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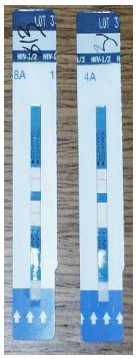
REPUBLIC OF MALAWI: HIV TEST KIT SUPPLY CHAIN ASSESSMENT AND QUANTIFICATION

MINISTRY OF HEALTH, HIV AND AIDS DEPARTMENT



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Abstract
In March and April 2008, the Ministry of Health, HIV and AIDS Department, with technical assistance from the USAID | DELIVER PROJECT funded by USAID | Malawi, conducted a national quantification of HIV test kit requirements for the Government of the Republic of Malawi's next two fiscal years, July 2008 – June 2010, and an assessment of the supply chain for managing HIV test kits in Malawi. This report documents the findings and recommendations from the supply chain assessment, as well as the methodology and results of the quantification with the total quantities and costs of the HIV test kits required and the funding requirements per year based on known funding commitments and funding gaps identified at the time of the quantification. Recommendations are proposed for addressing the supply chain issues identified and for continuing to build local capacity in the quantification methodology and the use of the PipeLine software tool for quantifying HIV test kits for the national HIV and AIDS program.

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TABLE OF CONTENTS

TABLE OF CONTENTS III

ACRONYMS V

ACKNOWLEDGEMENTS VII

EXECUTIVE SUMMARY IX

I. BACKGROUND 1
- A. Original Scope of Work for the Visit 1
- B. Expanded Scope of Work 2

II. METHODOLOGY AND DATA COLLECTION TOOLS 4
- A. Selection of Sample Sites for the Quantification and Supply Chain Assessment Data Collection 4
- B. Composition of Field Data Collection Teams and Adaptation of Data Collection Tools 4

III. PRINICIPAL FINDINGS 6
- A. Implementing Partners and Planned Expansion of HIV Testing Services 6
- B. Selection of HIV Test Kits and the National HIV Testing Algorithm 8
- C. Quantification of HIV Test Kits 8
- D. Financing and Procurement of HIV Test Kits 9
- E. Distribution of HIV Test Kits 11
- F. HIV Testing Services 12
- G. Adherence to National Testing Algorithm 13
- H. Human Resources 13
- I. Ordering, Reporting and Stockkeeping Procedures for HIV Test Kits 14
- J. Transport 15
- K. Availability of HIV Test Kits at Health Facilities 15
- L. Challenges to Scale-Up of HIV Testing and Counselling Services 16

IV. QUANTIFICATION METHODOLOGY 19
- A. Forecast Period for the Quantification 19
- B. Types of Data and Sources of Data 19
- C. General Forecasting Assumptions 20
- D. Summary of Forecasting Assumptions by Purpose of Testing 24
- E. Analysis of HIV Testing Forecasting Assumptions 37

V. QUANTIFICATION RESULTS 39
- A. HIV Test Kit Requirements, Shipment Receipt Dates and Costs for FY 2008 and FY 2009 40
- B. Global Fund RCC Proposal Budget, Year 1, 2, and 3 43
- C. Total Commodity Costs, Funding Commitments and Funding Gaps for FY 2008 and FY 2009 44

VI. RECOMMENDATIONS 47
- A. Short-term Recommendations 47
- B. Medium-term Recommendations 49

REFERENCES 59

Appendix A. Field Assessment and Quantification Data Collection Team 63

Appendix B. List of Stakeholders and Persons Interviewed 67
Appendix C. List of Facilities Visited 71
Appendix D. Facility Level Data Collection Tool 75
Appendix E. Regional Medical Stores Data Collection Tool 105
Appendix F. HIV Test Kit Quantification Workshop Agenda and List of Participants 125
Appendix G. HIV Testing Forecasting Assumptions 131
Appendix H. HIV Test Kit Requirements, Shipment Receipt Dates and Cost Estimates for FY 2008 and FY 2009 133
Appendix I. Global Fund RCC Proposal Budget: Year 1, 2 and 3 139
Appendix J. Total Commodity Costs, Funding Commitments and Funding Gaps for FY2008 and FY2009 143
Appendix K. Timeline for Funding and Procurement of HIV Test Kits 147
Appendix L. Timeline for Ordering and Scheduling Shipments of HIV Test Kits 151
Appendix M. Stakeholder Debriefing 155

TABLES

1. Testing Targets for HTC and PMTCT by Partner 7
2. Lead Time for Funding, Procurement and Delivery of HIV Test Kits 9
3. Number of Facilities Providing HIV Testing by Purpose of Testing 13
4. Estimated Number of People Tested for HIV and Testing Targets, by Year 24
5. Estimated Number of People to be Tested by Region and by Purpose of Testing: 2008, 2009 and 2010 25
6. HIV Prevalence for HTC and PMTCT, Adjusted by Region 26
7. Estimated No. to be Tested, No. of Positive Results and No. of Discordant Results by Purpose of Testing for 2008, 2009 and 2010 29
8. Total Quantities of HIV Tests Required for Quality Control for 2008, 2009 and 2010 31
9. Total Quantities of HIV Tests Required for Training by per Year, by Region 32
10. Total Quantities of Long ELISA Tests Required for Quality Control, Sentinel Surveillance, Behavioral Surveillance, Demographic Health Survey and Community-based Testing Projects for 2008, 2009 and 2010 34
11. Total Quantities of HIV Tests Required for All Purposes of Testing and Uses of HIV Tests for 2008, 2009 and 2010 36
12. Analysis of HIV Testing Forecasting Assumptions 37
13. HIV Test Kit Requirements and Costs for April 2008 Emergency Order for Shipment to Arrive in August 2008 40
14. Total HIV Test Kit Requirements and Costs FY 2008 (July 2008-June 2009) 41
15. Total HIV Test Kit Requirements and Costs FY 2009 (July 2009-June 2010) 42
16. Global Fund RCC Proposal Budget, Year 1, 2 and 3 43
17. Total Commodity Costs, Funding Commitments and Funding Gaps for FY 2008 and FY 2009 44

FIGURES

1. Funding, Procurement and Distribution of HIV Test Kits, MALAWI – April 2008 12
2. Distribution of HIV Test Kits from RMS to DHO to Health Centres (1) – April 2008 13
3. Distribution of HIV Test Kits from RMS to DHO to Health Centres (2) – April 2008 13

ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARVs	Antiretroviral Drugs
BLM	Banja La Mtsogolo
CHAM	Christian Health Association of Malawi
CITC	Client-Initiated Testing and Counseling
CHAI	Clinton Foundation HIV and AIDS Initiative
CHSU	Community Health Services Unit
CMS	Central Medical Stores
DBS	Dried Blood Spot
ELISA	Enzyme Linked Immunosorbent Assay
EMLS	Essential Medical Laboratory Services
FEFO	First to Expire-First Out
FHI	Family Health International
GF	Global Fund
GFATM	Global Fund to Fight AIDS, TB and Malaria
GOM	Government of Malawi
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counseling
HTSS	Health Technical Services Support – Pharmaceuticals Unit
HTSS	Health Technical Services Support – Diagnostics Unit
KHB	Kehua Bioengineering (HIV (1+2) Rapid Assay HIV Test Kit)
LIAT	Logistics Indicator Assessment Tool (USAID | DELIVER PROJECT)
LMIS	Logistics Management Information System
MACRO	Malawi AIDS Counseling and Resources Organization
MBTS	Malawi Blood Transfusion Service
M&E	Monitoring and Evaluation
MOH	Ministry of Health
MOS	Months of Stock
NAC	National AIDS Commission
NGO(s)	Non-governmental Organization(s)

PEP	Post-exposure Prophylaxis
PITC	Provider-Initiated Testing and Counseling
PMTCT	Prevention of Mother-to-Child Transmission of HIV
RCC	Rolling Continuation Channel (Global Fund)
SOH	Stock on Hand
SDP	Service Delivery Point
STI(s)	Sexually Transmitted Infection(s)
TB	Tuberculosis
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
VCT	Voluntary Counselling and Testing

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A complete list of stakeholders and persons interviewed is attached to this report as *Appendix B. List of Stakeholders and Persons Interviewed.*

In addition, the authors would like to acknowledge and express special thanks to USAID | Malawi for funding this activity in support of the Government of the Republic of Malawi's response to the HIV AND AIDS epidemic.

