> <li>TAP to assist in developing a process for preparing and updating SOPs.</li> </ul>
<b>Infrastructure/ Equipment</b>	Lockable, small refrigerator in secured area needed.	<ul style="list-style-type: none"> <li>Small lockable refrigerator will be needed for all sites that are to provide second line adult/child ART.</li> </ul>
	Procedure to monitor function of refrigerators needed.	<ul style="list-style-type: none"> <li>TAP to assist in developing a procedure to monitor refrigerators.</li> <li>Oversight could be provided by Quality Committee where exists or internal/external auditors for program.</li> </ul>
<b>Human Resources – Training</b>	CPGH - one pharmacist needs HIV/AIDS training to capacitate them as the key resource person for program.	<ul style="list-style-type: none"> <li>TAP to assist the four sites in developing materials and modality of training, using existing resources/organizations where possible with an initial focus on the essential elements needed for ART program implementation.</li> <li>Training will need to be ongoing to keep staff updated and also due to difficulty of releasing staff during working hours.</li> </ul>
	HIV/AIDS training needs: <ul style="list-style-type: none"> <li>➤ CPGH - three pharmacists and six pharmaceutical technologists.</li> <li>➤ PRDH - one pharmaceutical technologist, one pharmacy assistant and one drug inspector.</li> <li>➤ Magongo - one enrolled nurse/dispenser.</li> <li>➤ Bomu - one pharmaceutical technologist and one pharmacy assistant</li> </ul>	
	Pharmaceutical Management training needs: <ul style="list-style-type: none"> <li>➤ CPGH - Three pharmacists and six pharmaceutical technologists and three pharmacy assistants.</li> </ul>	

**Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up  
Section B: Issues Common to All Four Sites**

Component	Limitations	Options/Recommendations
<b>Human Resources – Training (continued)</b>	Pharmaceutical Management training needs (continued): <ul style="list-style-type: none"> <li>➤ PRDH - one pharmacist and one pharmaceutical technologist and yet to be determined number of storekeeping staff.</li> <li>➤ Magongo - one nurse/dispenser and one matron.</li> <li>➤ Bomu - one pharmaceutical technologist and one pharmacy assistant and one storekeeper.</li> </ul>	
	RDU training: <ul style="list-style-type: none"> <li>➤ CPGH - three pharmacists and yet to be determined number of doctors</li> <li>➤ PRDH - one pharmaceutical technologist and yet to be determined number of doctors.</li> <li>➤ Magongo - one nurse/dispenser, one matron and yet to be determined number of clinical officers</li> <li>➤ Bomu - one pharmaceutical technologist and one pharmacy assistant and two doctors.</li> </ul>	<ul style="list-style-type: none"> <li>• Most successful RDU intervention are problem focused – generic training courses shown to be of little success. Focusing on ARVs presents an opportunity to introduce concepts of RDU that can then be rolled out initially to other HIV/AIDS conditions and then broader (identify 10 top problems and focus on these).</li> <li>• Suggested process: begin with developing STGs and SOPs for ARVs. Monitoring and reviewing compliance with STGs/SOPs can then be used to develop an inclusive process to institutionalize RDU.</li> <li>• TAP to provide support to four sites through technical assistance.</li> </ul>
	System is needed to provide ongoing updates/training of existing/new staff in HIV/AIDS in all four sites.	<ul style="list-style-type: none"> <li>• TAP to work with four sites, stakeholders, professional organizations etc to identify a practical, feasible, replicable and sustainable process for keeping professional staff updated in HIV/AIDS clinical management.</li> </ul>
	All four sites will have difficulty releasing staff for training during working hours.	<ul style="list-style-type: none"> <li>• Need to explore options including after hours/ weekend sessions due to difficulty in releasing staff from site.</li> <li>• Training will need to be modular to allow flexibility to accommodate this constraint.</li> </ul>

<b>Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up</b>		
<b>Section B: Issues Common to All Four Sites</b>		
<b>Component</b>	<b>Limitations</b>	<b>Options/Recommendations</b>
<b>Quantification</b>	Lack of experience/training for complex quantification.	<ul style="list-style-type: none"> <li>• Training for complex quantification of ARVs would be an immediate priority for training program.</li> <li>• Ensuring that the existing manual record keeping/ inventory management system is functioning is an absolute pre-requisite to introduction of ARVs.</li> <li>• TAP to provide support to strengthening existing inventory management system, especially record keeping and to provide assistance in monitoring speed of scale up and quantification of needs.</li> <li>• These are serious constraints to ensuring constant availability of ARVs and will need to be addressed early in the program. USAID/TAP to provide technical assistance and support to setting up a computerized system as appropriate and feasible to facility-level context and capacity.</li> </ul>
	Lack of computerized HMIS for quantification and monitoring scale up of ART program.	
<b>Distribution – Inventory Management</b>	Internal auditing system for ARVs needs to be set up.	<ul style="list-style-type: none"> <li>• In two facilities, the existing internal auditing system for CDs could be used to audit ARVs.</li> <li>• TAP to provide assistance to four sites to develop criteria for and to set up internal auditing process as appropriate to each site.</li> <li>• Assess the feasibility of the Drug Inspector based at PRDH functioning as the external auditor for the program for four sites (responsibilities currently include auditing of CDs).</li> <li>• No objections were reported at facility-level for setting up such a system.</li> </ul>
	External auditing system for ARVs would need to be set up.	
<b>Distribution – Transportation</b>	Three of the four sites do not have own vehicle for pick up. In addition facility-level transportation at PRDH is hampered by lack of fuel and the shortage of drivers.	<ul style="list-style-type: none"> <li>• ARVs would need to be delivered to at least three out of the four sites due to lack/unreliability of facility-level transport.</li> <li>• Arrangements for transportation need to be incorporated into the procurement/delivery process for the ART program.</li> </ul>
<b>Use – Prescribing</b>	No RDU monitoring done.	<ul style="list-style-type: none"> <li>• Lack of medical records will need addressed at policy-level as it will be difficult to facilitate scale up in public sector (MOH and municipal clinics) if medical records are not available.</li> <li>• STGs and other key documents need to be made available for prescribers at clinic-level in addition to the pharmacy. TAP can assist sites in developing a list of documents to be made available.</li> </ul>
	Lack of medical records at three out of four sites makes it difficult to monitor RDU and develop problem-focused training.	

**Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up  
Section B: Issues Common to All Four Sites**

Component	Limitations	Options/Recommendations
<b>Use - Prescribing (continued)</b>	Limited availability of STGs for prescribers in clinics	<ul style="list-style-type: none"> <li>• Drug information reference books and resources need to be made available for both prescribers and for pharmacy staff (see below) in all four facilities. TAP can assist sites in developing a list of resources that should be available both at clinic-level and in the pharmacy and explore options for initial and on-going funding.</li> <li>• RDU training – see training in previous section.</li> </ul>
	Poor availability of drug information reference books/sources for prescribers in clinics	
	Some evidence of irrational prescribing at two out of the four sites from review of antibiotics prescribed.	
	Most prescribers/pharmacists reported a lack of RDU training.	
	ADR monitoring and reporting system reported as non-functional. ADR reporting forms and system exist in one site (CPGH) but does not appear to be used.	<ul style="list-style-type: none"> <li>• See ADR monitoring and reporting in Table 2: Overarching Issues for All Four Sites.</li> </ul>
<b>Use - Dispensing</b>	Dispensing practice needs to be strengthened in all four facilities. Some common problems are listed below.	<ul style="list-style-type: none"> <li>• Interventions to promote Good Dispensing Practice include a combination of training and regular monitoring/supervision with feedback to staff.</li> <li>• TAP can assist with developing training materials for Good Dispensing Practice to be incorporated into training course.</li> <li>• Oversight including M&amp;E with regular feedback can be taken on by Quality Committee where one exists. TAP can share tools for monitoring Good Dispensing Practice with Quality Committee.</li> </ul>
	Tablet counters seen to be available but staff count in hands.	
	Space/arrangement not conducive to confidential counseling. In particular, problems exist at CPGH and PRDH where fees are collected at pharmacy windows resulting in crowding at busy periods.	<ul style="list-style-type: none"> <li>• TAP to assist pharmacy/administrative staff at each site to look at feasible, low cost, sustainable options to improve patient flow and confidentiality at pharmacy window. ARVs can provide starting point for improving confidentiality and quality of counseling for other medicines as appropriate.</li> </ul>

**Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up  
Section B: Issues Common to All Four Sites**

<b>Component</b>	<b>Limitations</b>	<b>Options/Recommendations</b>	
<b>Use – Dispensing (continued)</b>	Tablets and capsules are dispensed in paper envelopes – risk of compromising stability of ARVs.	<ul style="list-style-type: none"> <li>• Due to lack of availability of appropriate dispensing containers, original containers should be dispensed where possible</li> <li>• Small quantities of plastic bags/glass or plastic bottles may need to be purchased if quantities of less than 1 months supply are to be dispensed.</li> <li>• Capacity to prepack ARVs is limited in 3 sites and non-existent in 1 site (Magongo). TAP to provide support to prepacking facilities to strengthen QA, especially recall, record keeping and batch labeling of prepacks. Availability of suitable containers and labeling would need to be addressed</li> </ul>	
	No glass bottles available – patients bring own. One site (Bomu) could make glass bottles available.		
	Prepacking of medicines is done in three of the four sites but QA procedures/record keeping are inadequate.		
	No reference books/sources available.		• See above under Use - Prescribing
	Need registers and eventually software to monitor use.		• See HMIS. Registers are needed for both inventory management and auditing purposes.
	No system exists to monitor adherence at the pharmacy.		• TAP to work with the four sites and clients to develop appropriate, feasible and sustainable strategies to support adherence
	No patient information leaflets generally not available at the pharmacy.		
Medication counseling inadequate in all four sites. Needs to be strengthened as part of improvements in Good Dispensing Practice. Other constraints include staff shortages, and space/ arrangement at pharmacy window not being conducive to confidential counseling.	<ul style="list-style-type: none"> <li>• Counseling in the pharmaceutical context needs to be distinguished from counseling as understood in an HIV/AIDS context. Counseling as part of Good Dispensing Practice involves explaining to the patient, the name, indication, dose, duration of the medicine together with other essential instructions. Pharmaceutical counseling is complementary to prescriber/nurse counseling.</li> <li>• TAP to provide support to strengthen counseling through developing training materials and sharing tools with the quality committee (where it exists) to monitor quality of counseling.</li> </ul>		
<b>Use – Patient Retention of Information</b>	Exit interviews indicate that information received and/or retained by patient is inadequate.	<ul style="list-style-type: none"> <li>• Support needs to be provided to both prescribers and dispensers to strengthen counseling as in all four facilities both professional groups have key and complementary roles to play.</li> </ul>	

<b>Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up</b>		
<b>Section B: Issues Common to All Four Sites</b>		
<b>Component</b>	<b>Limitations</b>	<b>Options/Recommendations</b>
<b>Use – Patient Retention of Information (continued)</b>	Exit interviews indicate that the doctor and pharmacy staff are main providers of information to patient. Patients reported getting name of medicine and indication mainly from doctors. Patients reported getting information on dose, duration of course and other instructions mainly from dispensers.	
<b>PMIS</b>	Inventory management, record keeping, medical records, RDU monitoring, ADR monitoring, record keeping for auditing purposes – all systems need to be strengthened. Lack of availability of inventory records in the storeroom at PRDH is an absolute constraint to introducing ARVs into that facility.	<ul style="list-style-type: none"> <li>• TAP to provide technical assistance to four sites to look at training needs, system needs, resource needs to strengthen PMIS for all components of the pharmaceutical management system and for clinical management for ART program.</li> <li>• TAP to provide support to four sites to address needs to develop sustainable, feasible, replicable systems.</li> </ul>
<b>M&amp;E</b>	Limited availability of data for monitoring.	

**Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up  
Section C: Coast Provincial General Hospital (CPGH)**

Component	Limitations	Options/Recommendations
<b>Infrastructure/ Equipment</b>	Indented counseling window for privacy needed. Space/arrangement not conducive to confidential counseling.	<ul style="list-style-type: none"> <li>• Improvements needed are feasible and low cost and can probably be funded by site.</li> <li>• Services provided at pharmacy windows needs to be reorganized (open up one more window) to improve patient flow and to facilitate confidentiality/quality of counseling.</li> </ul>
	Inefficient system at pharmacy window.	
	Secured cupboard next to CD cupboard in secured area needed to store ARV bulk stock.	
	Secured cupboard in dispensary for working ARV stock needed.	
	Bars on window to pharmacy office and strengthening of doors needed.	
	Lock on back door which can allow access to dispensary staff needed	
	Poor ventilation – needs to be improved.	
	General maintenance needed – e.g. replace non-functioning fluorescent lights.	
	Stand-alone computers available but need to be upgraded, linked to a network and software.	<ul style="list-style-type: none"> <li>• Incorporate as part of strategy to strengthen PMIS.</li> </ul>
<b>Human Resources – Staffing Levels</b>	Facility still needs three more pharmaceutical technologists (posts are reported to be vacant due to hiring freeze). Anecdotal reports of high pharmacist turnover due to low salaries relative to private sector. However staffing levels are adequate to support start up of ART program if ARVs are dispensed from main pharmacy.	<ul style="list-style-type: none"> <li>• Loss of pharmacists to the private sector has been a problem in the past. Services should be provided from the main pharmacy at current staff levels for sustainability and efficiency.</li> <li>• Hiring freeze in the public sector will probably constrain ultimate scale up of ART program.</li> </ul>
<b>Pharmaceutical Management - Availability</b>	Some problems with availability of HIV-related essential medicines observed. <i>Indicator:</i> ➤ <i>Average percent of time out of stock for a set of tracer medicines in storage and health facilities = 9.21% (n=16)</i>	<ul style="list-style-type: none"> <li>• Pharmaceutical management system needs to be strengthened through interventions described previously and will need ongoing monitoring of impact of interventions.</li> <li>• Quality committee/group can play a key role in monitoring performance of pharmaceutical management system</li> </ul>
<b>Distribution – Inventory Management</b>	Some problems with inventory management observed. <i>Indicator:</i> ➤ <i>Inventory stock records exist and available = Yes</i> ➤ <i>Average percent of stock records that correspond with physical counts for a set of tracer medicines in storage and health facilities = 47.1% (n=17)</i>	

**Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up  
Section D: Port Reitz District Hospital (PRDH)**

<b>Component</b>	<b>Limitations</b>	<b>Options/Recommendations</b>
<b>Pharmaceutical Management - Availability</b>	Problems with availability of HIV-related essential medicines perceived but unable to quantify as record cards unavailable.	<ul style="list-style-type: none"> <li>Pharmaceutical management system needs to be strengthened through interventions described previously and will need ongoing monitoring of impact of interventions.</li> <li>A quality committee/group needs to be established for auditing purposes and also to play a key role in monitoring performance of pharmaceutical management system.</li> </ul>
<b>Monitoring and Evaluation</b>	Quality committee irregular in monitoring and enforcement is limited.	
<b>Component</b>	<b>Major Constraints</b>	<b>Options/Recommendations</b>
<b>Infrastructure/ Equipment</b>	Major renovations currently underway funded by DANIDA but pharmacy is not scheduled for renovation until next year. Pharmacy is in some disrepair and would require renovations/ alterations (e.g. secured cupboards) that could be done as part of a major refit.	<ul style="list-style-type: none"> <li>Include pharmacy in first stage of renovations.</li> <li>Can be addressed as part of major renovations and refit of pharmacy.</li> </ul>
	Poor ventilation in pharmacy – cooling system inadequate.	
	Secured cupboards needed for ARV bulk storage and working stock. Shelving/storage space needs to be improved.	
	Pharmacy window does not allow for confidential counseling – would need to be rebuilt/ or counseling area nearby to be identified.	<ul style="list-style-type: none"> <li>New pharmacy storeroom should be assessed for adequacy for ART program once medicines have been transferred and management of the store established.</li> <li>Needs to be addressed as part of an overall plan of improving access to services at PRDH.</li> </ul>
	Transitional pharmacy storeroom inadequate, not secure, very hot, poor ventilation, no electricity, roof leaks, and record keeping poor. The storeroom is to be relocated as part of refit and put under new management shortly – will need to be reassessed after refit/move.	
	Very bad access road – especially in rainy season. Limited public transport.	
<b>Human Resources – Staffing Levels</b>	One pharmaceutical technologist and one pharmacy assistant – staffing inadequate to support start up of ART program due to hiring freeze.	<ul style="list-style-type: none"> <li>Current staffing levels are a major constraint to setting up ART program and to ultimate scale up of the program.</li> </ul>
	Patient counseling inadequate partly due to staff shortages.	