EXECUTIVE SUMMARY

A. Major Accomplishments

The original scope of work and objectives for this technical assistance were to conduct a national quantification exercise for HIV test kits and to build capacity of local counterparts in quantification methodology and use of the PipeLine software tool for quantifying HIV test kit requirements and for monitoring and managing the supply of HIV test kits in the country. Given the reported shortages and stockouts of HIV test kits in the country, and Ministry of Health concerns regarding the management of HIV test kits throughout the supply chain including the suspected leakage of HIV test kits from the public sector health system, the USAID | DELIVER PROJECT advisors were asked to add a supply chain assessment component to the existing scope of work. In addition, the MOH also requested to include the national requirements for long ELISA test kits to support HIV testing for sentinel surveillance and other surveillance studies and surveys, and for quality assurance as well as the simple rapid assay test kits for HIV screening and testing at health facilities as had originally been requested.

This resulted in a significant expansion of the data collection and analysis activities as well as a higher level of participation and commitment from counterparts from the Ministry of Health HIV and AIDS Department, CMS and local USAID | DELIVER PROJECT advisors who participated in the field data collection, interviews with facility level staff and central level stakeholders, and the final analysis and discussion of the assessment findings. Following the field visits, the selected members of the quantification team convened for an intense, five day quantification workshop in Lilongwe to review and analyze GOM program policies, strategies and scale up plans expected to affect the demand for HIV testing and counseling services, and to a conduct a national quantification exercise to capture the total HIV test kit requirements and costs for the next two GOM fiscal years, July 2008-June 2009 and July 2009-June 2010, which will allow the Ministry of Health to maintain the current volume of services being provided and to meet the government's plans for scaling up HIV testing and counseling services in the country.

The USAID | DELIVER PROJECT advisors assisted the quantification team in preparing separate forecasts of the HIV test kit needs for each region of the country based on regional differences in the proportion of HIV testing services being provided, HIV prevalence, and expected rates of scale-up. In addition, three separate PipeLine databases were created to be able to determine the total HIV test requirements for each region of the country taking into account the current lead times for funding, procurement and delivery of HIV test kits, the buffer stocks, and the maximum and minimum stock levels established during the quantification workshop. The PipeLine software was also used to plan the shipment quantities and delivery schedules for the country that will be required to be able to maintain the stock levels at the Regional Medical Stores between the agreed upon maximum and minimum levels, and to be able to monitor and manage the supply of HIV test kits at the regional as well as at the national level.

B. Summary of Findings

Assessment Findings

Key findings from the supply chain assessment discovered to be affecting the supply of HIV test kits to the country and the availability of HIV test kits at health facilities include:

1) The current 10 month lead time for funding, procurement and delivery of HIV test kits has not been taken into consideration in earlier quantifications nor used to guide the timing of

funding disbursements, procurements and shipment delivery schedules to be able to ensure a coordinated and continuous supply of HIV test kits to the country. This has led to an under-estimation of HIV test kit requirements on one hand, and unrealistic timeframes for planning and managing the funding, procurement and delivery of HIV test kits on the other. As such, this is a major factor contributing to the inadequate and interrupted supply of HIV test kits to the country.

2) Irregular and fragmented shipments of HIV test kits to the country and to RMSs which does not allow for efficient nor effective management of stock levels in the country.

3) Multiple distribution mechanisms exist for collection and/or delivery of HIV test kits to health facilities using different modes of transport and with different lead times.

4) While maximum and minimum stock levels and ordering procedures have been established for HIV test kits that are supposed to be ordered, stored and distributed together with essential medicines and contraceptive commodities, there is limited understanding of how to calculate order quantities and even if ordered correctly, facilities may not receive the quantities ordered. A large number (65%) of the facilities visited for the assessment reported placing an emergency order in the last six months.

5) The logistics management information system (LMIS) designed for collecting and reporting data on the consumption and stock on hand, and for ordering HIV test kits together with essential medicines and contraceptive commodities is not fully operational. Different versions of the LMIS reporting and ordering forms exist, some do not include all three of the HIV test kits currently in use in Malawi, and data on the HIV test kits is often omitted on the forms.

6) The LMIS data is not routinely reported to the RMSs nor routinely aggregated and used to monitor the stock status of HIV test kits in the country or to inform distribution to health facilities.

7) The availability of HIV test kits was identified by service providers as the major challenge to scale-up of HIV testing and counselling services.

The data collection for the supply chain assessment and the quantification also addressed factors affecting the provision and quality of the HIV testing services in Malawi. Some of these findings include:

8) All staff interviewed at all of the facilities visited were found to be in compliance with the national testing algorithm. Even when stockouts of one or another of the test kits occurred, staff did not substitute the use of test kits in the algorithm and appropriately referred clients to higher level facilities for confirmatory and tiebreaker testing if needed.

9) A highly visible and effective quality assurance program was evident at all the facilities visited including routine use of laboratory controls, observation and supervision of testing performance by all cadres of staff providing HIV testing, and routine collection and submission of blood samples for quality control testing.

10) Several expansion strategies implemented over the past two years have been successful in increasing the number and range of cadres of staff qualified to provide HIV testing and counseling and have increased the number of people being reported as tested in by 40% from 2006 to 2007.These include an active training program, introduction of outreach activities through the use of mobile units and door-to-door testing, an emphasis on provider-initiated testing and counseling, introduction of the HIV testing week, and expansion of access to HIV testing for pregnant women, their partners and HIV-exposed infants through ANC clinics.

These and other findings from the assessment are documented in detail in section *III. Principal Findings* of this report.

Findings from the Quantification Exercise

Key findings from the quantification exercise that were determined to be affecting the accuracy, usefulness and validity of earlier quantifications included:

1) Past quantifications and procurements of HIV test kits have been budget based rather than based on actual consumption of HIV test kits or numbers of people being tested.
2) No formal or documented quantification methodology has been used for quantifying the national HIV test kit requirements in the past.
3) The different purposes of HIV testing (e.g. HTC, PMTCT, PITC, Blood Safety) with different HIV prevalence and scale-up rates, and other known uses of HIV test kits, (sentinel surveillance and other studies, quality control and training), have not been captured and factored into the quantification of the HIV test kit requirements before, thereby limiting the accuracy of past quantifications.
4) The LMIS and the HMIS are currently not able to provide reliable, timely nor complete data that can be used for analyzing past consumption trends or past demand for HIV testing services, and therefore, are of limited use in forecasting future demand and consumption of HIV test kits.
5) A major policy change that will affect how HIV test kits will be used in the country that was incorporated into the methodology for quantifying the HIV test kit requirements is the GOM decision to change from a parallel to a serial HIV testing algorithm. This will mostly affect the proportion of confirmatory tests needed for re-testing of initially positive samples from the first screening test.
6) Expansion of provider-initiated testing and counselling is expected to significantly increase the number of people that will be tested for HIV who will be referred from in-patient wards, TB clinics, STI clinics and out-patient departments. Many of these patients will already be symptomatic are expected to have a higher HIV prevalence. Therefore, larger quantities of the Uni-Gold HIV test, used as the confirmatory test in the second step in the newly implemented serial testing algorithm, will be required.
7) Failure to account for the10 month lead time for funding, procurement and delivery of HIV test kits in previous quantifications has contributed to under-estimation of the HIV test kit requirements, insufficient funding, and unrealistic timeframes for planning procurement and shipment delivery schedules. This has contributed to the inconsistent supply of HIV test kits to the country and stockouts at health facilities.
8) A final important finding from the quantification uncovered the disparity between the total funding requirements and the funding commitments from various sources for procurement of HIV test kits. This includes commitments from all current sources of funding including the Global Fund Rd 2, the Global Fund RCC Budget Proposal, CDC, FHI, UNITAID, and AXIOS for the April 2008 – June 2010 time period.

The final results of the quantification culminated in the need for an emergency order estimated at US $2,482,475 to be placed by the MOH in April 2008 to ensure arrival of a shipment in August 2008 to ameliorate the ongoing stockouts and interruptions in HIV testing services, and for the MOH to be able to meet the needs for the HIV testing week in September 2008. In addition, the MOH also needs to submit a regular order and request for disbursement of funds to the Global Fund in April

2008 to ensure delivery by February 2009 (10 months later) in time to maintain ongoing HIV testing services and to support the GOM plans to scale-up HIV testing and counselling services.

The specific HIV test kit requirements and costs for Malawi for FY 2008 (July 2008-June 2009) and FY2009 (July 2009 – June 2010) are documented in the narrative and the tables presented in section *V. Quantification Results* and in the *Appendices* attached to this report. After completing the quantification exercise, the total commodity costs for the April 2008 – June 2010 time period amounted to US$10,501,500. A comparison of the funding commitments to the total estimated commodity costs revealed a US$6,977,286 funding gap at the time of the quantification. The total commodity costs, funding commitments by source of funding, and funding gaps remaining at the time the quantification are also presented in this section of the report.

C. Summary of Recommendations

Short-term and long-term recommendations for improving overall supply chain management of the HIV test kit supply in Malawi and for building in-country capacity in quantification including application of the quantification methodology and the software tools used for quantification of HIV test kits are documented in section *VI. Recommendations* of this report. In addition, specific actions to be taken immediately following the national quantification exercise that have already been communicated to the MOH HIV and AIDS Department in an earlier draft version of this technical report are presented in section *VII. Next Steps.*

The following is a summary of the key recommendations resulting from the supply chain assessment and the quantification exercise conducted during the technical assistance visit.

1. Selection, Registration and Use of HIV Test Kits

- If the national HIV testing algorithm is changed to include the selection of new HIV test kit(s) (e.g. if KHB is approved as the screening test) or if a change in the testing protocols is approved (e.g. a different test kit is selected to be used as the confirmatory or the tiebreaker test), then a new quantification exercise will need to be conducted to include the new brand(s) of HIV test kits to be procured and, if the testing protocol also changes, to adjust the quantities of each of the HIV test kits that will be required.

2. Quantification and Procurement of HIV Test Kits

- A routine review and update of the quantification data and assumptions is required every six months or sooner if major changes in the forecasting assumptions occur before six months from the last quantification. This is particularly true for programs that are scaling up services in which future demand for services and consumption of commodities may be changing rapidly.
- Future quantifications should cover the HIV test kit requirements for the next full two year period and should be coordinated with the GOM fiscal years to be able to undertake timely resource mobilization for any funding gaps identified, and to coordinate the timing of procurements and supplier shipment delivery schedules to ensure a continuous supply of HIV test kits to the country
- Current stock levels of HIV test kits in the country are low so that even when the already scheduled shipments arrive in April and May 2008, an emergency order will still need to be placed immediately to fill the supply pipeline to cover the 10 month lead time until the next

shipment arrives in February 2009, and to meet the increased demand for HIV test kits anticipated during the HIV testing week in September.

3. *Funding for Procurement of HIV Test Kits*

- The MOH HIV and AIDS Department should address the funding gaps for procurement of HIV test kits over the next two GOM fiscal years identified through this quantification exercise. Efforts should be coordinated with the National AIDS Commission and other stakeholders to mobilize the additional resources needed to address the current shortages and stockouts of test kits and to fill the in-country supply pipeline to cover the 10 month lead time to be able to maintain ongoing services and to support the MOH's planned scale-up of HIV testing and counseling.

4. *Ordering and Distribution of HIV Test Kits According to Established Maximum and Minimum Stock Levels*

- Maximum and minimum stock levels for HIV test kits at the RMSs and the health facility level have already been established according to the Standard Operating Procedures for the logistics system developed for essential medicines, contraceptives and HIV test kits. While the established maximum and minimum stock levels were reviewed and re-enforced during the quantification workshop, it was clear from the field visits to RMSs and health facilities that much technical support, monitoring and supervision is needed to strengthen capacity of health facility and RMS staff in ordering and distribution of HIV test kits according to the maximum/ minimum stock levels and for the RMSs to be able to effectively monitor the stock status of HIV test kits in the region.

5. *Storage and Distribution*

A goal of the Ministry of Health is to achieve integrated storage and distribution of HIV test kits together with essential medicines and contraceptives. In some facilities, HIV test kits are being stored and managed in the pharmacy stores, while in others, test kits are being stored and managed in the laboratories. As described in the findings of this report, different mechanisms currently exist for delivery and/or collection of HIV test kits between RMSs and facilities.

- A concerted effort is needed to provide ongoing monitoring, supervision and support to RMSs and health facilities to standardize storage, reporting and ordering of HIV test kits from pharmacy stores, and to unify the distribution system for HIV test kits from RMSs along with other non-pharmaceutical products and pharmaceutical products.

6. *Logistics Management Information System (LMIS)*

- The existing Monthly LMIS forms for collecting and reporting logistics data and ordering HIV test kits should be revised and standardized to include all of the rapid assay and ELISA HIV test kits currently in use.

- Ongoing monitoring, supervision and support is required to strengthen facility and district level staff knowledge and skills on how to collect and report the data on HIV test kits and how to calculate the order quantities for HIV test kits on the integrated Monthly LMIS forms for essential drugs, contraceptives and HIV test kits.

- The MOH curriculum for training facility level staff on HIV testing and counseling should include a component on basic logistics principles and the existing Standard Operating Procedures for facility reporting and ordering of HIV test kits.

- The RMSs should have a computerized program installed, like the Supply Chain Manager software program currently in use in many districts, or other software program that allows them to enter and analyze LMIS data and orders received from the health facilities and the districts, and to monitor the stock status of HIV test kits in the region.

7. Implement a medium-term, two year planning period for quantification, resource mobilization and supply planning for HIV test kits

- The MOH should adopt a medium-term, two year period for quantification, resource mobilization and procurement planning for HIV test kits and this should be incorporated into overall program planning and budgeting for the MOH HIV and AIDS Department.

8. Develop a medium-term workplan for continuing to build technical capacity in quantification and overall supply chain management in the country

While capacity building took place through the close collaboration and participation of local staff and MOH counterparts in the quantification exercise,

- Further technical assistance in quantification of HIV test kits will be required before the MOH HIV and AIDS Department will be able to independently conduct a national quantification exercise following the quantification methodology presented and modeled during this technical assistance.
- Additional training and technical support will also be needed for MOH staff at the program level and at the RMSs to fully master the use of the PipeLine software tool for estimating the total HIV test kit requirements and costs for the program, developing a national supply plan for coordinating the different funding sources and suppliers with the timing of the procurements and supplier delivery schedules, and for ongoing monitoring of the stock status of the HIV test kit supply in the country.

9. Develop a national HIV and AIDS Commodity Security Strategy

Develop a national HIV and AIDS commodity security strategy to promote policies and plans for securing long-term financing for procurement of commodities and for improving overall supply chain management of HIV test kits as well as other HIV-related commodities in the country.

This would include establishment of an HIV and AIDS commodities technical working group comprised of representatives from donor agencies, MOH and other government entities, technical assistance partners, and other key stakeholders. A few key activities of this proposed HIV and AIDS commodities technical working group would be to meet at least quarterly to:

- Share information and update all members on the status of planned shipments and the stock status (months of stock on hand) of HIV test kits and other HIV-related commodities in the country.
- Plan, coordinate and review the annual quantification exercise and the six-monthly review and update of the quantification data inputs, assumptions and results.
- Verify the amounts and timing of funding commitments for procurement of commodities each time the quantification is reviewed and updated.