<b>Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up</b>		
<b>Section D: Port Reitz District Hospital (PRDH)</b>		
<b>Component</b>	<b>Major Constraints</b>	<b>Options/Recommendations</b>
<b>Quantification</b>	Stock records for quantification and monitoring scale up of ART program are lacking.	<ul style="list-style-type: none"> <li>• Inventory record keeping in the new storeroom should be restarted using new stock cards.</li> <li>• Training in inventory management and record keeping is essential for storekeeper.</li> <li>• Record keeping should be re-evaluated after a length of time (6 months) to assess quality of record keeping to assure the constant availability of ARVs and other essential HIV/AIDS-related medicines.</li> <li>• Internal and external auditing procedures should be set up.</li> <li>• A quality committee/group needs to be established to monitor the performance of pharmaceutical management system.</li> </ul>
	Lack of computerized PMIS for quantification and monitoring scale up of ART program.	
	Pharmacy staff not involved in quantification of needs.	
	Lack of experience/training for complex quantification.	
<b>Distribution – Inventory Management</b>	Poor inventory management of storeroom. Unable to locate stock records and stock is piled up on floor waiting to be unpacked and entered. Impossible to carry out any kind of record review in storeroom.	
	No regular internal or external auditing of storeroom stock.	

**Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up  
Section E: Magongo Municipal Clinic**

Component	Limitations	Options/Recommendations
<b>Distribution – Inventory Management</b>	Poor inventory management of storeroom. <i>Indicators:</i> ➤ <i>Inventory stock records exist and available = YES</i> ➤ <i>Average percent of stock records that correspond with physical counts for a set of tracer medicines in storage and health facilities = 37.5% (n=8)</i>	<ul style="list-style-type: none"> <li>Pharmaceutical management system needs to be strengthened through interventions described previously and will need ongoing monitoring of impact of interventions.</li> <li>A quality committee/group needs to be established for auditing purposes and to play a key role in monitoring performance of pharmaceutical management system.</li> </ul>
<b>Use - Dispensing</b>	No tablet envelopes available – staff make own from used paper.	
<b>M&amp;E</b>	No Quality committee reported to exist.	
Component	Major Constraints	Options/Recommendations
<b>Infrastructure/ Equipment</b>	Clinic is in a general state of disrepair – maintenance is poor/non-existent with staff using own funds for repair of lock on front door. Would be difficult to assure on-going security. No grills on windows except pharmacy.	<ul style="list-style-type: none"> <li>Given that the municipal clinics are key to scaling up access to ARVs, stakeholders will need to discuss options to address these major constraints related to infrastructure, staffing levels and lack of availability of medicines from the municipal council if Magongo is representative of municipal clinics.</li> <li>Options could include discussion of a “mobile clinic” that could provide services at a number of municipal clinics.</li> </ul>
	No fans are working. No plug for refrigerator. No water – has been disconnected.	
	Inadequate storage space in bulk store (if all medicines were in stock). Secured cupboards needed for bulk stock and working stock.	
	Pharmacy window does not allow for confidential counseling – would need to be rebuilt/ or counseling area nearby to be identified.	
<b>Human Resources – Staffing Levels</b>	Enrolled nurse/dispenser disheartened by poor working conditions, delays in receiving salary.	
	General reluctance of staff to take on additional duties without increase in pay.	
	May be inadequate – depending on work load for ART program.	
	Difficult to recruit staff.	
	City council is retrenching staff.	
<b>Pharmaceutical Management - Availability</b>	Very poor availability of HIV-related essential medicines <i>Indicator:</i> ➤ <i>Average percent of time out of stock for a set of tracer medicines in storage and health facilities = 74.2% (n=6)</i>	
<b>Quantification</b>	Lack of experience/training for complex quantification.	

**Table 2: Options/Recommendations to Address Limitations/Constraints to ART Program Start Up  
Section F: Bomu Clinic**

Component	Limitations	Options/Recommendations
<b>Infrastructure/ Equipment</b>	Secured cupboard in secured area needed.	<ul style="list-style-type: none"> <li>• Improvements needed are feasible and low cost and can probably be funded by site.</li> </ul>
	Secured cupboard in dispensary for working stock needed.	
	Setting up of a private counseling area needed – area has been identified.	
	Small office space for pharmacy-in-charge needed.	
	Networked, relatively sophisticated computer system available. Add capacity for real-time management of pharmacy inventory stock to existing software.	
<b>Pharmaceutical Management - Availability</b>	<p>Some problems with availability of HIV-related essential medicines</p> <p><i>Indicator:</i></p> <p style="padding-left: 20px;">➤ <i>Average percent of time out of stock for a set of tracer medicines in storage and health facilities = 19.16% (n=14)</i></p>	<ul style="list-style-type: none"> <li>• Pharmaceutical management system needs to be strengthened through interventions described previously and will need ongoing monitoring of impact of interventions.</li> <li>• Quality committee can play a key role in monitoring performance of pharmaceutical management system.</li> </ul>
<b>Other</b>	Problems with referral of patients – patients referred to CPGH often get lost in system.	<ul style="list-style-type: none"> <li>• Need to have a named person or place at CPGH to refer patients for ART program.</li> </ul>

**Table 3: Capacity of the Pharmaceutical Management System to Support ART Program Scale Up  
Section A: Overarching Issues for All Four Sites – Initial Findings for Comment**

Strengths/Opportunities	Limitations	Major Constraints
<p><b>POLICIES, LEGISLATION, REGULATION</b></p> <ul style="list-style-type: none"> <li>• National STGs for ART and monitoring of ARVs exist.</li> <li>• At least one brand of all ARV preparations on national ART guidelines are registered.</li> <li>• National VCT guidelines exist.</li> <li>• Directive from the Director of Medical Services to set up ART centers in each province issued September 2002.</li> </ul>	<p><b>POLICIES, LEGISLATION, REGULATION</b></p> <ul style="list-style-type: none"> <li>• National policies on dispensing/prescribing ARVs do not exist.</li> <li>• National/local STGs for OIs and palliative care do not exist.</li> <li>• ARVs and many medicines for prophylaxis/treatment of OIs not on EDL.</li> </ul> <p><b>DRUG INFORMATION</b></p> <ul style="list-style-type: none"> <li>• National Drug Information Centre reported to exist but not yet functional.</li> <li>• No local network exists.</li> </ul> <p><b>ADR MONITORING AND REPORTING</b></p> <ul style="list-style-type: none"> <li>• National system to monitor and report on ADRs reported to exist but not yet functional.</li> <li>• Regional/local system to monitor and report on ADRs not functional.</li> </ul> <p><b>HMIS</b></p> <ul style="list-style-type: none"> <li>• National system to monitor resistance to ARVs does not exist.</li> </ul> <p><b>AVAILABILITY</b></p> <ul style="list-style-type: none"> <li>• Fluconazole not yet available through Axios donation program.</li> </ul> <p><b>TRAINING OF PHARMACY STAFF</b></p> <ul style="list-style-type: none"> <li>• Staff have received limited pre-service training of pharmacy staff in relevant clinical management of HIV/AIDS.</li> <li>• Staff have received limited pre-service training of pharmacy staff in pharmaceutical management.</li> <li>• Pharmaceutical technologists and pharmacists belong to different professional organizations – pharmaceutical technologists do not have access to PSK training.</li> <li>• Lack of agreement over roles and responsibilities of pharmacy staff and prescribers constrain collaboration on training/keeping updated.</li> </ul> <p><b>COST RECOVERY</b></p> <ul style="list-style-type: none"> <li>• Fees, exemptions, systems, retention of cost sharing fees vary across four facilities – no consensus.</li> <li>• Proposed bill to abolish cost-sharing pending approval.</li> </ul>	

**Table 3: Capacity of the Pharmaceutical Management System to Support ART Program Scale Up  
Section B: Coast Provincial General Hospital (CPGH) – Initial Findings for Comment**

<b>Strengths/ Opportunities</b>	<b>Limitations</b>	<b>Major Constraints</b>
<p><b>INFRASTRUCTURE / EQUIPMENT</b></p> <ul style="list-style-type: none"> <li>• Pharmacy storeroom               <ul style="list-style-type: none"> <li>➢ Bulk store is relatively secure</li> </ul> </li> </ul>	<p><b>INFRASTRUCTURE/ EQUIPMENT</b></p> <ul style="list-style-type: none"> <li>• Pharmacy storeroom               <ul style="list-style-type: none"> <li>➢ Poor ventilation</li> <li>➢ Lack of pallets</li> <li>➢ Needs cleaning and general maintenance</li> <li>➢ No refrigerators</li> <li>➢ Secure area to store ARVs will be needed</li> </ul> </li> </ul> <p><b>HUMAN RESOURCES – STAFFING LEVELS</b></p> <ul style="list-style-type: none"> <li>• Depending on extent of scale up more staff will be needed.</li> <li>• Currently still need three more pharmaceutical technologists but unable to recruit due to hiring freeze.</li> <li>• Anecdotal reports of high pharmacist turnover due to low salaries relative to private sector.</li> </ul> <p><b>HUMAN RESOURCES – TRAINING</b></p> <ul style="list-style-type: none"> <li>• System is needed to provide ongoing updates/training of existing/new staff in HIV/AIDS and pharmaceutical management and RDU.</li> </ul> <p><b>QUANTIFICATION</b></p> <ul style="list-style-type: none"> <li>• Lack of experience/training for complex quantification.</li> <li>• Lack of computerized HMIS for quantification and monitoring scale up of ART program.</li> </ul> <p><b>QUALITY</b></p> <ul style="list-style-type: none"> <li>• No system exists to monitor performance of suppliers.</li> </ul> <p><b>DISTRIBUTION – TRANSPORTATION</b></p> <ul style="list-style-type: none"> <li>• Pharmacy does not have own vehicle for pick up.</li> </ul> <p><b>USE - PRESCRIBING</b></p> <ul style="list-style-type: none"> <li>• Lack of medical records makes it difficult to monitor RDU.</li> </ul> <p><b>PMIS</b></p> <ul style="list-style-type: none"> <li>• Inventory management, record keeping, medical records, RDU monitoring, ADR monitoring – all systems need strengthening.</li> </ul>	<p><b>SELECTION</b></p> <ul style="list-style-type: none"> <li>• Lack of information for decision-making.</li> </ul> <p><b>PROCUREMENT</b></p> <ul style="list-style-type: none"> <li>• Local bulk purchases – take too long and under the direct control of supply office not pharmacy.</li> <li>• Local purchase order ceiling of KSh 10,000 is inadequate.</li> <li>• 3 quotations for local purchase order needed.</li> <li>• KEMSA operates a push system. Need pull system for ARVs.</li> </ul>

**Table 3: Capacity of the Pharmaceutical Management System to Support ART Program Scale Up  
Section C: Port Reitz District Hospital (PRDH) – Initial Findings for Comment**

<b>Strengths/ Opportunities</b>	<b>Limitations</b>	<b>Major Constraints</b>
<p><b>OTHER</b></p> <ul style="list-style-type: none"> <li>Integral part of referral system.</li> </ul>	<p><b>HUMAN RESOURCES – TRAINING</b></p> <ul style="list-style-type: none"> <li>System is needed to provide ongoing updates/training of existing/new staff in HIV/AIDS and pharmaceutical management and RDU.</li> </ul> <p><b>DISTRIBUTION – TRANSPORTATION</b></p> <ul style="list-style-type: none"> <li>Pharmacy does not have own vehicle for pick up.</li> <li>Hospital transportation hampered by lack of fuel and shortage of drivers.</li> </ul> <p><b>USE - PRESCRIBING</b></p> <ul style="list-style-type: none"> <li>Lack of medical records makes it difficult to monitor RDU.</li> </ul> <p><b>PMIS</b></p> <ul style="list-style-type: none"> <li>Inventory management, record keeping, medical records, RDU monitoring, ADR monitoring – all systems need strengthening.</li> </ul>	<p><b>HUMAN RESOURCES – STAFFING LEVELS</b></p> <ul style="list-style-type: none"> <li>Acute shortage of pharmacy staff.</li> <li>Hiring freeze.</li> <li>Anecdotal reports – high pharmacist turnover due to low salaries relative to private sector.</li> </ul> <p><b>SELECTION</b></p> <ul style="list-style-type: none"> <li>Pharmacy is not involved in decision-making about what to procure and where.</li> <li>Lack of information for decision-making.</li> </ul> <p><b>PROCUREMENT</b></p> <ul style="list-style-type: none"> <li>Local bulk purchases – take too long and under the control of supply office.</li> <li>Local purchase order has ceiling of KSh 10,000 – inadequate.</li> <li>Three quotations needed for local purchase order.</li> <li>Pharmacy is not involved in decision-making about what to procure, how much and where from.</li> <li>KEMSA operates a push system. Need pull system for ARVs.</li> </ul> <p><b>QUANTIFICATION</b></p> <ul style="list-style-type: none"> <li>Lack of stock records for quantification.</li> <li>Lack of computerized HMIS for quantification and monitoring scale up of ART program.</li> <li>Pharmacy staff not involved in quantification of needs.</li> <li>Lack of experience/training for complex quantification.</li> </ul> <p><b>DISTRIBUTION – INVENTORY MANAGEMENT</b></p> <ul style="list-style-type: none"> <li>Poor inventory management of storeroom. Unable to locate stock records and stock is piled up on floor waiting to be unpacked and entered.</li> </ul>

**Table 3: Capacity of the Pharmaceutical Management System to Support ART Program Scale Up  
Section D: Magongo Municipal Clinic – Initial Findings for Comment**

<b>Strengths/ Opportunities</b>	<b>Limitations</b>	<b>Major Constraints</b>
<p><b>OTHER</b></p> <ul style="list-style-type: none"> <li>• Geographical accessibility of municipal clinics can facilitate scale up of program in long term.</li> </ul>	<p><b>HUMAN RESOURCES – TRAINING</b></p> <ul style="list-style-type: none"> <li>• System is needed to provide ongoing updates/training of existing/new staff in HIV/AIDS and pharmaceutical management and RDU.</li> </ul> <p><b>QUANTIFICATION</b></p> <ul style="list-style-type: none"> <li>• Medicines are supplied to Magongo through a push system.</li> <li>• Lack of computerized HMIS for quantification and monitoring scale up of ART program.</li> <li>• Lack of experience/training for complex quantification.</li> </ul> <p><b>DISTRIBUTION – TRANSPORTATION</b></p> <ul style="list-style-type: none"> <li>• Facility does not have its own vehicle for pick up.</li> </ul> <p><b>USE - PRESCRIBING</b></p> <ul style="list-style-type: none"> <li>• Lack of medical records makes it difficult to monitor RDU.</li> </ul> <p><b>PMIS</b></p> <ul style="list-style-type: none"> <li>• Inventory management, record keeping, medical records, RDU monitoring, ADR monitoring – all systems need strengthening.</li> </ul>	<p><b>HUMAN RESOURCES – STAFFING LEVELS</b></p> <ul style="list-style-type: none"> <li>• Disheartened staff – poor working conditions, delays in receiving salaries.</li> <li>• General reluctance of staff to take on additional duties without increase in pay.</li> <li>• Staffing inadequate for scale up– depending on work load for ART program.</li> <li>• Difficult to recruit staff.</li> <li>• City council is retrenching staff.</li> </ul> <p><b>SELECTION</b></p> <ul style="list-style-type: none"> <li>• Not known who makes decisions about what to procure and where.</li> </ul> <p><b>PROCUREMENT</b></p> <ul style="list-style-type: none"> <li>• Availability of supplies from city council unreliable – major stock outs over last year.</li> </ul>

**Table 3: Capacity of the Pharmaceutical Management System to Support ART Program Scale Up  
Section E: Bomu Clinic – Initial Findings for Comment**

<b>Strengths/Opportunities</b>	<b>Limitations</b>	<b>Major Constraints</b>
<p><b>PROCUREMENT</b></p> <ul style="list-style-type: none"> <li>• Procurement fast and reliable.</li> <li>• Can procure ARVs from Mission for Essential Drugs and Supplies (MEDS).</li> </ul>	<p><b>HUMAN RESOURCES – STAFFING LEVELS</b></p> <ul style="list-style-type: none"> <li>• Staffing may be inadequate for scale up– depending on work load for ART program.</li> </ul> <p><b>HUMAN RESOURCES – TRAINING</b></p> <ul style="list-style-type: none"> <li>• System is needed to provide ongoing updates/training of existing/new staff in HIV/AIDS and pharmaceutical management and RDU.</li> </ul> <p><b>QUANTIFICATION</b></p> <ul style="list-style-type: none"> <li>• Lack of computerized HMIS for quantification and monitoring scale up of ART program.</li> <li>• Lack of experience/training for complex quantification</li> </ul> <p><b>MIS</b></p> <ul style="list-style-type: none"> <li>• Inventory management, record keeping, medical records, RDU monitoring, ADR monitoring – all systems need strengthening.</li> </ul> <p><b>OTHER</b></p> <ul style="list-style-type: none"> <li>• Problems with referral of patients – patients get lost in system when referred to CPGH.</li> </ul>	<p><b>SELECTION</b></p> <ul style="list-style-type: none"> <li>• Lack of information for decision-making.</li> </ul>



## ASSESSMENT OF LABORATORY CAPACITY TO SUPPORT THE INTRODUCTION OF ART AT FOUR SITES

The objective of the assessment conducted from September 2 to 29, 2002 was to assess the capacity of the laboratory services at four sites—CPGH, PRDH, Magongo Municipal Clinic and Bomu (Mkomani) Clinic—to support the safe and effective use of ART.