- Coordinate resource mobilization efforts for procurement of commodities when needed.
- Identify the needs for continued technical capacity building in supply chain management, make recommendations and advocate for resources and technical assistance when needed

D. Conclusion

It is hoped that the findings and recommendations from the supply chain assessment will be useful in two ways. First, in providing immediate steps the Ministry of Health can take to address the current shortages and stockouts of HIV test kits in the country, and second, that this technical report will provide the impetus for implementation of the interventions that are recommended for improving overall supply chain management of HIV test kits that will allow the Ministry of Health to maintain the current level of services and to achieve the planned scale-up of HIV testing and counselling in the country.

It is also hoped that the quantification methodology documented in this report and imparted through the participation and capacity building of Malawian counterparts throughout the quantification exercise will be replicated in upcoming quantification activities to improve the accuracy and usefulness of future quantifications. In addition, it is equally important that the PipeLine databases created for each of the three regions of the country are monitored and updated regularly to be able to effectively monitor and manage the national supply of HIV test kits in the country. And lastly, but not least, it is hoped that the results of this quantification will be used to guide decision-making and to coordinate the roles and inputs of different stakeholders in the funding, procurement and delivery of HIV test kits for Malawi.

I. BACKGROUND

This technical assistance was funded by the USAID | DELIVER PROJECT at the request of the Government of the Republic of Malawi, Ministry of Health. The Ministry of Health HIV and AIDS Department requested the USAID | DELIVER PROJECT to help conduct a credible forecast and quantification of HIV test kit requirements based on an assessment of the projected demand from utilization data on counselling and testing services. Previous quantifications based on budget allocations have resulted in under-ordering of commodities, frequent stockouts and the subsequent cessation of services at HIV testing facilities. In addition, Malawi has now adopted a serial rather than a parallel testing algorithm and a transitional plan is in place for all facilities to adopt the serial testing algorithm by May 1st 2008. The change to a serial testing algorithm has introduced challenges into the forecasting exercise as the demand for the confirmatory test (currently the Uni-Gold HIV test) is based on the number of expected positive results obtained from the first screening test (currently the Determine HIV 1/2 rapid assay test), rather than the simple one to one ratio under the parallel testing algorithm.

The Ministry of Health in Malawi has established a national quantification team with the mandate to quantify the national requirements for all pharmaceutical products, non- pharmaceutical products and medical devices in the country. The HIV and AIDS Department of the Ministry of Health is interested in building the capacity of a sub-set of the national quantification team to be responsible for carrying out the quantification of HIV test kits with the goal of subsequently integrating the quantification of all HIV-related commodities into the larger ministerial quantification activities. To that end, the USAID | DELIVER PROJECT was asked to include a capacity building component in the technical assistance focused on transferring specific skills and knowledge in quantification methodology for HIV test kits including the use of the PipeLine software tool for determining total commodity requirements and costs, and for national level supply planning.

A. ORIGINAL SCOPE OF WORK FOR THE VISIT

HIV test kits are currently being quantified by UNICEF in conjunction with several key partners, including the MOH HIV and AIDS Department, CMS, CHAM, training institutions and other partner organizations. Unlike ARV drugs, which are distributed through a parallel system, HIV test kits are currently stored and distributed through the integrated CMS system for public health commodities. At present there is debate between UNICEF and the Ministry of Health with regard to the accuracy of the most recent quantification. The Ministry of Health has requested that the USAID | DELIVER PROJECT streamline the quantification process for these HIV test kits and identify any specific gaps that might impact the availability of test kits over the next few years. Other points of concern is the Ministry's efforts to transition from a parallel to a serial testing algorithm using the Bioline, KHB and Uni-Gold rapid assay test kits.

Specific Activities:

- Prior to departure, draft a questionnaire to be distributed to counterparts currently working with HIV test kits that captures information on consumption, stock on hand, and losses and adjustments for those commodities. Service statistics will also be captured in the questionnaire.
- Work with the MOH to analyze data generated from questionnaires completed and submitted by counterparts.

- Identify the other types and sources of data currently available for forecasting of HIV test kit needs and obtain necessary data.
- With the MOH counterparts, discuss approaches to conducting the national HIV test kit quantification and reach consensus on that approach.
- Interview program managers and relevant donor partners for information required for the quantification.
- Conduct site visits to assess test kit management and use at various facility levels and to interview SDP staff
- Document the quantification methodology and assumptions used.
- Use available data, along with program expansion plans, to conduct a medium-term forecast and supply plan for the national HIV test kit requirements through 2010.
- Obtain information on shipment schedules, procurement plans, and available funding for all partners.
- Orient local staff and MOH counterparts on the use of the PipeLine software for monitoring national consumption and stock levels of HIV test kits, coordinating different sources of supply of HIV test kits in the national supply plan, and planning and monitoring shipment quantities and delivery schedules.
- Prepare and present the quantification results at a stakeholder debriefing at the end of the technical assistance visit.
- Incorporate inputs from in-country counterparts into a report for presentation to the USAID | DELIVER PROJECT in Arlington.

B. EXPANDED SCOPE OF WORK

Given the Ministry of Health's concerns about the reported leakage of HIV test kits and ongoing stockouts at health facilities, the consultants were asked to include an assessment of the HIV test kit supply chain at the facilities to be visited for the data collection for the quantification exercise. The consultants were also asked to include long ELISA assay test kits as well as rapid assay test kits in the quantification. Therefore, the original Scope of Work was expanded and amended to include the following activities:

- Adaptation and pilot testing of the quantification data collection tools to also collect data and interview facility staff be able to assess how HIV test kits are currently being ordered, distributed and managed at the HIV testing facilities and at the three Regional Medical Stores. The USAID | DELIVER PROJECT HIV Test Kit Logistics Indicator Assessment Tool (LIAT) was adapted for this purpose.
- Increase the number of facilities to be visited for the quantification data collection to accommodate the assessment component. Train the quantification team members in the use of the expanded Facility Level and RMS data collection tools to understand the purpose and the use of the tools for collecting data and interviewing facility staff for both the quantification and the supply chain assessment.
- While in country, provide a preliminary analysis of the findings from the supply chain assessment based on the quantitative data collected and a qualitative description of the HIV test kit supply chain.

- As part of the capacity building in quantification of HIV test kits, fully include MOH and CMS counterparts in all steps of the quantification process from review and piloting of the data collection tools, conducting the site visits for the data collection and the supply chain assessment, and participation in the quantification workshop described below.
- Conduct a 5-day quantification workshop to provide training on the process and the methodology used for quantifying HIV test kits, review the sources of data for the quantification exercise, examine the quality of the data available, and determine the types of data to be used for the quantification.
- Introduce participants to the PipeLine software tool used for quantification and supply planning including specific features for analyzing national consumption trends, assessing the in-country stock status of each HIV test kit, and for determining shipment quantities and delivery schedules.
- Consult with the Community Health Services Unit (CHSU) national AIDS laboratory to estimate the need for long ELISA assay tests to be used for quality control (both for re-testing of blood samples tested at HIV testing facilities at Central Hospitals and CHSU, and for testing of external panels of 5 known blood samples by HTC counsellors), and for conducting sentinel surveillance and special survey studies. The need for long ELISA assay tests are to be included in the national quantification of HIV test kit requirements for the Ministry of Health.
- In close collaboration with the Ministry of Health HIV and AIDS Department and other implementing partners, agree on the forecasting assumptions for demand of HIV test kits, determine the total program requirements and cost estimates for the period between April 2008 and June 2010, and prepare a shipment schedule that will guide the timely procurement and delivery of HIV tests over the forecast period. Specifically, the USAID | DELIVER PROJECT was asked to identify the HIV test kit requirements and funding needs over the next two GOM fiscal years, FY 2008 (July 1, 2008 – June 30, 2009) and FY 2009 (July 1, 2009 – June 30, 2010).
- And lastly, the USAID | DELIVER PROJECT was asked to conduct the supply chain assessment and quantification by region of the country. Therefore, the assessment findings and the quantification results were to be presented separately for each of the three regions, as well as aggregated for the national level.

II. METHODOLOGY AND DATA COLLECTION TOOLS

A. SELECTION OF SAMPLE SITES FOR THE QUANTIFICATION AND SUPPLY CHAIN ASSESSMENT DATA COLLECTION

A sample of 20 facilities and all three Regional Medical Stores were selected for the supply chain assessment and the data collection for the quantification. The sample consisted of various strata of public health facilities including high volume central hospitals, district hospitals, and lower volume rural hospitals and health centres. Stand-alone NGO sites such as MACRO and integrated projects, e.g. University of North Carolina, were also included in the sample. Mission facilities and private hospitals were represented in the selected sample. Collectively, the facilities visited included the three Regional Medical Stores and 20 facilities of which 12 are public sector health facilities, - two are CHAM managed facilities -, three private facilities, and five NGO facilities. Thirteen districts out of the total 28 districts in Malawi were represented in the sample which covered all three of Malawi's administrative regions. The sample size was limited by the time available for conducting both the assessment and the quantification exercises, therefore the results are indicative and diagnostic but do not represent a full assessment. See *Appendix C. List of Facilities Visited* attached to this report.

B. COMPOSITION OF FIELD DATA COLLECTION TEAMS AND ADAPTATION OF DATA COLLECTION TOOLS

The seven data collection team members consisted of MOH and CMS counterparts as well as USAID | DELIVER PROJECT logistics advisors. All team members participated in the review, piloting and final revision of the data collection tools in Lilongwe before departing on the field visits to the regions. Please see *Appendix B. Field Assessment and Quantification Data Collection Team*.

The data collection tools used for the supply chain assessment portion of the technical assistance were adapted from the USAID | DELIVER PROJECT HIV Test Kit Logistics Indicator Assessment Tool (LIAT) which collects both qualitative and quantitative information on the in-country supply chain for test kits. The tool was modified for the Malawi HIV testing environment and piloted by the team members at sites in Lilongwe prior to traveling for the assessment/quantification data collection visits. Please see the final version of the data collection tools attached to this report as *Appendix D. Facility Level Data Collection Tool* and *Appendix E. Regional Medical Stores Data Collection Tool*.

A large part of the data collection for the quantification consisted of

- verifying how HIV testing services are currently being provided including the number and cadres of staff providing HIV testing and counselling services,
- assessing adherence to the national testing algorithm, and
- collecting service statistics data on the number of people being tested at health facilities by purpose of testing, (HTC, PMTCT, Blood Safety, Clinical Diagnosis), and the prevalence rates of the different populations being served.

In addition, the supply chain assessment questions and data collection were specifically targeted at

- collecting logistics data where possible on the quantities of HIV tests used (consumption), stock on hand, and any losses or adjustments in the quantities of HIV test kits in stock for reasons other than consumption,
- assessing the existing logistics management information system (LMIS) for collecting, reporting and monitoring data on the consumption and stock levels of HIV test kits for the national program,
- describing the inventory management procedures for HIV test kits at the facilities and RMSs visited including ordering, storage and basic stockkeeping practices, and
- documenting the distribution system for HIV test kits between all levels of the supply chain.

III. PRINICIPAL FINDINGS

On arrival in country, the consultants initially met with the Ministry of Health HIV and AIDS Department, the HTSS Pharmaceutical Unit, and the HTSS Diagnostics Unit to discuss the scope of work for the quantification team, review the schedule of activities, and to discuss program targets and plans for expansion of HIV testing services with policy makers at the Ministry of Health. Within those meetings, the Ministry of Health asked that the quantification team carry out an assessment of the supply chain for HIV test kits based on speculation about leakage of test kits due to apparent discrepancies between the quantities of HIV test kits coming into the country and the number of people being reported as tested.

A. IMPLEMENTING PARTNERS AND PLANNED EXPANSION OF HIV TESTING SERVICES

The major implementing partners in the provision and expansion of HIV testing services in Malawi identified by the Ministry of Health included CHAM, BLM, MACRO, University of North Carolina, Partners in Hope, and Lighthouse Trust. A full list of the organizations visited and persons interviewed is attached to this report as *Appendix A. List of Persons Contacted*. Program targets and expansion plans were discussed at length with all implementing partners and documented to be able to inform the assumptions for the national HIV test kit quantification exercise.

Among the multiple initiatives for scaling up HIV testing services that are expected to increase demand for HIV test kits over the next two years are:

- the Government of the Republic of Malawi's continued mandate to integrate HIV testing services at all health facilities on an opt-out basis;
- NAC support to MACRO to provide mobile HIV testing services in all three regions of the country;
- BLM addition of stand-alone HIV testing sites;
- Lighthouse Trust expansion to support integration of HIV testing services in 40 health facilities in Lilongwe;
- a major effort to expand HIV testing of pregnant mothers and exposed infants through PMTCT services;
- further integration of HIV testing and counselling services within STI clinics, TB clinics and hospital wards - also referred to as Provider Initiated Testing and Counselling (PITC); and
- continuation of the highly successful HIV testing week in July of each year (currently shifted to September for 2008).

The testing targets for the various implementing partners over the quantification period were collated and are presented in Table 1. below:

TABLE 1. Testing Targets for HTC and PMTCT by Partner

Targets for HTC and PMTCT by Partner			
Partner Organization	**2008**	**2009**	**2010**
Malawi AIDS Counseling and Resources Organization (MACRO)	165,000	200,000	
Christian Health Association of Malawi (CHAM)	?	?	
Banja La Mtsogolo (BLM)	100,000	125,000	
Howard University (Early Infant Diagnosis)	20,000	20,000	
Partners in Hope	10,000	10,000	
Lighthouse Trust	42,000	81,000	119,200
University of North Carolina (UNC)	28,000	30,000	
Salema AIDS Support Organization	4,000	5,000	
Nkota Nkota AIDS Support Organization	12,000	14,000	
Tovwirane (NGO)	10,800	10,800	
Defense Forces	7,800	7,800	
Private Sector (Malawi Business Coalition Against HIV AND AIDS)	21,600	28,800	3,600
FHI (Procuring for 2 districts - Chikwawa and Dowa)	53,592	53,808	
Total Testing Targets by Partner	**474,792**	**586,208**	

An effort was made to compare the partner targets to the total program targets (see Table 4. on page 21 of this report) keeping in mind that the contribution of these partners in the expansion of services is likely to be quite significant in the future. The quantification team, in consideration of the initiatives by partners and NAC, concluded that the contribution made by the various innovations in the NGO and private sectors would likely decrease the proportion of testing provided by the Ministry of Health. In 2006, approximately one third of all HIV tests performed were recorded at district and major CHAM hospitals, followed by health centres (30%).In view of the plans for aggressive expansion of HIV testing in the NGO and private sectors, the proportion of testing provided by these sectors was estimated at 60% of all HTC for the quantification period. Given that partner targets are dependent on the provision of funding for activities and that, at the time of the quantification exercise, a number of partners were awaiting funding approval, these targets were considered indicative. Nonetheless, the quantification team factored in the expected contributions by the partners identified above and concluded that these targets will be able to be met within the overall program targets for HTC and PMTCT agreed upon in the forecasting assumptions for the quantification. See section *IV. Quantification Methodology* of this report.

Other uses of HIV test kits in Malawi, currently not being routinely captured and reported, include quantities of HIV tests used for laboratory controls at HIV testing facilities on a daily, weekly or bi-weekly basis, and quantities of HIV tests used for Quality Control. This includes HIV tests used for external Quality Control through testing of panels of known blood samples sent to HIV testing sites on a quarterly basis for all cadres of HTC staff to perform testing under the supervision of laboratory technicians, as well as internal Quality Control which is re-testing of 5% (1 in 20) of all blood

samples tested at health facilities through submission of Dried Blood Spot specimens to CHSU and the Central Hospitals for re-testing with long ELISA tests.