The initial findings of the assessment of the laboratory capacity at the four sites to support the introduction of ART are presented in the following table together with initial recommendations for comment. Some additional data on the functioning of equipment and stock outs was collected during follow on visits to the sites in early 2003. The findings and recommendations are organized as follows—

- Section A: Overarching issues that apply to all four sites
- Section B: CPGH
- Section C: PRDH
- Section D: Magongo Municipal Clinic
- Section E: Bomu Clinic

These initial findings and options/recommendations are presented as *drafts for comment* and are to be reviewed with the staff from each site.

### Key Considerations

The key considerations reported on in this evaluation are—

- Normative (standards) – policies, standard operating procedures (SOPs), and guidelines
- Capacity
  - Infrastructure – structural and equipment
  - Human resources – staffing levels and training
  - Systemic – how well the laboratory systems are functioning and capacity to support the introduction of the ART program
    - Referral system for specimens and return of results
    - Selection, procurement, distribution of reagents and equipment
    - Management information systems and record keeping
    - Good laboratory practice
    - Quality control procedures
    - Quality control, monitoring and evaluation
    - Financing, including cost sharing
- Variables reported on—
  - Availability and functionality of equipment for—
    - Blood sample collection
    - HIV diagnosis
    - Hematology

- Clinical chemistry - renal function and liver function tests (LFT)
- Microbiology
- CD4
- Viral load
- Preparation and storage of samples for viral resistance

**Assessment of Laboratory Capacity to Support the Introduction of ART**

**Section A: Overarching Issues that Apply to All Four Sites – Initial Findings and Recommendations for Comment**

<b>Policies/ Procedures</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ National STGs for ART and monitoring of ARVs exist.</li> <li>▪ National VCT guidelines exist.</li> <li>▪ National OI guidelines exist.</li> <li>▪ Directive from the Director of Medical Services to set up ART centers in each province issued September 2002.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Kenya does not currently have SOPs for laboratory at provincial level.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Site-specific/ART program specific SOPs will need to be developed as national SOPs are not available. SOPs should include preventive maintenance for existing equipment.</li> </ul>	
<b>Human Resources – Staffing</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ The Chief Pathologist at CPGH is the Chairman of the Scientific Committee for the ART program. Can act as lead resource person for the program and provide local oversight for implementation, including supervision and guidance for the laboratory coordinator for the program. He currently provides technical oversight and assistance to PRDH and Magongo Municipal Clinic.</li> <li>▪ The laboratory supervisor at CPGH can act as coordinator for the ART program and provide assistance to the other three sites initially, until the program scales up.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ A laboratory coordinator will need to be identified preferably from CPGH and MOH for the program – initially can be part of existing duties but may need to be a part time post as the program scales up. Duties will include coordinating training, monitoring and evaluation of laboratory performance for ART program.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Scientific Committee/CPGH/TAP to identify duties and responsibilities of ART program laboratory coordinator.</li> <li>▪ Establish the laboratory supervisor at CPGH as the laboratory coordinator for the ART program initially, until the program scales up. The laboratory coordinator for the ART program can be supported by CPGH Chief Pathologist on a day-to-day basis.</li> <li>▪ A part/full time laboratory coordinator position may need to be established as the ART program scales up. Workload should be reviewed annually.</li> <li>▪ Develop terms of reference and identify an external laboratory specialist to provide technical assistance and external evaluation of laboratory performance for ART program.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section A: Overarching Issues that Apply to All Four Sites – Initial Findings and Recommendations for Comment</b>		
<b>Human Resources - Training</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Laboratory staff have received training in performing HIV testing at all four sites.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Laboratory staff need immediate and ongoing training for ART program. Ongoing training must be flexible and appropriate.</li> <li>▪ Prioritize training in general HIV/AIDS and ART management, laboratory monitoring for ART, quantification, inventory management, principles of Good Laboratory Management and QA/quality control (QC) procedures.</li> <li>▪ Include training on ELISA.</li> <li>▪ Site-specific training will be needed as new equipment technologies are introduced.</li> <li>▪ One person needs to be identified as the key resource person for training. Responsibilities will be to coordinate trainings, keep records of persons trained and to participate as a trainer.</li> <li>▪ An information/reference center is needed to keep laboratory staff and clinicians updated.</li> <li>▪ It was reported that some doctors ask laboratory staff to give patient HIV test results but laboratory staff lack training in counseling.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Develop site-specific and ART program-specific curriculum and training materials for lab training.</li> <li>▪ Initial training should address priority issues and allow team training by cadre and also by site for team building.</li> <li>▪ Develop a plan for ongoing training to include site-specific training as new equipment technologies are introduced.</li> <li>▪ One person needs to be identified as the key resource person for training. Responsibilities will be to coordinate trainings, keep records of person trained and to participate as a trainer.</li> <li>▪ Set up an information/reference center is needed to keep laboratory staff and clinicians updated in developments in laboratory monitoring for ART.</li> <li>▪ Ensure staff follow standard procedures for releasing VCT results to clients - HIV results should be released by requesting clinician/counselor. Prepare standard sets of responses for laboratory staff.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section A: Overarching Issues that Apply to All Four Sites – Initial Findings and Recommendations for Comment</b>		
<b>Capacity to perform laboratory monitoring other than CD4/viral load</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Sufficient capacity exists initially between the four sites to perform testing for the program for HIV diagnosis, complete blood count (CBC)/ total lymphocyte count (TLC), renal function (urea, creatinine, electrolytes, anion gap), LFT (including bilirubin, creatine phosphokinase [CPK]), amylase, lipid profile (triglycerides, cholesterol, high-density lipoproteins [HDL], low-density lipoproteins [LDL]), serum lactate, anion gap, serum glucose.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ As the program scales up, additional equipment may be needed at PRDH to strengthen capacity in the referral chain. See report for PRDH for list of equipment needs.</li> <li>▪ Back up arrangements need to be put in place for all four sites in case of equipment failure.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Review the capacity of each site to perform laboratory monitoring for ART program, three monthly for one year after introduction of ART program then annually.</li> <li>▪ SOP/forms will need to be developed for referral of patients/samples and return of results for tests which cannot be performed onsite.</li> <li>▪ Back up arrangement for equipment failure:                             <ul style="list-style-type: none"> <li>○ CPGH to provide back up for PRDH.</li> <li>○ Bomu Clinic to sign memorandum of understanding with private hospital if possible. Look at feasibility of agreement with CPGH.</li> <li>○ Investigate feasibility of PRDH providing back up to Magongo Municipal Clinic</li> <li>○ CPGH to investigate feasibility of signing a memorandum of understanding with a local private hospital for reciprocal back up for biochemistry and haematology.</li> </ul> </li> <li>▪ Also see site specific recommendations</li> </ul>	
<b>Capacity to perform CD4</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Two private hospitals in Mombasa have CD4 technologies available that are not currently working at full capacity. Aga Khan Hospital has a Partek CyFlow machine and Mombasa Hospital has a FacsCount machine.</li> <li>▪ GOK will make CD4 technology available at Provincial Hospitals. Director of Medical Services has approved Partek CyFlow as the CD4 technology (March 2003).</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Capacity at the four sites to monitor CD4 counts for the program is insufficient – estimated number of CD4 tests for 300 patients for 5 years is approximately 5050 tests.</li> <li>▪ One site (CPGH) currently performs CD4 monitoring using a manual system (chamber counting) and which could be used during the start up phase. CPGH also has a FacsCount machine and is soon to have Dynabead technology for research purposes. Both are unavailable to GOK/USAID program.</li> <li>▪ CD4 samples must be analyzed within 24 hours.</li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>			
<b>Section A: Overarching Issues that Apply to All Four Sites – Initial Findings and Recommendations for Comment</b>			
<b>Capacity to perform CD4 (continued)</b>	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ FHI/IMPACT to procure Partek in line with GOK policy. CPGH Chief Pathologist and RPM Plus consultant to advise on conditions included in procurement contract.</li> <li>▪ In the interim, CD4 testing can be contracted out to either Mombasa Hospital (FacsCount) or Aga Khan Hospital, (Partek CyFlow). Also FHI/IMPACT to negotiate with manufacturer for a loan of Partek equipment.</li> <li>▪ SOPs/forms will need to be developed for referral of patients/samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ Laboratory coordinator to be responsible for managing CD4 testing referral system.</li> </ul>		
<b>Capacity to perform viral load</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;"> <p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ GOK is planning to procure four viral load technologies using reverse transcriptase polymerase chain reaction (RT-PCR) methods – one will be based in Mombasa at CPGH.</li> </ul> </td> <td style="width: 50%; vertical-align: top;"> <p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ No capacity exists to perform viral load at four sites or in Mombasa. Viral load testing is available in Nairobi.</li> <li>▪ Estimated number of viral load tests for 300 patients for 5 years is approximately 55 tests.</li> <li>▪ Biological safety cabinet is needed for preparing samples for viral load testing off site to prevent sample-to-sample contamination. Two are available for research purposes – may be possible to share.</li> <li>▪ Blood samples need to be centrifuged to separate plasma which should be collected in EDTA tubes. May need both plasma and peripheral blood mononuclear cell (PBMC) for viral load and viral resistance testing respectively.</li> </ul> </td> </tr> </table> <p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Scientific Committee and TAP to select a site to contract out viral load testing to – should be set up before ART program begins although samples can be frozen for later testing if necessary. Site should use RT-PCR methodology in line with GOK procurement.</li> <li>▪ CPGH to use existing biological safety cabinet for preparing samples for viral load testing.</li> <li>▪ Ensure EDTA tubes for both plasma and PBMC for viral load and viral resistance testing respectively are available.</li> <li>▪ SOP/forms will need to be developed for referral of samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ Laboratory coordinator to be responsible for managing viral load testing referral system.</li> </ul>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ GOK is planning to procure four viral load technologies using reverse transcriptase polymerase chain reaction (RT-PCR) methods – one will be based in Mombasa at CPGH.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ No capacity exists to perform viral load at four sites or in Mombasa. Viral load testing is available in Nairobi.</li> <li>▪ Estimated number of viral load tests for 300 patients for 5 years is approximately 55 tests.</li> <li>▪ Biological safety cabinet is needed for preparing samples for viral load testing off site to prevent sample-to-sample contamination. Two are available for research purposes – may be possible to share.</li> <li>▪ Blood samples need to be centrifuged to separate plasma which should be collected in EDTA tubes. May need both plasma and peripheral blood mononuclear cell (PBMC) for viral load and viral resistance testing respectively.</li> </ul>
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<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section A: Overarching Issues that Apply to All Four Sites – Initial Findings and Recommendations for Comment</b>		
<b>Capacity to prepare and store samples for viral resistance testing (participation in WHO/GOK surveillance)</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Although national system to monitor resistance to ARVs does not currently exist, blood samples are to be collected by the ART program for the study on the surveillance of resistance to ARVs conducted by the WHO Network on the Surveillance of ART Resistance.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Capacity at the four sites to prepare and store blood samples for viral resistance testing at the end of the program may not be sufficient depending on the number of samples to be stored.</li> <li>▪ Blood samples need to be centrifuged to separate plasma which should be collected in EDTA tubes. May need both plasma and PBMC for viral load and viral resistance testing respectively</li> <li>▪ -80 degree freezer is needed for storage of samples. One is available in CPGH laboratory but only for research and has limited space available. Another -80 degree freezer is available in Blood Transfusion Unit located at CPGH – can be used for first year of program then reevaluate.</li> <li>▪ Biological safety cabinet is needed for preparing samples for viral resistance testing to prevent sample-to-sample contamination. One is available for research purposes – may be possible to share.</li> <li>▪ Liquid nitrogen with a jacket will be needed for transportation of samples for testing.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ All samples for future viral resistance testing are to be sent to CPGH</li> <li>▪ CPGH to follow up on whether existing -80 freezer and biological safety cabinet can be used for preparing samples for viral resistance testing for ART program.</li> <li>▪ Ensure EDTA tubes for both plasma and PBMC for viral load and viral resistance testing respectively are available.</li> <li>▪ SOP/forms will need to be developed for preparation, storage and eventual transportation of samples. Should be based on existing procedures/forms where possible.</li> </ul>	
<b>Referral system and return of results of specimens</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ System exists for referral of samples in all three GOK facilities.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Lack of staff to manage referral.</li> <li>▪ Lack of transport to transfer samples.</li> <li>▪ Lack of communication for results – email and telephone.</li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>			
<b>Section A: Overarching Issues that Apply to All Four Sites – Initial Findings and Recommendations for Comment</b>			
<b>Referral system and return of results of specimens (continued)</b>	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Establish a procedure/system for referring patients/transporting samples between the four sites for central testing and a system for delivering/returning of test results from central laboratories to patient records.</li> <li>▪ Need to establish procedure/system for transporting samples that are to be tested externally and a system for delivering/returning of test results to patient records.</li> <li>▪ Investigate setting up email communication between CPGH and PRDH with Bomu and Magongo Municipal Clinics collecting results from PRDH – need to look at feasibility and issues of confidentiality.</li> </ul>		
<b>Management Information System (MIS)</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;"> <p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Records department exists at PRDH and CPGH with some computerization at CPGH</li> </ul> </td> <td style="width: 50%; vertical-align: top;"> <p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ ART program will need laboratory request and report forms that fit the repertoire of each laboratory.</li> <li>▪ Need to set up a laboratory report form with cumulated laboratory results in each patient’s medical record file.</li> <li>▪ Shortages of data entry clerks.</li> </ul> </td> </tr> </table>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Records department exists at PRDH and CPGH with some computerization at CPGH</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ ART program will need laboratory request and report forms that fit the repertoire of each laboratory.</li> <li>▪ Need to set up a laboratory report form with cumulated laboratory results in each patient’s medical record file.</li> <li>▪ Shortages of data entry clerks.</li> </ul>
	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Records department exists at PRDH and CPGH with some computerization at CPGH</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ ART program will need laboratory request and report forms that fit the repertoire of each laboratory.</li> <li>▪ Need to set up a laboratory report form with cumulated laboratory results in each patient’s medical record file.</li> <li>▪ Shortages of data entry clerks.</li> </ul>	
<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Scientific Committee/TAP/sites to develop laboratory request and report forms, including cumulated laboratory results form for patient records for ART program. Forms should be based on existing forms where possible.</li> <li>▪ Strengthen HMIS of CPGH generally – clinical and diagnostic.</li> </ul>			