In addition, significant quantities of HIV test kits will also be needed to support the numerous training sessions planned to boost the number and cadres of health care workers that will be able to provide HIV testing and counselling services at integrated health facilities.

The final factor in the use of HIV tests that had not been taken into consideration yet in Malawi is a certain amount of wastage of HIV tests that occurs through normal handling and use during HIV testing. Spillage, damage or contamination of HIV tests, or the need to repeat a test due to errors in the testing procedure, are accounted for by adding an agreed upon wastage factor to the total quantity of HIV tests needed for testing. All of the above initiatives and uses of HIV tests have been addressed in this quantification of HIV test kit requirements for the Ministry of Health to be able to more accurately estimate the demand for HIV test kits over the next two years. The quantification methodology and the results are documented in detail in the following sections *IV. Quantification Methodology* and *V. Quantification Results* of this report

B. SELECTION OF HIV TEST KITS AND THE NATIONAL HIV TESTING ALGORITHM

Discussions were held with the HTSS Diagnostics Unit and the Community Health Services Unit (CHSU) with regards to the selection of HIV test kits as there is currently a proposal to introduce a new rapid assay test kit, the Kehua Bio-engineering (KHB) HIV (1+2) rapid test, to replace the Determine HIV 1/2 currently in use, and to change the sequence of the rapid test kits used in the national testing algorithm. At the time the decision to change the selection of test kits and the national testing algorithm occurs, expected to be towards the last quarter of 2008, this quantification of HIV test kit requirements will need to be completely revised since the quantification assumptions and results are based on the selection of HIV test kits and the national testing algorithm currently in use in the country.

In addition, and as is noted in other sections of this report, given the current lead time for disbursement of GF funds for procurement (six months) and the UNICEF lead time for procurement (four months), the quantities of the new HIV test kits and the change in the proportions amongst the three different HIV test kits that would be required by the new testing algorithm, could not be physically available in the country until 10 months after the MOH submits the revised quantification figures to the Global Fund. A transition period would also be needed to utilize the remaining stocks of Determine HIV 1/2 at health facilities, to revise and disseminate the new HIV testing algorithm, and to train HTC counsellors and other HIV testing staff in the use of the new KHB HIV test kit.

C. QUANTIFICATION OF HIV TEST KITS

Discussions with various stakeholders involved in managing the supply of HIV test kits revealed that previous quantifications of HIV test kits for the Ministry of Health have been primarily based on budget allocations rather than on formal estimates of need based on actual usage of HIV test kits or actual numbers of people tested. And most importantly, as a result of this technical assistance, it was discovered that significant quantities of HIV test kits used by HTC counsellors and other HIV testing staff as routine laboratory controls, for Quality Control, and for training activities are not routinely recorded or reported to the MOH HIV and AIDS Department or the HTSS Pharmaceuticals Unit. Therefore the additional quantities of HIV test kits needed for these purposes has not been considered in determining the quantities of HIV test kits to procure in earlier quantification exercises. At this time, it appears that the undocumented use of HIV tests for these purposes may be contributing to the purported leakage of HIV test kits from the system.

D. FINANCING AND PROCUREMENT OF HIV TEST KITS

The Global Fund is currently the major donor for HIV test kits in the country with supplementary supplies funded by UNITAID (procured by UNICEF), the AXIOS donation programme, Family Health International, and the U.S. Centers for Disease Control and Prevention (CDC) – the latter specifically for long ELISAs supplied to CHSU. The Clinton HIV AND AIDS Initiative (CHAI) has also historically purchased small amounts of HIV test kits to supplement HIV testing supplies for sites piloting Early Infant Diagnosis. However, the proportion contributed by the Global Fund far outweighs that of any other donor.

All procurement of Global Fund supported rapid HIV test kits for the Ministry of Health is currently conducted by UNICEF. Given recent proposals to shift the procurement functions for the Global Fund from UNICEF to the Central Medical Stores in Lilongwe, the consultants met with the outgoing management agent for the CMS to discuss the current procurement, storage and distribution strategy for HIV test kits, as well as gain insight into the evolution of the Central Medical Stores into a Public Trust. While the Central Medical Stores continues to grow in strength and capacity, it is anticipated that in the immediate future, UNICEF will continue to carry out procurements on behalf of the Global Fund and the Ministry of Health. Therefore, for the purposes of this quantification, it was assumed that all procurements of HIV test kits will be conducted by UNICEF during the next two year period.

Procurement of HIV test kits by UNICEF is currently bi-annual with funding disbursements from the Global Fund expected to be made available in April and October of each year. A key factor affecting the supply chain and the quantification of the HIV test kits is the reported six month lead time for disbursement of Global Fund funding and the four month lead time for procurement and delivery of HIV test kits through the UNICEF procurement mechanism. This results in a total 10 month lead time for HIV test kits from the time the MOH submits an order and request for disbursement of funds to the Global Fund and for UNICEF to procure HIV test kits once the funds are available, until shipments are actually received in the country. Table 2. below outlines the steps and the procedures in the timeline that comprise the total 10 month lead time for HIV test kits.

TABLE 2. Lead Time for Funding, Procurement and Delivery of HIV Test Kits

Lead Time for Funding, Procurement and Delivery of HIV Test Kits	
1 month* Quantification and Order Preparation	▪ MOH conducts national quantification of HIV test kit requirements and prepares order quantities and cost estimates for the next two year period. ▪ MOH submits the order and request for funding disbursement for procurement of HIV test kits to Global Fund. * The time required for the MOH to conduct the data collection and analysis, review and update the assumptions and program targets, and prepare the estimate of HIV test kit requirements and costs is not currently recognized as part of the lead time but should be included as the first step and component of the total 10 month lead time for HIV test kits.
6 months Global Fund approval for disbursement of funds	Global Fund approval of disbursement request. The GF approval process requires the following: ▪ An accounting of how funds were used in the previous procurement which is then reported to the Global Fund Price Reporting Mechanism ▪ Documented justification for the quantities of HIV test kits being ordered and how they will be distributed and used that must be presented in a Procurement and Supply Management (PSM) plan ▪ A review of the cost estimates which must be valid for the period of the disbursement

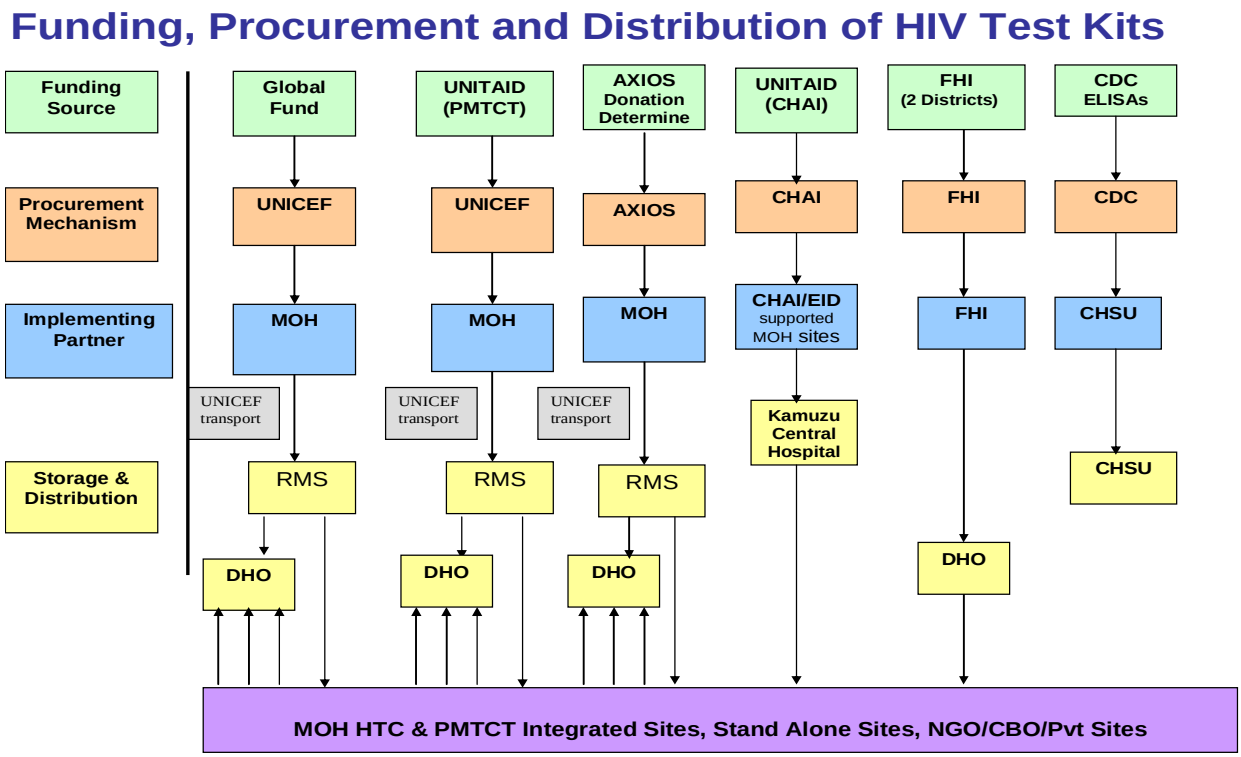
	request. This may require several steps for verification and completion of the information required. This step in the process is particularly time sensitive because the period of validity for the cost estimates is limited. ▪ Global Fund approves the disbursement request and instructs the World Bank to wire funds to UNICEF. This may take 2-3 weeks.
4 months UNICEF procurement and shipment delivery	The UNICEF process for procurement and delivery of HIV test kits includes the following steps: ▪ UNICEF places tenders through limited international bidding amongst WHO pre-qualified suppliers. This can take 2-4 weeks. ▪ Once suppliers have been identified, order quantities and shipment delivery schedules must be confirmed. This may take from 3-4 weeks to 3-4 months depending on stock availability at supplier and manufacturer production times if stocks are not available. Estimated manufacturer production times for the test kits currently in use in Malawi are o Determine HIV 1/2: 1 month o Uni-gold HIV Tests: 2 months o SD Bioline HIV 1/2: 6 weeks – 2 months ▪ HIV test kits are all air-shipped to Malawi. Generally takes 2-4 weeks but can take longer due to limited availability of flights to Malawi.
= 10 months	**Total Average Lead Time**
4 months** Emergency Order	** Average total lead time for funding, procurement and delivery of an emergency order of HIV test kits as quoted by UNICEF

The importance of the lead time in the supply chain cannot be understated. The longer the lead time, the more HIV test kits must be available in the country to ensure that sufficient quantities are available to respond to the demand for HIV test kits while the quantification is conducted, the funding is approved and disbursed, and procurement is carried out until the test kits finally arrive in the country, are distributed to the RMSs and are finally received at the health facilities that actually use them. Not accounting for the current 10 month lead time for HIV test kits is a key factor that has been undermining the MOH HIV and AIDS Department efforts to maintain ongoing services and plans to scale-up HIV testing and counselling services in the country.

The timing and the quantities of the HIV test kit procurements to date have not been sufficient to cover this 10 month lead time because the order quantities are not based on the actual usage of HIV tests as discussed earlier in this report, and have never been enough to fill the supply pipeline to cover 10 months of consumption. Coupled with the growing demand for HIV test kits due to the rapid scale up of HIV testing services in Malawi, all of these factors have contributed to under-estimation in the quantification of HIV test kit requirements, delayed timing of procurements, and irregular shipment schedules ultimately resulting in stockouts at facilities. These funding and procurement lead times, and the need to establish regular shipment intervals for Malawi have been taken into consideration in determining the total program commodity quantities, costs and shipment delivery schedules for the quantification discussed in section *V. Quantification Results* of this report.

The following diagram depicts the current funding sources, procurement mechanisms, and distribution channels in the current supply chain for HIV test kits in Malawi as far as could be determined at the time of the technical assistance:

FIGURE 1. Funding, Procurement and Distribution of HIV Test Kits – April 2008



E. DISTRIBUTION OF HIV TEST KITS

According to the Ministry of Health HIV and AIDS Department, HIV testing and counselling is offered at all ANC clinics and at approximately 410 HTC centres countrywide as of March 2008. In principle, test kits are to be received through the integrated distribution of health commodities as the facility orders essential drugs and other commodities from the Regional Medical Stores. In practice, the assessment team found a wide variation in the distribution of test kits across the supply chain: the Regional Medical Stores were distributing to some facilities directly, while others were accessing test kits from the district pharmacy stores or from NGOs. The assessment team also documented instances where two supply chains were functioning within the same facility as the PMTCT program collected kits with a project vehicle from the central hospital, while the HTC counsellor used public transport to travel to the district hospital to collect test kits from the district pharmacy store.

The following two diagrams illustrate the different modes of collection and delivery of HIV test kits found in operation at the health facilities visited:

FIGURE 2. Distribution of HIV Test Kits from RMS to DHO to Health Centres (1)