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section A: Overarching Issues that Apply to All Four Sites – Initial Findings and Recommendations for Comment</b>		
<b>Quality Control/ M&amp;E</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Chief Pathologist at CPGH is the Chairman of the Scientific Committee for the program. Can act as lead resource person for the program and provide local oversight for implementation, including supervision and guidance for the laboratory coordinator for the program. He currently provides technical oversight and assistance to PRDH and Magongo Municipal Clinic. In addition, he currently provides oversight and technical assistance informally to Bomu Clinic.</li> <li>▪ The laboratory supervisor at CPGH can act as laboratory coordinator for the ART program and provide technical assistance to the other three sites initially, until the program scales up.</li> <li>▪ External QC system is currently in place for HIV testing performed at Bomu and Magongo clinics. In addition, PRDH receives unstained TB slides for QC.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Internal QA/Good Laboratory Practice needs to be reviewed and strengthened in all four sites.</li> <li>▪ Documented daily QC needs to be established for all routine tests performed.</li> <li>▪ Need to set up a system for external evaluation of laboratory performance in all four sites.</li> <li>▪ Need to plan for interim analysis – mid-program evaluation.</li> <li>▪ Budget for QA/QC can be significant.</li> <li>▪ Establishing QA/QC may require training of staff.</li> <li>▪ No accident/incident registers are kept in any of the sites.</li> <li>▪ No postexposure prophylaxis [for HIV] (PEP) reported to be available in three sites.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Establish a system to perform documented internal QC for each parameter daily for the first month. Thereafter check different parameters every day resulting in at least weekly check for each parameter to reduce costs.</li> <li>▪ Need to identify financial resources to set up a QA/QC system – could require significant resources.</li> <li>▪ Develop/adapt existing SOPs that are site-specific for QC/QA to include actions to be taken if QC problems occur.</li> <li>▪ Local laboratory coordinator should be responsible for Good Laboratory Practice and for reviewing QC in all four sites for ART program. Oversight to be provided by CPGH Chief Pathologist.</li> <li>▪ CPGH should establish and manage an external QC program to submit to other sites. Arrangements should be made to obtain samples from national/international sources.</li> <li>▪ Develop terms of reference and identify an external laboratory specialist to monitor overall laboratory performance for the ART program.</li> <li>▪ Perform external evaluation of performance during the training phase prior to ART program start at each site.</li> <li>▪ Perform external evaluation after 3 months and then every 6 months throughout the ART program.</li> <li>▪ Training for laboratory staff should include QC and QA procedures and principles of Good Laboratory Practice.</li> <li>▪ Establish accident/incident register at all sites, especially for spills and needle stick injuries of hazardous materials.</li> <li>▪ Establish PEP in all sites.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section A: Overarching Issues that Apply to All Four Sites – Initial Findings and Recommendations for Comment</b>		
<b>Financing – cost sharing</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ All four sites have a cost sharing system that incorporates exemptions for those who cannot pay.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Fees, exemptions, systems, retention of cost sharing fees vary across four facilities.</li> <li>▪ The cost of laboratory monitoring for ART program as per Scientific Committee recommendations for monitoring response to ART together and for ADRs will be a considerable annual cost for patients. The sites may need additional support in order to provide exemptions for those who cannot afford to pay.</li> <li>▪ Estimated total cost to perform laboratory tests excluding CD4 and viral load for 300 patients for 5 years will be approx. 5,721,500KSh (approximately \$76,300) using current cost of tests at CPGH.</li> <li>▪ Estimated total number of CD4 tests to be performed for 300 patients for 5 years is 5045 (estimated total cost using 2000 KSh/test (cost per test in Kenya, April 2003) is 10,090,000KSh (approximately \$134,500).</li> <li>▪ Estimated total number of viral load tests to be performed for 300 patients for 5 years is 55 (estimated total cost using 7,500 KSh/test (cost per test in Kenya, April 2003) is 412,500KSh (approximately \$5,500).</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Sites/USAID/TAP to discuss the need to provide external support to program for laboratory monitoring.</li> <li>▪ Recalculate quantification of laboratory tests at 3 monthly intervals for first year based on actual numbers used.</li> <li>▪ Examine options to secure funding to ensure a constant supply of reagents for ART program.</li> <li>▪ Reach consensus on cost sharing for laboratory monitoring for four sites to ensure consistency and equity.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section B: Coast Provincial General Hospital (CPGH) – Initial Findings and Recommendations for Comment</b>		
<b>Policies and Procedures</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ National STGs for ART and monitoring of ARVs exist.</li> <li>▪ National VCT guidelines exist.</li> <li>▪ National OI guidelines exist.</li> <li>▪ Directive from the Director of Medical Services to set up ART centers in each province issued September 2002.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ No SOPs for laboratory exist.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ In line with GOK policy, set up CPGH as reference laboratory for ART program.</li> <li>▪ Ensure that updated copies of national ART guidelines, VCT and OI guidelines are available for use by all CPGH laboratory staff.</li> <li>▪ Develop site-specific SOPs for the ART program – adapt existing procedures/forms where possible. SOPs should include preventive maintenance for existing equipment.</li> <li>▪ Develop site-specific SOPs for all laboratory procedures – adapt existing procedures/forms where possible. SOPs should include preventive maintenance for existing equipment.</li> </ul>	
<b>Infrastructure/ Equipment</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Laboratory was renovated in 1999 with Japanese assistance.</li> <li>▪ No major renovation needed - can support start up of project with existing infrastructure.</li> <li>▪ Most of the laboratory equipment is new.</li> <li>▪ Has research facility – conducts research with many international groups.</li> <li>▪ Service contracts are reported to be operational for haematology and clinical chemistry (July 2003)</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Staff are not always diligent about wearing protective clothing – eye protection and white coats partly due to the heat in the laboratory – lack of air conditioning.</li> <li>▪ Servicing of equipment is not always performed regularly and service contracts are not always renewed promptly.</li> <li>▪ Autolab AMS has been out of order from January 2002 until July 2003 – problems with getting filters replaced under service contract.</li> <li>▪ Back up arrangements are not in place for all tests when equipment breaks down.</li> <li>▪ The result is that patients are either not tested or they are referred to private laboratories resulting in a much greater cost for patients.</li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section B: Coast Provincial General Hospital (CPGH) – Initial Findings and Recommendations for Comment</b>		
<b>Infrastructure/ Equipment (continued)</b>	<ul style="list-style-type: none"> <li>▪ Existing equipment:               <ul style="list-style-type: none"> <li>○ AT Coulter Counters (2)</li> <li>○ Photometer 5010</li> <li>○ Chiron Diagnostic 644 Na/Cl Analyzer</li> <li>○ Autolab AMS</li> <li>○ Glucometer</li> <li>○ Electrophoresis</li> <li>○ Gas analyzer</li> <li>○ Refrigerator</li> <li>○ -20C Freezer</li> <li>○ Revco Freezer in Blood Transfusion Unit (Revco Freezer for research samples is full)</li> <li>○ Incubator</li> <li>○ Refrigerated high-speed centrifuge</li> <li>○ Centrifuge</li> <li>○ Microscope</li> <li>○ Autoclave</li> <li>○ Sterilization Oven</li> <li>○ Stainer</li> <li>○ Sharps container</li> <li>○ Safety cupboard</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Essential equipment needed:               <ul style="list-style-type: none"> <li>○ Partek CyFlow (1)</li> <li>○ Multichannel pipettes (2)</li> <li>○ Precision pipette (2)</li> <li>○ Rotor (1)</li> </ul> </li> <li>▪ Other equipment needed:               <ul style="list-style-type: none"> <li>○ Consider upgrading Coulter counters to allow automatic generation of white blood count (WBC) differentials as program scales up.</li> <li>○ -80C Freezer if Revco Freezer in Blood Transfusion Unit cannot be used for storing samples for viral resistance testing (see below).</li> <li>○ Liquid Nitrogen with jacket to send samples for viral resistance testing at end of ART program.</li> </ul> </li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Procure essential equipment needed for ART Program</li> <li>▪ Improve air circulation in the laboratory – look at the feasibility of installing air conditioning unit.</li> <li>▪ Ensure that all procurement of equipment is linked to the signing of a maintenance contract.</li> <li>▪ Ensure that budgets include the renewal of maintenance contracts for equipment and that funds are made available.</li> <li>▪ Explore feasibility of establishing back up arrangements with private hospitals in Mombasa to provide reciprocal arrangements in case of equipment failure. CPGH to investigate the feasibility of signing a memorandum of understanding with a local private hospital laboratory for reciprocal back up for biochemistry and haematology.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section B: Coast Provincial General Hospital (CPGH) – Initial Findings and Recommendations for Comment</b>		
<b>Human Resources – Staffing</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Chief Pathologist at CPGH is the Chairman of the Scientific Committee for the program. Can act as lead resource person for the program and provide local oversight for implementation, including supervision and guidance for the laboratory coordinator for ART program. He currently provides technical oversight and assistance to PRDH and Magongo Municipal Clinic.</li> <li>▪ The laboratory supervisor at CPGH can act as laboratory coordinator for ART program and provide assistance to the other three sites initially, until the program scales up.</li> <li>▪ CPGH has 35 technologist posts available of which 23 currently filled.</li> <li>▪ Have capacity to support start up of ART program.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Shortages of laboratory staff are reported to impact the performance of the laboratory - nine (9) technologists are currently on diploma training leave until 2004. Eight will return to CPGH.</li> <li>▪ If ART program scales up quickly and CPGH introduces CD4 testing, a dedicated laboratory technologist may be needed to perform CD4 testing and to provide assistance to laboratory supervisor in fulfilling his responsibilities as laboratory coordinator for ART program.</li> <li>▪ Work load:               <ul style="list-style-type: none"> <li>○ 88,000 samples/year,</li> <li>○ 60-70% inpatients HIV related.</li> <li>○ VCT 300/month</li> </ul> </li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Establish the laboratory supervisor at CPGH as the laboratory coordinator for the ART program initially, until the program scales up. The ART laboratory coordinator can be supported by CPGH Chief Pathologist on a day-to-day basis.</li> <li>▪ Scientific Committee/CPGH/TAP to identify duties and responsibilities for laboratory coordinator for ART Program.</li> <li>▪ A part/full time laboratory coordinator position may need to be established as the ART program scales up. Workload should be reviewed annually.</li> <li>▪ Additional workload for ART program at CPGH should be reviewed 3 monthly after the start of the program for 1 year and then annually to determine if additional staff are needed.</li> </ul>	
<b>Human Resources – Training</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Laboratory staff have received some training in performing HIV testing – ELISA and rapid tests.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ None of the laboratory technologists have received training in ART at time of assessment.</li> <li>▪ 4 technologists attended the initial training for the ART program held in April 2003.</li> <li>▪ Ongoing training for other staff members who did not attend and in topics not covered in initial training will be needed - must be flexible and appropriate.</li> <li>▪ Site-specific training will be needed as new equipment technologies are introduced.</li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section B: Coast Provincial General Hospital (CPGH) – Initial Findings and Recommendations for Comment</b>		
<b>Human Resources - Training (continued)</b>		<p><b>Limitations (continued)</b></p> <ul style="list-style-type: none"> <li>▪ The ART program laboratory coordinator may need additional training and assistance from the TAP in performing his duties. Can act as the key resource person for training. Responsibilities will be to coordinate trainings, keep records of persons trained and to participate as a trainer.</li> <li>▪ An information/reference center is needed to keep laboratory staff and clinicians updated.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Develop a plan for ongoing training to include site-specific training as new equipment technologies are introduced.</li> <li>▪ Identify training needs and TAP technical assistance needs for the laboratory coordinator based on duties/responsibilities.</li> <li>▪ Identify a list of key documents/ laboratory information resources to be made available at CPGH.</li> <li>▪ Also see recommendations for training in overarching issues that apply to all four sites</li> </ul>	
<b>Specimen Collection</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Use vacutainers for out patients.</li> <li>▪ Procedures in place in main laboratory reception to document specimens received for testing are adequate.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Procedures in place to document specimens sent for processing by HIV clinic are inadequate.</li> <li>▪ No register in HIV clinic to record who has been bled and what tests are to be performed</li> <li>▪ No person has been assigned to transfer samples to main laboratory – samples can spoil due to the delay.</li> <li>▪ Labeling of samples at HIV clinic is inadequate.</li> <li>▪ Vacutainers not used for inpatients.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Introduce a register at the outpatient department to record all patients bled and samples collected/ tests to be performed.</li> <li>▪ Procure/repair existing rotor for haematology and CD4 samples which are waiting for transfer to the main laboratory.</li> <li>▪ Establish a regular delivery/collection service at HIV clinic.</li> <li>▪ Label specimen with HIV clinic number, date and time specimen taken, tests to be done and name of requesting doctor.</li> <li>▪ The person receiving the sample in the main laboratory should check the request forms are complete and that the specimen is correctly labeled and of acceptable quality.</li> <li>▪ Establish registers in each section at the main laboratory for recording specimens received.</li> <li>▪ Routinely check expiry dates of vacutainers before use as part of SOP for Good Laboratory Practice.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section B: Coast Provincial General Hospital (CPGH) – Initial Findings and Recommendations for Comment</b>		
<b>HIV diagnosis</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Use ELISA (Sanofi, Rosanths and Abbott) and rapid HIV tests (UniGold and Determine) - rapid tests limited to emergency situations.</li> <li>▪ Has the capacity to support start up of ART program.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Stock outs of kits and/or changing of kits reported to occur. CPGH was out of stock of ELISA reagents and Unigold at time of visit (July 2003). HIV diagnostic equipment and supplies comes primarily from the National Public Health Laboratories in Nairobi.</li> <li>▪ Additional costs will be incurred for ART program as patients who are referred to CPGH will need to be retested to have their HIV serostatus confirmed.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Supply system for HIV kits/reagents needs to be strengthened to reduce outages. Ongoing training sessions can be used to bring stores and laboratory staff together to identify where problems occur and identify strategies to improve supply.</li> <li>▪ Decide if patients who are to be retested should pay cost sharing fee for ART program or if this should be covered by the program.</li> <li>▪ Re-evaluate capacity annually.</li> </ul>	
<b>Haematology</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Two automated equipment (AT Coulter) are available to perform CBC (including TLC and platelets).</li> <li>▪ WBC differential calculated manually.</li> <li>▪ Has the capacity to support start up of ART program.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Calibration is not routinely done.</li> <li>▪ Equipment breakdown reported to occur which take time to resolve due to lack of funding for repairs .</li> <li>▪ Occasional outages of reagents reported.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Purchase calibration reagents and institutionalize calibration of the Coulters as per manufacturer's recommendations.</li> <li>▪ Ensure that budgets include the renewal of maintenance contract for Coulter and that funds are made available. Check if existing service agreements need to be strengthened.</li> <li>▪ Review the capacity of to perform haematology monitoring for ART program, 3 monthly for one year after introduction of ART program then annually.</li> <li>▪ Consider upgrading equipment to allow automatic generation of WBC differentials as program scales up.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section B: Coast Provincial General Hospital (CPGH) – Initial Findings and Recommendations for Comment</b>		
<b>Clinical Chemistry</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Photometer 5010 back up unit available.</li> <li>▪ Chiron Diagnostic 644 Na/Cl Analyzer.</li> <li>▪ Fasting blood glucose can be performed manually – glucometer.</li> <li>▪ Has the capacity to support start up of ART program.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Automated equipment (Autolab AMS) is available to perform                             <ul style="list-style-type: none"> <li>○ Urea and electrolytes (U &amp; E) – urea/creatinine/ electrolytes (including serum lactate, anion gap)</li> <li>○ LFT (including bilirubin, CPK)</li> <li>○ Amylase</li> <li>○ Lipid profile – triglycerides, cholesterol, HDL, LDL</li> <li>○ Blood gases</li> </ul> </li> <li>▪ However Autolab AMS unit has been out of order since January 2002 – due to be repaired August 2003 (filters need to be replaced).</li> <li>▪ Photometer does not have the capacity to perform multiple parameters simultaneously – very time consuming.</li> <li>▪ Calibration is not routinely done.</li> <li>▪ Occasional outages of reagents reported.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Purchase calibration reagents and institutionalize calibration of the Coulters as per manufacturer’s recommendations.</li> <li>▪ Ensure that budgets include the renewal of maintenance contracts for Autolab AMS and that funds are made available</li> <li>▪ Review the capacity of to perform clinical chemistry monitoring for ART program, 3 monthly for one year after introduction of ART program then annually.</li> </ul>	
<b>Microbiology/ Serology</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Have capacity to perform TB smear, malaria thick smear, stool for parasitology, gonococcus culture, urine and swabs, disc diffusion susceptibility testing, syphilis, hepatitis B, media production, culture facilities for urine, stool, blood, swabs etc, other routine serological testing.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Shortage/irregular supply of reagents.</li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section B: Coast Provincial General Hospital (CPGH) – Initial Findings and Recommendations for Comment</b>		
<b>CD4</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ GOK will make CD4 technology - Partek CyFlow – available at Provincial Hospitals.</li> <li>▪ FHI/IMPACT is procuring a Partek CyFlow with USAID funding.</li> <li>▪ CPGH currently performs CD4 monitoring using a manual system (chamber counting: 15-20min/sample and costs \$1/test). CPGH also has a FacsCount machine and is soon to have Dynabead technology for research purposes – both are unavailable to GOK/USAID program.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Capacity to monitor CD4 counts at CPGH for the whole ART program is insufficient – estimated number of CD4 tests for 300 patients for 5 years is approximately 5050 tests.</li> <li>▪ CD4 samples must be analyzed within 24 hours.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Centralize CD4 testing at CPGH for all four sites initially and then re-evaluate annually.</li> <li>▪ CD4 testing can be contracted out to either Mombasa Hospital (FacsCount) or Aga Khan Hospital (Partek CyFlow) in interim. Also explore loan of Partek until procured equipment arrives.</li> <li>▪ Ensure maintenance contract is included as part of procurement.</li> <li>▪ Sign a memorandum of understanding with the University of Seattle, New York University and either Mombasa or Aga Khan Hospital to provide backup in event of equipment failure.</li> <li>▪ SOPs/forms will need to be developed for referral of patients/samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ Laboratory coordinator to be responsible for managing CD4 testing referral system and logistics for Partek training.</li> </ul>	
<b>Viral load</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ GOK is planning to procure three viral load technologies using RT-PCR methods – one will be based in Mombasa at CPGH.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ No capacity currently exists to perform viral load at CPGH</li> <li>▪ Estimated number of viral load tests for 300 patients for 5 years is approximately 55 tests.</li> <li>▪ Biological safety cabinet is needed for preparing samples for viral load testing off site to prevent sample-to-sample contamination. One is available for research purposes – may be possible to use.</li> <li>▪ Blood samples need to be centrifuged to separate plasma which should be collected in EDTA tubes.</li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>					
<b>Section B: Coast Provincial General Hospital (CPGH) – Initial Findings and Recommendations for Comment</b>					
<b>Viral load (continued)</b>	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Scientific Committee and TAP to select a site to contract out viral load testing to – will need to be set up before ART program begins although samples can be frozen for later testing if necessary. Site should use RT-PCR methodology in line with GOK procurement.</li> <li>▪ Centralize the preparation of samples for viral load testing and the management of off site referral/return of results at CPGH for all four sites initially and then re-evaluate annually.</li> <li>▪ CPGH should act as the central laboratory for preparing samples for viral load testing, CPGH to follow up on whether existing biological safety cabinet can be used for preparing samples for viral load testing.</li> <li>▪ Ensure EDTA tubes for both plasma and PBMC for viral load and viral resistance testing respectively are available.</li> <li>▪ SOP/forms will need to be developed for referral of samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ Laboratory coordinator to be responsible for managing viral load testing referral system.</li> </ul>				
<b>Preparing and storing samples for viral resistance testing (participation in WHO/GOK surveillance)</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;"> <p><b>Strengths</b></p> </td> <td style="width: 50%; vertical-align: top;"> <p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Capacity at CPGH to prepare and store blood samples for viral resistance testing at the end of the program may not be sufficient depending on the number of samples to be stored.</li> <li>▪ -80 degree freezer is needed for storage of samples. One is available in CPGH laboratory but only for research and has limited space available. Another -80 degree freezer is available in Blood Transfusion Unit located at CPGH – permission would be needed for storing samples for viral resistance testing for ART program.</li> <li>▪ Biological safety cabinet is needed for preparing samples for viral resistance testing to prevent sample-to-sample contamination. Two are available for research purposes – may be possible to share.</li> <li>▪ Blood samples need to be centrifuged to separate plasma which should be collected in EDTA tubes.</li> </ul> </td> </tr> <tr> <td colspan="2" style="vertical-align: top;"> <p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Centralize the preparation and storage of samples for viral resistance testing at CPGH for all four sites initially and then re-evaluate annually.</li> <li>▪ CPGH to follow up on whether existing -80 freezer and biological safety cabinet can be used for preparing samples for viral resistance testing for ART program.</li> <li>▪ Ensure EDTA tubes for both plasma and PBMC for viral load and viral resistance testing respectively are available.</li> <li>▪ SOP/forms will need to be developed for preparation, storage and eventual transportation of samples. Should be based on existing procedures/forms where possible.</li> <li>▪ Laboratory coordinator to be responsible for managing viral resistance preparation and storage.</li> </ul> </td> </tr> </table>	<p><b>Strengths</b></p>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Capacity at CPGH to prepare and store blood samples for viral resistance testing at the end of the program may not be sufficient depending on the number of samples to be stored.</li> <li>▪ -80 degree freezer is needed for storage of samples. One is available in CPGH laboratory but only for research and has limited space available. Another -80 degree freezer is available in Blood Transfusion Unit located at CPGH – permission would be needed for storing samples for viral resistance testing for ART program.</li> <li>▪ Biological safety cabinet is needed for preparing samples for viral resistance testing to prevent sample-to-sample contamination. Two are available for research purposes – may be possible to share.</li> <li>▪ Blood samples need to be centrifuged to separate plasma which should be collected in EDTA tubes.</li> </ul>	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Centralize the preparation and storage of samples for viral resistance testing at CPGH for all four sites initially and then re-evaluate annually.</li> <li>▪ CPGH to follow up on whether existing -80 freezer and biological safety cabinet can be used for preparing samples for viral resistance testing for ART program.</li> <li>▪ Ensure EDTA tubes for both plasma and PBMC for viral load and viral resistance testing respectively are available.</li> <li>▪ SOP/forms will need to be developed for preparation, storage and eventual transportation of samples. Should be based on existing procedures/forms where possible.</li> <li>▪ Laboratory coordinator to be responsible for managing viral resistance preparation and storage.</li> </ul>	
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<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Centralize the preparation and storage of samples for viral resistance testing at CPGH for all four sites initially and then re-evaluate annually.</li> <li>▪ CPGH to follow up on whether existing -80 freezer and biological safety cabinet can be used for preparing samples for viral resistance testing for ART program.</li> <li>▪ Ensure EDTA tubes for both plasma and PBMC for viral load and viral resistance testing respectively are available.</li> <li>▪ SOP/forms will need to be developed for preparation, storage and eventual transportation of samples. Should be based on existing procedures/forms where possible.</li> <li>▪ Laboratory coordinator to be responsible for managing viral resistance preparation and storage.</li> </ul>					

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section B: Coast Provincial General Hospital (CPGH) – Initial Findings and Recommendations for Comment</b>		
<b>Referral system and return of results of specimens</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ System exists for referral of samples in all three GOK facilities.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ No delivery system exists for returning results to HIV clinic from the main laboratory – patients must come to laboratory which is time consuming for laboratory supervisor.</li> <li>▪ Need to streamline disbursement of HIV test results to wards or clinics – present system is time consuming for laboratory supervisor.</li> <li>▪ Lack of staff to manage referral.</li> <li>▪ Lack of transport to transfer samples.</li> <li>▪ Lack of communication for results – email and telephone.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Establish a procedure/system for delivering laboratory results from CPGH main laboratory to HIV clinic.</li> <li>▪ Establish a procedure/system for delivering HIV results from CPGH main laboratory to wards and clinics.</li> <li>▪ Establish a procedure/system for referring patients/transporting samples between CPGH and the other four sites for central testing and a system for delivering/returning of test results from central laboratories to patient records. Develop SOPs and forms based on existing SOPs/forms where possible.</li> <li>▪ Establish procedure/system for transporting samples that are to be tested externally and a system for delivering/returning of test results to patient records. Develop SOPs and forms based on existing SOPs/forms where possible.</li> <li>▪ Laboratory coordinator to be responsible for coordinating and monitoring referral systems with back up from CPGH Chief Pathologist.</li> </ul>	
<b>Selection/ Procurement and Distribution of Reagents/ Equipment</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Laboratory staff are primarily responsible for selecting equipment and reagents and for quantifying needs of reagents to procure.</li> <li>▪ The order is initiated by the laboratory and endorsed by deputy chief.</li> <li>▪ Generally use the same systems as pharmacy.</li> <li>▪ Supply purchased by direct order or tender depending on quantity.</li> <li>▪ HIV test kits come free from NASCOP.</li> <li>▪ Some products come directly from National Public Health Laboratory e.g. blood bank supplies. Some of these supplies are provided free.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Other supplies are bought with cost recovery money</li> <li>▪ However stock outages occur for a number of reasons:                             <ul style="list-style-type: none"> <li>○ Inadequate allocation of funds or funds are not available</li> <li>○ Lack of prioritization for laboratory supplies for local purchase orders – no laboratory involvement in prioritization.</li> <li>○ Sometimes mistakes are made – incorrect reagents are bought.</li> <li>○ Local funds are used to buy stocks when supplies from NASCOP/Public Health Laboratory are unavailable resulting in an inadequate lead time.</li> </ul> </li> <li>▪ System does not exist to regularly inform HIV clinic doctor of availability of reagents/functioning of equipment.</li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>			
<b>Section B: Coast Provincial General Hospital (CPGH) – Initial Findings and Recommendations for Comment</b>			
<b>Selection/ Procurement and Distribution of Reagents/ Equipment (continued)</b>	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Need to look at strategies for securing supplies of reagents for ART patients.</li> <li>▪ Supply system needs to be strengthened to reduce outages. Ongoing training sessions can be used to bring stores and laboratory staff together to identify where problems occur and identify strategies to improve supply.</li> <li>▪ Ensure that supplies of reagents are adequately budgeted for and that the importance of having laboratory reagents available is conveyed to persons who prioritize local purchase order procurement.</li> <li>▪ All procurement of equipment should be connected to the signing of a maintenance contract.</li> <li>▪ Set up a system to provide a weekly update on CPGH testing capability to HIV clinic.</li> </ul>		
<b>Management Information System (MIS)</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;"> <p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Specimen identification on tubes includes patient name and inpatient/outpatient number.</li> <li>▪ Results are recorded in the laboratory in a chronological book - record number and name in register.</li> </ul> </td> <td style="width: 50%; vertical-align: top;"> <p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Request forms do not have a check list.</li> <li>▪ Procedures in place to document specimens sent for processing by HIV clinic are inadequate.</li> <li>▪ No register in OPD to record who has been bled and what tests are to be performed.</li> <li>▪ Labeling of samples at OPD is inadequate.</li> <li>▪ Results are reported to the patient file on paper – official forms are only used for haematology and a range is given for clinical chemistry only.</li> </ul> </td> </tr> </table> <p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Introduce a register at OPD to record all patients bled and samples collected/ tests to be performed.</li> <li>▪ ART program will need standardized laboratory request and report forms that fit the repertoire of CPGH.</li> <li>▪ Need to set up a laboratory report form with cumulated laboratory results in each patient's medical record file</li> <li>▪ Samples and request forms should be carefully labeled with HIC clinic number, date and time specimen taken, tests to be done and name of requesting doctor.</li> <li>▪ Scientific Committee/TAP/sites to develop laboratory request and report forms, including cumulated laboratory results form for patient records for ART program. Forms should be based on existing/approved forms where possible.</li> <li>▪ The person receiving the sample in the main laboratory should check the request forms are complete and that the specimen is correctly labeled and of acceptable quality.</li> <li>▪ Establish registers in each section at the main laboratory for recording specimens received.</li> <li>▪ Establish registers in the main laboratory for recording specimens sent outside of CPGH for testing and results received.</li> <li>▪ Laboratory staff should record the type of test used, batch number and expiry date alongside the test result in notebooks.</li> <li>▪ Results should also be recorded by ART patient.</li> <li>▪ Establish a procedure/system for delivering laboratory results from CPGH main laboratory to HIV clinic.</li> <li>▪ Establish a procedure/system for delivering HIV results from CPGH main laboratory to wards and clinics.</li> </ul>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Specimen identification on tubes includes patient name and inpatient/outpatient number.</li> <li>▪ Results are recorded in the laboratory in a chronological book - record number and name in register.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Request forms do not have a check list.</li> <li>▪ Procedures in place to document specimens sent for processing by HIV clinic are inadequate.</li> <li>▪ No register in OPD to record who has been bled and what tests are to be performed.</li> <li>▪ Labeling of samples at OPD is inadequate.</li> <li>▪ Results are reported to the patient file on paper – official forms are only used for haematology and a range is given for clinical chemistry only.</li> </ul>
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<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section B: Coast Provincial General Hospital (CPGH) – Initial Findings and Recommendations for Comment</b>		
<b>Good Laboratory Practice</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ All sharps are disposed of in an official needle box and emptied into the incinerator.</li> <li>▪ All microbiological waste is autoclaved before incineration.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Staff are not always diligent about wearing protective clothing – eye protection and white coats partly due to the heat in the laboratory – lack of air conditioning.</li> <li>▪ No PEP procedure available in laboratory.</li> <li>▪ No accident/incident register available.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Improve air circulation in the laboratory – look at feasibility of installing air conditioning unit.</li> <li>▪ Procure 1 multichannel and 1 precision pipette for handling of samples.</li> <li>▪ Develop site-specific SOPs to incorporate the principles of Good Laboratory Practice including health and safety of staff and assuring patient confidentiality.</li> <li>▪ Develop SOP and ensure staff are trained in steps to be taken for PEP.</li> <li>▪ On going training should include activities to promote Good Laboratory Management.</li> <li>▪ Record the type of test used, batch number and expiry date alongside the test result in notebooks.</li> <li>▪ A system for regularly monitoring and reporting on Good Laboratory Practice needs to be set up.</li> <li>▪ Establish accident/incident register.</li> </ul>	
<b>Quality Control/ M&amp;E</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Chief Pathologist at CPGH is the Chairman of the Scientific Committee for the program. Can act as lead resource person for the program and provide local oversight for implementation, including supervision and guidance for the laboratory coordinator for the program.</li> <li>▪ The laboratory supervisor at CPGH can act as coordinator for the ART program until the program scales up.</li> <li>▪ CPGH laboratory is a site for HIV test kit testing and accreditation.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Internal QA needs to be reviewed and strengthened.</li> <li>▪ Documented daily QC needs to be established for all routine tests performed.</li> <li>▪ No QC sample from external source - need to set up a system for external evaluation of laboratory performance.</li> <li>▪ Need to plan for interim analysis – mid-program evaluation.</li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section B: Coast Provincial General Hospital (CPGH) – Initial Findings and Recommendations for Comment</b>		
<b>Quality Control/ M&amp;E</b>	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Establish a system to perform documented internal QC for each parameter daily for the first month. Thereafter check different parameters every day resulting in at least weekly checks for each parameter to reduce costs.</li> <li>▪ Develop/adapt existing SOPs for QC/QA to include actions to be taken if QC problems occur.</li> <li>▪ Local laboratory coordinator should be responsible for Good Laboratory Practice and for reviewing QC for ART program. Oversight to be provided by CPGH Chief Pathologist.</li> <li>▪ CPGH should establish and manage an external QC program to submit to other sites. Arrangements should be made to obtain samples from national/international sources.</li> <li>▪ Perform external evaluation of performance during the training phase prior to ART program start at CPGH.</li> <li>▪ Perform external evaluation after 3 months and then every 6 months throughout the ART program.</li> <li>▪ Training for laboratory staff should include QC and QA procedures and principles of Good Laboratory Practice.</li> </ul>	
<b>Financing – cost sharing</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ CPGH has a cost sharing system that incorporates exemptions for those who cannot pay.</li> <li>▪ Cost sharing pays for reagents and partly for operations and maintenance.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ HIV clinic patients are exempt from all cost sharing charges.</li> <li>▪ CPGH will be the main referral laboratory for the program – may require additional funding to be able to provide necessary exemptions for patients who cannot pay for laboratory monitoring.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ CPGH to revise laboratory budget to include estimates for ART program.</li> <li>▪ Sites/USAID/TAP to discuss the need to provide external support to CPGH for laboratory monitoring.</li> <li>▪ Recalculate quantification of laboratory tests at 3 monthly for first year based on actual numbers used.</li> <li>▪ Examine options to secure funding to ensure a constant supply of reagents for ART program.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section C: Port Reitz District Hospital (PRDH) – Initial Findings and Recommendations for Comment</b>		
<b>Policies and Procedures</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ National STGs for ART and monitoring of ARVs exist.</li> <li>▪ National VCT guidelines exist.</li> <li>▪ National OI guidelines exist.</li> <li>▪ Directive from the Director of Medical Services to set up ART centers in each province issued September 2002.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ <i>Indicators</i> <ul style="list-style-type: none"> <li>○ <i>National ART guidelines reported to be available and seen in laboratory (July 2003) = NO</i></li> <li>○ <i>National VCT guidelines reported to be available and seen in laboratory (July 2003) = NO</i></li> </ul> </li> <li>▪ No SOPs for laboratory exist.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Ensure that updated copies of national ART guidelines, VCT and OI guidelines are available for use by all PRDH laboratory staff.</li> <li>▪ Develop site-specific SOPs for the ART program – adapt existing procedures/forms where possible. SOPs should include preventive maintenance for existing equipment.</li> <li>▪ Develop site-specific SOPs for all laboratory procedures – adapt existing procedures/forms where possible. SOPs should include preventive maintenance for existing equipment.</li> </ul>	
<b>Infrastructure/ Equipment</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Laboratory has been recently renovated by DANIDA – handed over to hospital March 2003.</li> <li>▪ There are plans to purchase some new equipment using cost sharing funds.</li> <li>▪ Colorimeter is still under warranty.</li> <li>▪ <i>Indicator</i> <ul style="list-style-type: none"> <li>○ <i>Average percentage of a tracer list of laboratory equipment functioning at time of visit (July 2003) = 90%</i></li> </ul> </li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Laboratory is very hot – fans are available but the laboratory needs air-conditioning.</li> <li>▪ Water supply is not reliable (July 2003). Hospital plans to sink a new borehole.</li> <li>▪ The laboratory lacks essential laboratory equipment - compromises the ability of the laboratory to act as a referral centre for Magongo Municipal Clinic and Bomu Clinic and for scale up.</li> <li>▪ The colorimeter (clinical chemistry) is broken and cannot be repaired (September 2002). (Replaced at time of visit in July 2003).</li> <li>▪ Autoclave is not functioning at time of visit (July 2003) (no gas available).</li> <li>▪ Culture of samples was not being performed at time of visit (July 2003) – weights to measure ingredients for media production were lacking.</li> <li>▪ Back up arrangements are not in place for when equipment breaks down.</li> <li>▪ Laboratory is not built to make RT-PCR possible.</li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section C: Port Reitz District Hospital (PRDH) – Initial Findings and Recommendations for Comment</b>		
<b>Infrastructure/ Equipment (continued)</b>	<ul style="list-style-type: none"> <li>▪ Existing equipment:                             <ul style="list-style-type: none"> <li>○ Automated Colorimeter for renal function test (RFT)/LFT</li> <li>○ Sahli Haemometer</li> <li>○ Lifescan glucometer (blood sugar)</li> <li>○ Autoclave (no gas connection at time of visit)</li> <li>○ Refrigerator (3)</li> <li>○ Incubator</li> <li>○ Hot air oven</li> <li>○ Centrifuge (3)</li> <li>○ Microscopes (3)</li> <li>○ Hood</li> <li>○ Hot plate</li> <li>○ VDRL rotator/shaker</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Essential supplies needed:                             <ul style="list-style-type: none"> <li>○ Vacutainers (see below)</li> </ul> </li> <li>▪ Equipment to be considered for procurement if PRDH is to act as referral laboratory for ART program and to strengthen all services provide by laboratory:                             <ul style="list-style-type: none"> <li>○ Multichannel pipette</li> <li>○ Precision pipette</li> <li>○ Automated 3-5 parameter Coulter for CBC/TLC</li> <li>○ Automated Electrolyte Analyzer</li> <li>○ Weights or balance</li> <li>○ ELISA</li> </ul> </li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Secure a reliable supply of water.</li> <li>▪ Examine options to keep the laboratory cooler – e.g. install air conditioning.</li> <li>▪ Procure gas for autoclave – see if can use theatre autoclave in the interim.</li> <li>▪ Ensure that all procurement of equipment is linked to the signing of a maintenance contract.</li> <li>▪ Ensure that budgets include the renewal of maintenance contracts for equipment and that funds are made available.</li> <li>▪ Establish back up arrangements with CPGH.</li> </ul>	
<b>Human Resources – Staffing</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Chief Pathologist at CPGH is the Chairman of the Scientific Committee for the ART program and currently provides technical oversight and assistance to PRDH.</li> <li>• Current staffing levels - 8 technicians and 3 technologists of whom 2 have a higher diploma).</li> <li>• Have capacity to support start up of ART program.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Staff shortages.</li> <li>▪ Financial constraints.</li> <li>▪ Frequent transfer of staff.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Additional workload for ART program at PRDH laboratory should be reviewed 3 monthly after the start of the program for 1 year and then annually to determine if additional staff are needed.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section C: Port Reitz District Hospital (PRDH) – Initial Findings and Recommendations for Comment</b>		
<b>Human Resources - Training</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Laboratory staff have received some training in performing HIV testing.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ None of the laboratory staff have received training in ART at time of assessment.</li> <li>▪ 1 technologist attended the initial training for the ART program held in April 2003.</li> <li>▪ Ongoing training for other staff members who did not attend and in topics not covered in initial training will be needed - must be flexible and appropriate.</li> <li>▪ Site-specific training will be needed as new equipment technologies are introduced.</li> <li>▪ An information/reference center is needed to keep laboratory staff and clinicians updated.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Develop a plan for ongoing training to include site-specific training as new equipment technologies are introduced.</li> <li>▪ Identify a list of key documents/ laboratory information resources to be made available at PRDH.</li> <li>▪ Also see recommendations for training in overarching issues that apply to all 4 sites.</li> </ul>	
<b>Specimen Collection</b>	<b>Strengths</b>	<b>Limitations</b>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Use vacutainers for blood sample collection for ART patients.</li> <li>▪ Routinely check expiry dates of vacutainers before use as part of SOP for Good Laboratory Practice.</li> </ul>	
<b>HIV diagnosis</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Use rapid HIV tests (UniGold and Determine).</li> <li>▪ Has the capacity to support start up of ART program.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ No ELISA is available so samples with discordant results have to be referred to CPGH – clients do not want to wait/return for results.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Re-evaluate capacity annually.</li> <li>▪ Consider procurement of ELISA if PRDH is to function as a referral center for ART program.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section C: Port Reitz District Hospital (PRDH) – Initial Findings and Recommendations for Comment</b>		
<b>Haematology</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Manual equipment (Sahli haemometer) is available to perform haemoglobin.</li> <li>▪ WBC differential calculated manually.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Does not have capacity to perform CBC and TLC.</li> <li>▪ Back up arrangements are not in place for when equipment breaks down.</li> <li>▪ Does not have the capacity to support start up of ART program – samples would need to be referred to CPGH.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Consider procuring kits to perform haemoglobin using colorimeter.</li> <li>▪ Refer patients/samples to CPGH for CBC/TLC.</li> <li>▪ Review work load annually - consider procurement of automated 3-5 parameter Coulter for CBC/TLC if PRDH is to act as a referral centre when ART program is scaled up.</li> <li>▪ Ensure maintenance contract is included as part of procurement. Set up backup arrangements with CPGH in case of equipment breakdown.</li> <li>▪ SOPs/forms will need to be developed for referral of patients/samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ 1 person will need to be identified for managing the referral system.</li> </ul>	
<b>Clinical Chemistry</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Fasting blood glucose can be performed manually.</li> <li>▪ Can use colorimeter to perform:                             <ul style="list-style-type: none"> <li>○ U &amp; E – urea/creatinine</li> <li>○ Some LFTs</li> </ul> </li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Does not have the capacity to perform:                             <ul style="list-style-type: none"> <li>○ U &amp; E – electrolytes (including serum lactate, anion gap)</li> <li>○ Some LFTs (including bilirubin, CPK)</li> <li>○ Amylase</li> <li>○ Lipid profile – triglycerides, cholesterol, HDL, LDL</li> </ul> </li> <li>▪ Reagents for LifeScan (blood sugar) reported to be out of stock for 2-3 months per year.</li> <li>▪ Reagent supply for colorimeter is erratic – procurement is frequently held up when board meetings for cost sharing are delayed.</li> <li>▪ Back up arrangements are not in place for when equipment breaks down.</li> <li>▪ Does not have the capacity to support start up of ART program. Some samples would need to be referred to CPGH.</li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section C: Port Reitz District Hospital (PRDH) – Initial Findings and Recommendations for Comment</b>		
<b>Clinical Chemistry (continued)</b>	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Refer patients/samples to CPGH for unavailable clinical chemistry tests.</li> <li>▪ Review work load annually - consider procurement of an automated Electrolyte Analyzer if PRDH is to act as a referral centre when ART program is scaled up. May need more sophisticated automated clinical chemistry unit when program scales up.</li> <li>▪ Ensure maintenance contract is included as part of procurement. Set up backup arrangements with CPGH in case of equipment breakdown.</li> <li>▪ SOPs/forms will need to be developed for referral of patients/samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> <li>▪ Need to secure funding for reagents – can procure reagents for colorimeter to perform blood glucose. Examine options to ensure that postponed or cancelled board meetings do not hold up procurement of reagents. Ongoing training sessions can be used to bring stores and laboratory staff together to identify where problems occur and identify strategies to improve supply.</li> </ul>	
<b>Microbiology/ Serology</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Have capacity for:                             <ul style="list-style-type: none"> <li>○ TB – sputum for acid-fast bacilli (AFB)</li> <li>○ Urinalysis (microscopy)</li> <li>○ Malaria thick smear</li> <li>○ Stool for parasitology</li> <li>○ Syphilis VDRL</li> <li>○ Hepatitis B</li> </ul> </li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Culture (urine, stool, sputum etc) unavailable.                             <ul style="list-style-type: none"> <li>○ Autoclave is out of order.</li> <li>○ No weights available for balance to produce media.</li> </ul> </li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Procure gas for the autoclave – look at feasibility of using theatre autoclave in the interim.</li> <li>▪ Procure weights for the balance or buy an electronic balance.</li> <li>▪ Set up culture facilities. In the interim, refer patients/samples to CPGH for culture.</li> <li>▪ SOPs/forms will need to be developed for referral of patients/samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section C: Port Reitz District Hospital (PRDH) – Initial Findings and Recommendations for Comment</b>		
<b>CD4</b>	<b>Strengths</b>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ No capacity exists to perform CD4 at PRDH – refer patients/samples to CPGH.</li> <li>▪ CD4 samples must be analyzed within 24 hours.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Centralize CD4 testing at CPGH for all four sites initially and then re-evaluate annually.</li> <li>▪ SOPs/forms will need to be developed for referral of patients/samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	
<b>Viral load</b>	<b>Strengths</b>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ No capacity exists to perform viral load at PRDH – refer patients to CPGH.</li> <li>▪ Blood samples need to be centrifuged to separate plasma which should be collected in EDTA tubes.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ SOPs/forms will need to be developed for referral of samples to CPGH and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	
<b>Preparing and storing samples for viral resistance testing (participation in WHO/GOK surveillance)</b>	<b>Strengths</b>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ No capacity currently exists to prepare and store samples for viral resistance testing at PRDH – refer samples to CPGH.</li> <li>▪ Blood samples need to be centrifuged to separate plasma which should be collected in EDTA tubes.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Centralize the preparation and storage of samples for viral resistance testing at CPGH for all four sites initially and then re-evaluate annually.</li> <li>▪ SOPs/forms will need to be developed for referral of patients. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section C: Port Reitz District Hospital (PRDH) – Initial Findings and Recommendations for Comment</b>		
<b>Referral system and return of results of specimens</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ GOK system already exists and links the sites.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Staff and transport constraints.</li> <li>▪ Limited communications.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Establish a procedure/system for referring patients/ transporting samples between PRDH and CPGH for central testing and a system for delivering/returning of test results from central laboratories to patient records. Investigate feasibility of using emails for communicating results from CPGH to PRDH.</li> <li>▪ Develop SOPs and forms based on existing SOPs/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	
<b>Selection/Procurement and Distribution of Reagents/Equipment</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Laboratory in charges are primarily responsible for selecting equipment and reagents and for quantifying needs of reagents to procure.</li> <li>▪ The order is initiated by the laboratory.</li> <li>▪ Generally use the same systems as pharmacy.</li> <li>▪ Supply purchased by direct order or tender depending on quantity.</li> <li>▪ HIV test kits are supplied free of charge by NASCOP.</li> <li>▪ Some products come directly from National Public Health Laboratory. Some of these supplies are provided free of charge.</li> <li>▪ Other supplies are bought with cost recovery money.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Delays are reported to occur in delivery of supplies.</li> <li>▪ Reagents for LifeScan (blood sugar) reported to be out of stock for 2-3 months per year.</li> <li>▪ Reagent supply for colorimeter is erratic – procurement is frequently held up when Board meetings for cost sharing are delayed.</li> <li>▪ <i>Indicator</i> <ul style="list-style-type: none"> <li>○ <i>Average percent of a set of unexpired tracer reagents/supplies available in laboratory at time of visit (July 2003) = 92%</i></li> </ul> </li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Supply system needs to be strengthened to reduce outages. Ongoing training sessions can be used to bring stores and laboratory staff together to identify where problems occur and identify strategies to improve supply.</li> <li>▪ Ensure that supplies of reagents are adequately budgeted for and that the importance of having laboratory reagents available is conveyed to persons who prioritize local purchase order procurement. Examine options to ensure that postponed or cancelled board meetings do not hold up procurement of reagents.</li> <li>▪ All procurement of equipment should be connected to the signing of a maintenance contract.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section C: Port Reitz District Hospital (PRDH) – Initial Findings and Recommendations for Comment</b>		
<b>Management Information System (MIS)</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Specimen identification on tubes includes patient name and inpatient/outpatient number.</li> <li>▪ Results are recorded in the laboratory in a chronological book - record number and name in register.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Request forms do not have a check list.</li> <li>▪ Results are reported to the patient file on piece of paper – no normal ranges are given.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ ART program will need standardized laboratory request and report forms that fit the repertoire of PRDH.</li> <li>▪ Need to set up a laboratory report form with cumulated laboratory results in each patient’s medical record file.</li> <li>▪ Samples and request forms should be carefully labeled with patient name and inpatient/outpatient number.</li> <li>▪ Scientific Committee/TAP/sites to develop laboratory request and report forms, including cumulated laboratory results form for patient records for ART program. Forms should be based on existing/approved forms where possible.</li> <li>▪ Laboratory staff should record the type of test used, batch number and expiry date alongside the test result in notebooks.</li> </ul>	
<b>Good Laboratory Practice</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ All sharps are disposed of in an unofficial needle box and emptied into the incinerator.</li> <li>▪ All microbiological waste is autoclaved before incineration.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Water supplies are erratic.</li> <li>▪ Needles and syringes are used to collect blood samples.</li> <li>▪ Shortages of laboratory coats and protective equipment reported.</li> <li>▪ Staff are not always diligent about wearing protective clothing – eye protection and white coats due to the heat in the laboratory – lack of air conditioning.</li> <li>▪ No accident/incident register exists.</li> <li>▪ No policy for PEP available in laboratory.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Secure the supply of water.</li> <li>▪ Use vacutainers for sample collection for ART patients.</li> <li>▪ Ensure that adequate supplies of coats and protective equipment are made available to laboratory staff.</li> <li>▪ Consider air conditioning the laboratory.</li> <li>▪ Develop site-specific SOPs to incorporate the principles of Good Laboratory Practice including health and safety of staff and assuring patient confidentiality.</li> <li>▪ Establish an accident/incident register.</li> <li>▪ Develop SOP and ensure policy is available in laboratory and staff are trained in steps to be taken for PEP.</li> <li>▪ On going training should include activities to promote Good Laboratory Management.</li> <li>▪ Record the type of test used, batch number and expiry date alongside the test result in notebooks.</li> <li>▪ A system for regularly monitoring and reporting on Good Laboratory Practice needs to be set up.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section C: Port Reitz District Hospital (PRDH) – Initial Findings and Recommendations for Comment</b>		
<b>Quality Control/ M&amp;E</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ PRDH laboratory is inspected by CPGH.</li> <li>▪ Receive unstained TB slides for quality control.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Internal QA needs to be reviewed and strengthened.</li> <li>▪ Documented daily QC needs to be established for all routine tests performed.</li> <li>▪ No QC sample from external source - need to set up a system for external evaluation of laboratory performance.</li> <li>▪ Need to plan for interim analysis – mid-program evaluation.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Maintain a formal relationship with CPGH for monitoring and supervision as well as receiving standards and testing test specimens for reconfirmation. Local laboratory coordinator should be responsible for Good Laboratory Practice and for reviewing QC for ART program. Oversight to be provided by CPGH Chief Pathologist.</li> <li>▪ Establish a system to perform documented internal QC for each parameter daily for the first month. Thereafter check different parameters every day resulting in at least weekly check for each parameter to reduce costs.</li> <li>▪ Develop/adapt existing SOPs for QC/QA to include actions to be taken if QC problems occur.</li> <li>▪ CPGH should establish and manage an external QC program to submit to other sites. Arrangements should be made to obtain samples from national/international sources.</li> <li>▪ Perform external evaluation of performance during the training phase prior to ART program start at PRDH.</li> <li>▪ Perform external evaluation after 3 months and then every 6 months throughout the ART program.</li> <li>▪ Training for laboratory staff should include QC and QA procedures and principles of Good Laboratory Practice.</li> <li>▪</li> </ul>	
<b>Financing – cost sharing</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ PRDH has a cost sharing system that incorporates exemptions for those who cannot pay.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ The laboratory lacks essential laboratory equipment - compromises the ability of the laboratory to act as a referral centre for Magongo Municipal Clinic and Bomu Clinic and for scale up.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Sites/USAID/TAP to discuss the need to provide external support to PRDH for laboratory monitoring.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section D: Magongo Municipal Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Policies and Procedures</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ National STGs for ART and monitoring of ARVs exist.</li> <li>▪ National VCT guidelines exist.</li> <li>▪ National OI guidelines exist.</li> <li>▪ Directive from the Director of Medical Services to set up ART centers in each province issued September 2002.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ <i>Indicators:</i> <ul style="list-style-type: none"> <li>○ <i>National ART guidelines reported to be available and seen in laboratory (July 2003) = NO</i></li> <li>○ <i>National VCT guidelines reported to be available and seen in laboratory (July 2003) = NO</i></li> </ul> </li> <li>▪ No SOPs for laboratory exist.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Ensure that updated copies of national ART, OI and VCT guidelines are available for use by laboratory staff.</li> <li>▪ Develop site-specific SOPs for the ART program – adapt existing procedures/forms where possible. SOPs should include preventive maintenance for existing equipment.</li> <li>▪ Develop site-specific SOPs for all laboratory procedures – adapt existing procedures/forms where possible. SOPs should include preventive maintenance for existing equipment.</li> </ul>	
<b>Infrastructure/ Equipment</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Laboratory is well secured although lock to the side door of the clinic needs repairing.</li> <li>▪ Existing equipment: <ul style="list-style-type: none"> <li>○ Sahli Haemometer</li> <li>○ Refrigerator (1)</li> <li>○ Microscope (2) One is slightly defective – will not hold 100 objective in place so cannot perform AFB</li> <li>○ Hood</li> </ul> </li> <li>▪ <i>Indicators:</i> <ul style="list-style-type: none"> <li>○ <i>Average percent of a tracer list of laboratory equipment functioning at time of visit (July 2003) = 83%</i></li> </ul> </li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Laboratory needs painting and some general repairs and maintenance.</li> <li>▪ No running water as the bills have not been paid (September 2002) – reconnected at time of visit in July 2003.</li> <li>▪ Laboratory gets very hot and is uncomfortable to work in.</li> <li>▪ Maintenance and back up arrangements are not in place for when equipment breaks down.</li> <li>▪ One microscope (slightly defective – will not hold 100 objective in place so cannot perform AFB).</li> <li>▪ Equipment/supplies needed: <ul style="list-style-type: none"> <li>○ Vacutainers (see below).</li> <li>○ Shaker for VDRL/rapid plasma reagin (RPR).</li> <li>○ Centrifuge for urine microscopy/blood separation.</li> </ul> </li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Secure funding to pay the bills to assure a regular supply of water.</li> <li>▪ Secure funding for general maintenance and paint the facility.</li> <li>▪ Repair the microscope lens – send to Chief Pathologist for maintenance at CPGH. Arrange ongoing maintenance.</li> <li>▪ Install additional fans to cool the laboratory.</li> <li>▪ Establish back up arrangements with PRDH for equipment breakdown and when reagents are unavailable, if arrangements can be made between municipal clinic and MOH.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section D: Magongo Municipal Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Human Resources – Staffing</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Chief Pathologist at CPGH is the Chairman of the Scientific Committee for the ART program and currently provides technical oversight and assistance to Magongo Municipal Clinic.</li> <li>▪ Current staffing levels - 2 technologists with higher diploma, 1 technician (September 2002).</li> <li>▪ Have capacity to support start up of ART program.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Payment of salaries are frequently delayed for months and staff are demoralized and reluctant to take on additional work.</li> <li>▪ Frequent unplanned transfers or staff resignations – all staff were transferred in March 2003.</li> <li>▪ Laboratory technologist trained in April 2003 had been transferred.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Secure funding to pay staff on time.</li> <li>▪ Restrict transfers of key ART program staff.</li> <li>▪ Additional workload for ART program at Magongo should be reviewed 3 monthly after the start of the program for 1 year and then annually to determine if additional staff are needed.</li> </ul>	
<b>Human Resources - Training</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Laboratory staff have received some training in performing HIV testing</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ None of the laboratory staff have received training in ART at time of assessment (September 2002).</li> <li>▪ 1 technologist attended the initial training for the ART program held in April 2003 but has been transferred.</li> <li>▪ Ongoing training for other /new staff members who did not attend and in topics not covered in initial training will be needed - must be flexible and appropriate.</li> <li>▪ Site-specific training will be needed as new equipment technologies are introduced.</li> <li>▪ An information/reference center is needed to keep laboratory staff and doctors updated.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Develop a plan for ongoing training to include site-specific training as new equipment technologies are introduced.</li> <li>▪ Identify a list of key documents/ laboratory information resources to be made available at Magongo.</li> <li>▪ Also see recommendations for training in overarching issues that apply to all four sites.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section D: Magongo Municipal Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Blood Sample Collection</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Phlebotomy can be performed</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Vacutainers not used as not currently needed</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Use vacutainers for blood sample collection for ART program.</li> <li>▪ Ensure expiry dates of vacutainers are checked before use as part of SOP for Good Laboratory Practice.</li> </ul>	
<b>HIV diagnosis</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Use rapid HIV tests (UniGold and Determine).</li> <li>▪ Has the capacity to support start up of ART program.</li> <li>▪ Workload VCT 45/month</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ HIV testing only done for VCT and not routine clinical diagnosis or management.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Re-evaluate capacity annually.</li> </ul>	
<b>Haematology</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Manual equipment (Sahli haemometer) is available to perform haemoglobin.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Does not have capacity to perform CBC and TLC.</li> <li>▪ Does not currently have the capacity to support start up of ART program – patients/samples would need to be referred to CPGH.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Refer patients/samples to CPGH for CBC/TLC (PRDH cannot currently perform these tests).</li> <li>▪ Review work load annually.</li> <li>▪ SOPs/forms will need to be developed for referral of patients/samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section D: Magongo Municipal Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Clinical Chemistry</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Have capacity for:                             <ul style="list-style-type: none"> <li>○ Serum glucose – One Touch.</li> </ul> </li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Does not have the capacity to perform                             <ul style="list-style-type: none"> <li>○ U &amp; E – urea/creatinine/electrolytes (including serum lactate, anion gap)</li> <li>○ LFT (including bilirubin, CPK)</li> <li>○ Amylase</li> <li>○ Lipid profile – triglycerides, cholesterol, HDL, LDL</li> </ul> </li> <li>▪ Reagents for serum glucose erratic.</li> <li>▪ Does not have the capacity to support start up of ART program – patients/samples would need to be referred to CPGH.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Secure adequate supplies of One Touch reagents to prevent outages.</li> <li>▪ Refer patients/samples to CPGH for clinical chemistry tests (PRDH cannot currently perform these tests).</li> <li>▪ Review work load annually.</li> <li>▪ SOPs/forms will need to be developed for referral of patients/samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	
<b>Microbiology</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Have capacity for:                             <ul style="list-style-type: none"> <li>○ TB smear</li> <li>○ Malaria thick smear</li> <li>○ Stool for parasitology</li> <li>○ Urine microscopy</li> <li>○ Urine dipstick – Combur-9</li> </ul> </li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Culture (urine, stool, sputum etc) unavailable.</li> <li>▪ No centrifuge available so urine microscopy is based on sedimentation.</li> <li>▪ Microscope (slightly defective – will not hold 100 objective in place so cannot perform AFB).</li> <li>▪ Malaria stains are currently diluted with water to stretch supplies (September 2002).</li> <li>▪ No reagents available for syphilis testing.</li> <li>▪ No shaker for VDRL/RPR.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Procure centrifuge and VDRL shaker.</li> <li>▪ Repair the microscope lens – send to Chief Pathologist with letter for maintenance at CPGH.</li> <li>▪ Secure adequate supplies of malaria stains, VDRL and Combur-9 reagents to prevent outages.</li> <li>▪ Refer patients/samples to CPGH for culture and sensitivity (PRDH cannot currently culture).</li> <li>▪ SOPs/forms will need to be developed for referral of patients/samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section D: Magongo Municipal Clinic – Initial Findings and Recommendations for Comment</b>		
<b>CD4</b>	<b>Strengths</b>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ No capacity exists to perform CD4 at Magongo – refer patients to CPGH.</li> <li>▪ CD4 samples must be analyzed within 24 hours.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Centralize CD4 testing at CPGH for all 4 sites initially and then re-evaluate annually.</li> <li>▪ SOPs/forms will need to be developed for referral of patients and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	
<b>Viral load</b>	<b>Strengths</b>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ No capacity exists to perform viral load at Magongo – refer patients to CPGH.</li> <li>▪ Blood samples need to be centrifuged to separate plasma which should be collected in EDTA tubes.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ SOPs/forms will need to be developed for referral of patients /samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	
<b>Preparing and storing samples for viral resistance testing (participation in WHO/GOK surveillance)</b>	<b>Strengths</b>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ No capacity exists to prepare and store samples for viral resistance testing at Magongo – refer patients to CPGH.</li> <li>▪ Blood samples need to be centrifuged to separate plasma which should be collected in EDTA tubes.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Centralize the preparation and storage of samples for viral resistance testing at CPGH for all four sites initially and then re-evaluate annually.</li> <li>▪ SOPs/forms will need to be developed for referral of patients. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section D: Magongo Municipal Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Referral system and return of results of specimens</b>	<b>Strengths</b>	<b>Limitations</b>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Establish a procedure/system for referring patients/ transporting samples between Magongo and CPGH for central testing and a system for delivering/returning of test results from central laboratories to patient records. Develop SOPs and forms based on existing SOPs/forms where possible.</li> <li>▪ 1 person will need to be identified to manage the referral system.</li> </ul>	
<b>Selection/Procurement and Distribution of Reagents/Equipment</b>	<b>Strengths</b>	<b>Limitations</b>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Supply system needs to be strengthened to reduce outages. Magongo depends on the municipal council to order/coordinate supplies for the clinic.</li> <li>▪ Municipal council needs to secure funding for procurement of laboratory reagents and supplies and to make funding available as needed for central procurement.</li> </ul>	
<b>Management Information System (MIS)</b>	<b>Strengths</b>	<b>Limitations</b>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ ART program will need standardized laboratory request and report forms that fit the repertoire of Magongo.</li> <li>▪ Need to set up a laboratory report form with cumulated laboratory results in each patient's medical record file.</li> <li>▪ Samples and request forms should be carefully labeled with patient name and outpatient number.</li> <li>▪ Scientific Committee/TAP/sites to develop laboratory request and report forms, including cumulated laboratory results form for patient records for ART program. Forms should be based on existing/approved forms where possible.</li> <li>▪ Laboratory staff should record the type of test used, batch number and expiry date alongside the test result in notebooks.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section D: Magongo Municipal Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Good Laboratory Practice</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ All sharps are disposed of in an official needle box.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ No running water (September 2002). Reconnected at time of visit July 2003.</li> <li>▪ No soap – staff buy own.</li> <li>▪ Bleach supplied by ICRH.</li> <li>▪ Staff reported not being sure what to do when a needle stick injury occurred.</li> <li>▪ No accident/incident register exists.</li> <li>▪ No policy for PEP available in laboratory.</li> <li>▪ Access to incinerator not assured.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Secure funding to pay the bills to assure a regular supply of water.</li> <li>▪ Ensure that adequate supplies of soap and bleach are made available to laboratory staff.</li> <li>▪ Use vacutainers for sample collection.</li> <li>▪ Develop site-specific SOPs to incorporate the principles of Good Laboratory Practice including health and safety of staff and assuring patient confidentiality.</li> <li>▪ Establish an accident/incident register.</li> <li>▪ Develop SOP and ensure policy is available in laboratory and staff are trained in steps to be taken for PEP.</li> <li>▪ On going training should include activities to promote Good Laboratory Management.</li> <li>▪ Record the type of test used, batch number and expiry date alongside the test result in notebooks.</li> <li>▪ A system for regularly monitoring and reporting on Good Laboratory Practice needs to be set up.</li> <li>▪ Assure facility has access to incinerator.</li> </ul>	
<b>Quality Control/ M&amp;E</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Magongo laboratory is inspected by CPGH for TB diagnostics.</li> <li>▪ Every fifth HIV test blotted for reference laboratory as per national VCT protocol.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Internal QA needs to be reviewed and strengthened.</li> <li>▪ Documented daily QC needs to be established for all routine tests performed.</li> <li>▪ No QC sample from external source. Need to set up a system for external evaluation of laboratory performance.</li> <li>▪ Need to plan for interim analysis – mid-program evaluation.</li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section D: Magongo Municipal Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Quality Control/ M&amp;E (continued)</b>	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Maintain a formal relationship with CPGH for monitoring and supervision as well as receiving standards and testing test specimens for reconfirmation. Local laboratory coordinator (based at CPGH) should be responsible for Good Laboratory Practice and for reviewing QC for ART program. Oversight to be provided by CPGH Chief Pathologist.</li> <li>▪ Establish a system to perform documented internal QC for each parameter daily for the first month. Thereafter check different parameters every day resulting in at least weekly check for each parameter to reduce costs.</li> <li>▪ Develop/adapt existing SOPs for QC/QA to include actions to be taken if QC problems occur.</li> <li>▪ CPGH should establish and manage an external QC program to submit to other sites. Arrangements should be made to obtain samples from national/international sources.</li> <li>▪ Perform external evaluation of performance during the training phase prior to ART program start at Magongo.</li> <li>▪ Perform external evaluation after 3 months and then every 6 months throughout the ART program.</li> <li>▪ Training for laboratory staff should include QC and QA procedures and principles of Good Laboratory Practice.</li> </ul>	
<b>Financing – cost sharing</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Magongo has a cost sharing system that incorporates exemptions for those who cannot pay.</li> <li>▪ VCT is provided free of charge.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Magongo does not retain any of the cost sharing fees collected – all return to municipal council.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Consider allowing Magongo to retain a portion of cost sharing fees for clinic use.</li> <li>▪ Sites/USAID/TAP to discuss the need to provide external support to Magongo for laboratory monitoring.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section E: Bomu (Mkomani) Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Policies and Procedures</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ National STGs for ART and monitoring of ARVs exist.</li> <li>▪ National VCT guidelines exist.</li> <li>▪ National OI guidelines exist.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ <i>Indicators:</i> <ul style="list-style-type: none"> <li>○ <i>National ART guidelines reported to be available and seen in laboratory (July 2003) = NO</i></li> <li>○ <i>National VCT guidelines reported to be available and seen in laboratory (July 2003) = NO</i></li> </ul> </li> <li>▪ No SOPs for laboratory exist.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Ensure that updated copies of national ART, OI and VCT guidelines are available for use by laboratory staff.</li> <li>▪ Develop site-specific SOPs for the ART program – adapt existing procedures/forms where possible. SOPs should include preventive maintenance for existing equipment.</li> <li>▪ Develop site-specific SOPs for all laboratory procedures – adapt existing procedures/forms where possible. SOPs should include preventive maintenance for existing equipment.</li> <li>▪</li> </ul>	
<b>Infrastructure/ Equipment</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Built in 2001: 3 sections with no dividing walls - serology/microbiology (infectious); hematology (non-infectious) and a reception area.</li> <li>▪ Facility is adequate for existing equipment, workload and 2 staff.</li> <li>▪ Have a maintenance contact with Mombasa Polytechnic for all laboratory equipment.</li> <li>▪ Existing equipment: <ul style="list-style-type: none"> <li>○ Sahli haemometer</li> <li>○ Glucometer</li> <li>○ Refrigerators (3 – one each for microbiology, reagents and blood)</li> <li>○ Small freezer compartment in 1 refrigerator</li> <li>○ Incubator</li> <li>○ Centrifuge (3)</li> <li>○ Microscopes (5)</li> <li>○ Hood</li> </ul> </li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Policy is to buy (not lease equipment) and to link procurement to 1-2 year maintenance contract.</li> <li>▪ Back up arrangements are not in place for when equipment breaks down.</li> <li>▪ Space for new equipment may be limited.</li> <li>▪ Equipment expected to be in place at end of 2003: <ul style="list-style-type: none"> <li>○ Automated Coulter counter (haematology).</li> <li>○ Automated Clinical Chemistry unit.</li> </ul> </li> <li>▪ Essential supplies needed: <ul style="list-style-type: none"> <li>○ Vacutainers (see below)</li> </ul> </li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section E: Bomu (Mkomani) Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Infrastructure/ Equipment (continued)</b>	<ul style="list-style-type: none"> <li>▪ Existing equipment (continued)                             <ul style="list-style-type: none"> <li>○ Autoclave for media</li> <li>○ Hot air oven</li> <li>○ Water bath</li> <li>○ Mini-orbital shaker</li> <li>○ Water distiller (just purchased, not operational yet)</li> </ul> </li> <li>▪ <i>Indicator:</i> <ul style="list-style-type: none"> <li>○ <i>Average percent of a tracer list of laboratory equipment functioning at time of visit (July 2003) = 100%</i></li> </ul> </li> </ul>	
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ CPGH Chief Pathologist offered to provide assistance in drawing up specifications for new equipment.</li> <li>▪ Ensure that all procurement of equipment is linked to the signing of a maintenance contract.</li> <li>▪ Ensure that budgets include the renewal of maintenance contracts for equipment and that funds are made available.</li> <li>▪ Investigate the feasibility of establishing memorandum of understanding for back up arrangements with CPGH or with another private facility.</li> </ul>	
<b>Human Resources – Staffing</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Current staffing levels – 2 technologists with higher diploma.</li> <li>▪ Plan to take on 2 new staff by end of 2003 (one is a previous employee who will return from training).</li> <li>▪ Have capacity to support start up of ART program but need to follow up on new equipment, training and staff.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Current staff levels limit rapid scale up of ART program at Bomu Clinic.</li> <li>▪ Will need at least one extra staff when operating theatres open for 24 hours per day.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Additional workload for ART program at Bomu Clinic should be reviewed 3 monthly after the start of the program for 1 year and then annually to determine if additional staff are needed.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section E: Bomu (Mkomani) Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Human Resources - Training</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Laboratory staff have received some training in performing HIV testing</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ None of the laboratory staff have received training in ART at time of assessment (September 2002).</li> <li>▪ 1 technologist attended the initial training for the ART program held in April 2003.</li> <li>▪ Ongoing training for the other staff member who did not attend and for the 2 new staff members and in topics not covered in initial training will be needed - must be flexible and appropriate.</li> <li>▪ Site-specific training will be needed as new equipment technologies are introduced.</li> <li>▪ An information/reference center is needed to keep laboratory staff and clinicians updated.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Develop a plan for ongoing training to include site-specific training as new equipment technologies are introduced.</li> <li>▪ Identify a list of key documents/ laboratory information resources to be made available at Bomu Clinic.</li> <li>▪ Also see recommendations for training in overarching issues that apply to all four sites</li> </ul>	
<b>Specimen Collection</b>	<b>Strengths</b>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Vacutainers not used as not currently needed.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Use vacutainers for blood sample collection for ART program.</li> <li>▪ Routinely check expiry dates of vacutainers before use as part of SOP for Good Laboratory Practice.</li> </ul>	
<b>HIV diagnosis</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Use rapid HIV tests (UniGold and Determine).</li> <li>▪ Send discordant results for ELISA.</li> <li>▪ Has the capacity to support start up of ART program.</li> <li>▪ Workload VCT 110/month.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ HIV testing only done for VCT and not routine clinical diagnosis or management.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Re-evaluate capacity annually.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section E: Bomu (Mkomani) Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Haematology/</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Manual equipment (Sahli haemometer) is available to perform haemoglobin.</li> <li>▪ WBC differential is calculated manually.</li> <li>▪ Automated haematology unit expected to be in place by end of 2003.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Does not currently have capacity to perform CBC and TLC.</li> <li>▪ Does not currently have the capacity to support start up of ART program – patients/samples would need to be referred to CPGH.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Refer patients/samples to CPGH for CBC/TLC (PRDH cannot currently perform these tests).</li> <li>▪ Review work load annually</li> <li>▪ Ensure maintenance contract is included as part of procurement. Sign memorandum of understanding for backup arrangements with CPGH in case of equipment breakdown.</li> <li>▪ When automated haematology is acquired, check quality of testing before transferring routine monitoring for ART patients from CPGH to Bomu Clinic.</li> <li>▪ SOPs/forms will need to be developed for referral of patients/samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ 1 person will need to be identified to manage the referral system.</li> </ul>	
<b>Clinical Chemistry</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Fasting blood glucose can be performed manually.</li> <li>▪ Clinical Chemistry Unit expected by end of 2003.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Does not currently have the capacity to perform:                             <ul style="list-style-type: none"> <li>○ U &amp; E – urea/creatinine/electrolytes (including serum lactate, anion gap)</li> <li>○ LFT (including bilirubin, CPK)</li> <li>○ Amylase</li> <li>○ Lipid profile – triglycerides, cholesterol, HDL, LDL</li> </ul> </li> <li>▪ Patients are referred either to Aga Khan or CPGH depending on ability to pay.</li> <li>▪ Does not have the capacity to support start up of ART program – patients/samples would need to be referred to CPGH.</li> <li>▪ Even when clinical chemistry unit is in place some tests will still need to be referred to CPGH e.g.                             <ul style="list-style-type: none"> <li>○ Amylase</li> <li>○ Lipid profile – triglycerides, cholesterol, HDL, LDL</li> </ul> </li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section E: Bomu (Mkomani) Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Clinical Chemistry (continued)</b>	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Refer patients/samples to CPGH for clinical chemistry tests (PRDH cannot currently perform these tests).</li> <li>▪ Review work load annually.</li> <li>▪ Ensure maintenance contract is included as part of procurement. Sign memorandum of understanding for backup arrangements with CPGH in case of equipment breakdown.</li> <li>▪ SOPs/forms will need to be developed for referral of patients/samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ 1 person will need to be identified to manage the referral system.</li> <li>▪ When automated haematology is acquired, check quality of testing before transferring routine monitoring for ART patients from CPGH to Bomu Clinic.</li> </ul>	
<b>Microbiology/ Serology</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Have capacity for:                             <ul style="list-style-type: none"> <li>○ TB –sputum for AFB</li> <li>○ Malaria thick smear</li> <li>○ Stool for parasitology</li> <li>○ Widal</li> <li>○ Syphilis VDRL/RPR</li> <li>○ Hepatitis B</li> <li>○ Culture and sensitivity – urine and throat</li> <li>○ Urinalysis( microscopy)</li> </ul> </li> </ul>	<p><b>Limitations</b></p>
<b>CD4</b>	<p><b>Strengths</b></p>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ No capacity exists to perform CD4 at Bomu Clinic – refer patients to CPGH.</li> <li>▪ CD4 samples must be analyzed within 24 hours.</li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Centralize CD4 testing at CPGH for all four sites initially and then re-evaluate annually.</li> <li>▪ SOPs/forms will need to be developed for referral of patients/samples and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section E: Bomu (Mkomani) Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Viral load</b>	<b>Strengths</b>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ No capacity exists to perform viral load at Bomu Clinic – refer patients to CPGH.</li> <li>▪ Blood samples need to be centrifuged to separate plasma which should be collected in EDTA tubes.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ SOPs/forms will need to be developed for referral of patients/sample and return of results. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	
<b>Preparing and storing samples for viral resistance testing (participation in WHO/GOK surveillance)</b>	<b>Strengths</b>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ No capacity exists to prepare and store samples for viral resistance testing at Bomu Clinic – refer patients to CPGH.</li> <li>▪ Blood samples need to be centrifuged to separate plasma which should be collected in EDTA tubes.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Centralize the preparation and storage of samples for viral resistance testing at CPGH for all four sites initially and then re-evaluate annually.</li> <li>▪ SOPs/forms will need to be developed for referral of patients. Should be based on existing procedures/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	
<b>Referral system and return of results of specimens</b>	<b>Strengths</b>	<b>Limitations</b>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Establish a procedure/system for referring patients/transporting samples between Bomu (Mkomani) Clinic and CPGH for central testing and a system for delivering/returning of test results from central laboratories to patient records. . Investigate feasibility of CPGH sending results to PRDH for collection by Bomu</li> <li>▪ Develop SOPs and forms based on existing SOPs/forms where possible.</li> <li>▪ One person will need to be identified to manage the referral system.</li> </ul>	

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section E: Bomu (Mkomani) Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Selection/ Procurement and Distribution of Reagents and Equipment</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Laboratory staff are primarily responsible for selecting equipment and reagents and for quantifying needs of reagents to procure. Use bin cards which are kept in the laboratory and quantify needs based on consumption. Orders are sent by email to MEDS.</li> <li>▪ Generally use the same systems as pharmacy.</li> <li>▪ Mostly use MEDS.</li> <li>▪ Use local pharmacies/suppliers only occasionally as stop gap measure – more expensive.</li> <li>▪ Equipment :               <ul style="list-style-type: none"> <li>○ Contract for 1-2 years maintenance.</li> <li>○ Laboratory prepares specifications.</li> <li>○ Doctors confirm product appropriateness and need.</li> <li>○ Quality management team reviews specifications, back up service and reliability of supplier and recommends procurement.</li> <li>○ Hospital board approves 3-5 quotations.</li> <li>○ Awarded and procured.</li> </ul> </li> <li>▪ <i>Indicators</i> <ul style="list-style-type: none"> <li>○ <i>Average percent of a set of unexpired tracer reagents/supplies available in laboratory at time of visit (July 2003) = 100%</i></li> </ul> </li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Equipment :               <ul style="list-style-type: none"> <li>○ Prefer to procure machine and not use service contract.</li> <li>○ Laboratory specialists not involved in confirming product appropriateness and need.</li> </ul> </li> </ul>
	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Consult a laboratory specialist to confirm product appropriateness and need and to assist in drawing up specifications for procurement.</li> </ul>	
<b>Management Information System (MIS)</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Request forms have a check list.</li> <li>▪ Specimen identification on tubes includes patient name and inpatient/outpatient number.</li> <li>▪ Results are recorded in the laboratory in a chronological book - record number and name in register.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ Results are reported to the patient file on a piece of paper (hand written) – no normal ranges are given.</li> </ul>

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>			
<b>Section E: Bomu (Mkomani) Clinic – Initial Findings and Recommendations for Comment</b>			
<b>Management Information System (MIS) (continued)</b>	<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ ART program will need standardized laboratory request and report forms that fit the repertoire of Bomu Clinic.</li> <li>▪ Need to set up a laboratory report form with cumulated laboratory results in each patient’s medical record file.</li> <li>▪ Samples and request forms should be carefully labeled with patient name and inpatient/outpatient number.</li> <li>▪ Scientific Committee/TAP/sites to develop laboratory request and report forms, including cumulated laboratory results form for patient records for ART program. Forms should be based on existing/approved forms where possible.</li> <li>▪ Laboratory staff should record the type of test used, batch number and expiry date alongside the test result in notebooks.</li> </ul>		
<b>Good Laboratory Practice</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;"> <p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Have a standardized record keeping system using a laboratory notebook.</li> </ul> </td> <td style="width: 50%; vertical-align: top;"> <p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ All sharps are disposed of in an unofficial needle box and sent to the incinerator – no incinerator available at the site.</li> <li>▪ Are considering hiring a private company to collect medical waste.</li> <li>▪ All microbiological waste is decontaminated in 1 in 6 bleach (JIK, washed and then dried in a hot air oven – should be decontaminated by autoclaving not drying in a hot air oven.</li> <li>▪ No accident/incident register exists.</li> <li>▪ No policy for PEP available in laboratory.</li> </ul> </td> </tr> </table>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Have a standardized record keeping system using a laboratory notebook.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ All sharps are disposed of in an unofficial needle box and sent to the incinerator – no incinerator available at the site.</li> <li>▪ Are considering hiring a private company to collect medical waste.</li> <li>▪ All microbiological waste is decontaminated in 1 in 6 bleach (JIK, washed and then dried in a hot air oven – should be decontaminated by autoclaving not drying in a hot air oven.</li> <li>▪ No accident/incident register exists.</li> <li>▪ No policy for PEP available in laboratory.</li> </ul>
	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Have a standardized record keeping system using a laboratory notebook.</li> </ul>	<p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>▪ All sharps are disposed of in an unofficial needle box and sent to the incinerator – no incinerator available at the site.</li> <li>▪ Are considering hiring a private company to collect medical waste.</li> <li>▪ All microbiological waste is decontaminated in 1 in 6 bleach (JIK, washed and then dried in a hot air oven – should be decontaminated by autoclaving not drying in a hot air oven.</li> <li>▪ No accident/incident register exists.</li> <li>▪ No policy for PEP available in laboratory.</li> </ul>	
<p><b>Recommendations</b></p> <ul style="list-style-type: none"> <li>▪ Use vacutainers for sample collection.</li> <li>▪ Consider procuring a small incinerator.</li> <li>▪ Decontaminate microbiological waste in autoclave.</li> <li>▪ Establish an accident/incident register.</li> <li>▪ Develop SOP and ensure policy is available in laboratory and staff are trained in steps to be taken for PEP.</li> <li>▪ Develop site-specific SOPs to incorporate the principles of Good Laboratory Practice including health and safety of staff and assuring patient confidentiality. Develop SOP and ensure staff are trained in steps to be taken for PEP.</li> <li>▪ On going training should include activities to promote Good Laboratory Management.</li> <li>▪ Record the type of test used, batch number and expiry date alongside the test result in notebooks.</li> <li>▪ A system for regularly monitoring and reporting on Good Laboratory Practice needs to be set up.</li> </ul>			

<b>Assessment of Laboratory Capacity to Support the Introduction of ART</b>		
<b>Section E: Bomu (Mkomani) Clinic – Initial Findings and Recommendations for Comment</b>		
<b>Quality Control/ M&amp;E</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Every fifth HIV test blotted and sent to reference laboratory for dual testing.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Internal QA needs to be reviewed and strengthened.</li> <li>▪ Documented daily QC needs to be established for all routine tests performed.</li> <li>▪ No QC sample from external source - need to set up a system for external evaluation of laboratory performance.</li> <li>▪ Need to plan for interim analysis – mid-program evaluation.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Establish a formal relationship with CPGH for monitoring and supervision as well as receiving standards and testing test specimens for reconfirmation. Local laboratory coordinator should be responsible for Good Laboratory Practice and for reviewing QC for ART program. Oversight to be provided by CPGH Chief Pathologist.</li> <li>▪ Establish a system to perform documented internal QC for each parameter daily for the first month. Thereafter check different parameters every day resulting in at least weekly check for each parameter to reduce costs.</li> <li>▪ Develop/adapt existing SOPs for QC/QA to include actions to be taken if QC problems occur.</li> <li>▪ CPGH should establish and manage an external QC program to submit to other sites. Arrangements should be made to obtain samples from national/international sources.</li> <li>▪ Perform external evaluation of performance during the training phase prior to ART program start at Bomu Clinic.</li> <li>▪ Perform external evaluation after 3 months and then every 6 months throughout the ART program.</li> <li>▪ Training for laboratory staff should include QC and QA procedures and principles of Good Laboratory Practice.</li> </ul>	
<b>Financing – cost sharing</b>	<b>Strengths</b> <ul style="list-style-type: none"> <li>▪ Bomu Clinic has a cost sharing system that incorporates exemptions for those who cannot pay.</li> </ul>	<b>Limitations</b> <ul style="list-style-type: none"> <li>▪ Need to understand what will be the policy for charging for tests, particularly if ART blood specimens will be referred to CPGH for testing where tests are currently provided free of charge.</li> </ul>
	<b>Recommendations</b> <ul style="list-style-type: none"> <li>▪ Sites/USAID/TAP to discuss the need to provide external support to Bomu (Mkomani) Clinic for laboratory monitoring.</li> </ul>	

## NEXT STEPS

### Immediate Follow-up Activities

- The initial results will be shared with the Scientific Committee at a meeting in November 2002 for review and comments.
- The TAP partners will present initial findings from the assessment and draft options/recommendations to the Steering Committee and local stakeholders and partners at the end of November 2002.
- The initial findings and draft options/recommendations will be discussed with each site beginning early in January 2003 to solicit feedback, prioritize activities and to develop a work plan for each site.



## ANNEX 1. LIST OF PERSONS MET AND FACILITIES VISITED

### *ART Program Scientific Committee*

Dr. K. Mandaliyia  
Dr. F. Mwanyumba  
Dr. V. Ombeka  
Dr. P. Kimuu  
Dr. V. P. Vaghela  
Dr. F. P. N. Otieno  
Dr. C. E. Muyodi

### *Kenya MOH*

Dr. K. Chebet  
Dr. S. K. Sharif  
Dr. P. M. N. Musya  
Dr. K. Shikelly  
Dr. E. Getambu  
Dr. K. Baya

### *GOK ART Program – Planned Sites*

Coast Provincial General Hospital  
Port Reitz District Hospital  
Bomu (Mkomani) Clinic  
Magongo Municipal Clinic

### *Private Practitioners*

Dr. Chibule  
Dr. M. Gudka  
Dr. Hassanali  
Mr. A Jezani  
Dr. Karega  
Dr. P. Kisia  
Dr. M. Lewa  
Dr. Munyi  
Dr. Okanga  
Dr. Oguna  
Dr. Sebor  
Dr. J. Shangala  
Dr. Thuo  
Dr. Waudu  
Dr. Yossa

### *Private Pharmacy Outlets*

Badar Pharmacy  
House & McGeorge Laborex  
C. Mehta Pharmacy

Makadara Pharmacy  
Makupa Pharmacy  
Oceanview Pharmaceuticals  
Palmland Pharmacy

***Private Health Institutions***

Aga Khan Hospital  
Mombasa Hospital  
Pandhya Hospital  
Kenya Ports Authority

***NGO Personnel***

Mr. J. Mitto  
Mr. J. Waimiri

People of Mombasa living with HIV

***U.S. Agency for International Development***

Cheryl Sönnichsen

***Family Health International/IMPACT***

Y.D. Mukadi  
John Adungosi

***Population Council/Horizons***

Avina Sarna

***International Centre for Reproductive Health***

Mark Hawken