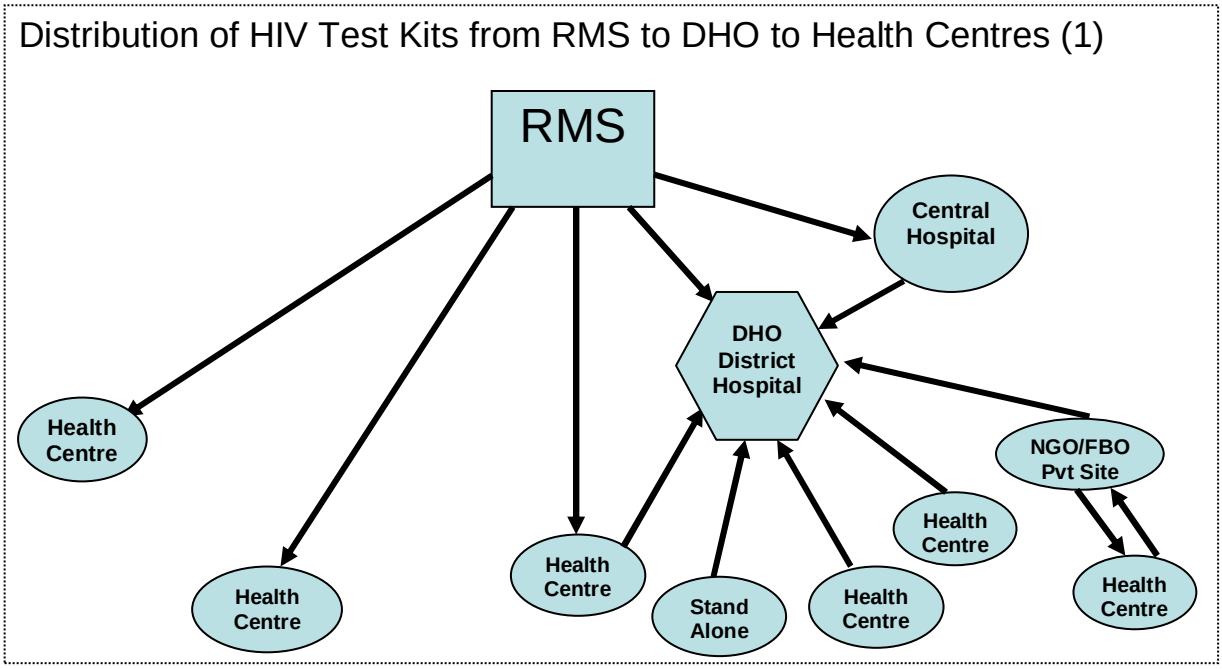
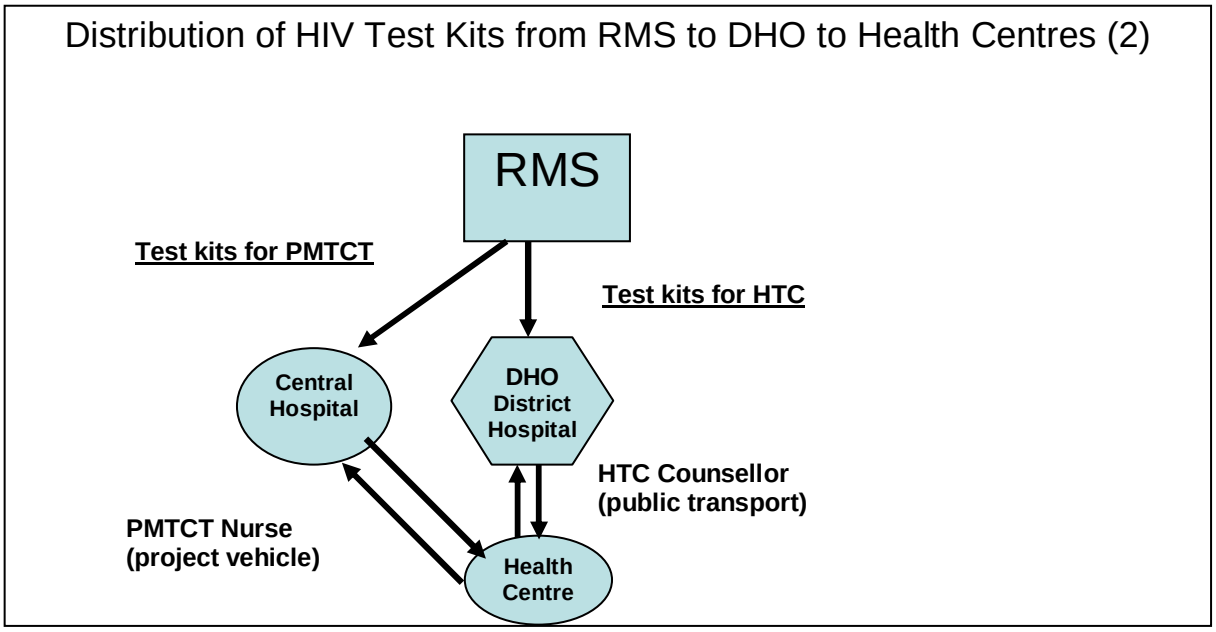


FIGURE 3. Distribution of HIV Test Kits from RMS to DHO to Health Centres (2)



F. HIV TESTING SERVICES

The different purposes of testing and other uses of HIV tests observed at the facilities visited are summarized in Table 3. below. HTC, PMTCT and Quality Control were the most frequent purposes

of testing for which HIV test kits were being used, indicating the presence of a commendably strong Quality Control program for HIV testing in Malawi.

TABLE 3. Number of Facilities Providing HIV Testing by Purpose of Testing

Purpose of Testing	No. of Facilities (N=20)
HTC	19
PMTCT	16
Quality Control	14
HIV Testing Week	10
Clinical Diagnosis	9
Blood Safety	7
Early Infant Diagnosis	4
Training	3
Blood Donor Drive	3
Sentinel Surveillance	1

G. ADHERENCE TO NATIONAL TESTING ALGORITHM

At the facilities visited, all HIV testing staff self-reported adherence to the current testing algorithms. Examination of the HTC Registers and laboratory registers for screening of blood donors verified that all facilities adhered to the parallel testing algorithm as prescribed by policy. In cases where facilities were lacking either of the screening tests (Determine or Uni-Gold), clients were asked to return on another date in anticipation of receiving the commodities. Where facilities lacked the tiebreaker kit, Bioline, clients were either referred to a higher-level facility or asked to return to be re-tested within the three-month window period.

H. HUMAN RESOURCES

At the 20 facilities visited, on average, 66% of all staff trained to provide HTC were providing HIV testing and counselling services on a part time basis as opposed to 34% who provide testing and counselling on a full time basis. The proportion of HTC counsellors providing services on a full time basis was 60%, while only 27% of the nurse counsellors and 30% of the PMTCT nurses provided counselling and testing services every day. As HIV counselling and testing services continue to expand, it will be important to note that the majority of staff are providing counselling and testing in addition to their regular duties in an integrated setting and human resource constraints may limit expansion of services in the future.

Supervision for the purposes of quality control was evident in the majority of facilities visited. 70% of facilities had received a supervision visit within the last three months, while only one facility reported

never having received a supervision visit related to HIV testing and counselling. While supervision of the HIV test kit supply at facilities e.g. examination of the stock cards for HIV test kits, was mentioned as an objective of supervision in 75% of the health facilities visited, the mission hospitals and central hospitals visited had not received regular supervision visits that covered any aspect of stock management.

I. ORDERING, REPORTING AND STOCKKEEPING PROCEDURES FOR HIV TEST KITS

Some of the key logistics indicators measured among the sampled facilities to be able to assess the HIV test kit supply chain were:

1. % of facilities ordering correctly,
2. % of facilities receiving the quantities of HIV test kits ordered,
3. % of facilities submitting LMIS data when ordering commodities,
4. % of facilities using stock cards for HIV test kits,
5. % of facilities with updated stock cards for HIV test kits.

Ordering Procedures

Staff at only 25% of the facilities visited could describe how to correctly calculate the order quantity for HIV test kits using logistics data, i.e. using the past month's consumption, multiplying the consumption by the three months maximum stock level, and subtracting the stock on hand. In general, staff at the district pharmacy stores were more familiar with the process for correctly calculating order quantities. At 30% of the health facilities visited, staff did not know how to calculate the order quantity for HIV test kits at all, while the remainder used service statistics data on the number of people tested to calculate HIV test kit orders.

80% of all facilities visited order HIV test kits on a monthly basis, while 20% do not have a fixed schedule for ordering. 20% of the facilities reported always receiving the quantities of HIV test kits ordered while 55% of facilities only sometimes receive the quantity of HIV test kits ordered. And most importantly, 65% of facilities had placed emergency orders for HIV test kits in the last six months.

Reporting on Consumption and Stock on Hand of HIV Test Kits

Only two out of five District Pharmacy Stores visited reported receiving reports on consumption and stock on hand (SOH) of HIV test kits from lower level facilities. One district with 13 health facilities only received this data from three facilities. On examination of the forms used for reporting on the quantities of HIV tests used (consumption) and stock on hand, five facilities used the standard Monthly LMIS Report form for reporting this data on HIV test kits. Four of these were district hospitals - while the fifth, a health centre, carried their stock cards to the NGO every month in order to obtain supplies.

In total, 70% of the facilities reported stock on hand data to a higher level but only three out of 12 health facilities visited actually report this data to the district level. Most facilities used self-improvised reports - especially those reporting to NGOs or program donors affiliated with the sites - rather than using the established Monthly LMIS Report forms for reporting to the Ministry of Health HTSS Pharmaceuticals Unit or the HIV and AIDS Department. On the other hand, all district hospital pharmacy stores visited did report stock on hand of HIV test kits to the Regional Medical Store. This indicates a need to standardize the reporting requirements and the use of the established Monthly LMIS Report forms within MOH health facilities to improve routine collection and reporting of logistics

data to the central level to be able to more effectively monitor and manage the national supply of HIV test kits.

Storage and Stockkeeping Practices

In regards to stock management, the pharmacy stores and the laboratory stores were identified as areas within health facilities from which test kits could be issued to multiple HIV testing sites within the hospitals. Seven facilities stored HIV test kits primarily at the Pharmacy Stores, while 14 facilities also stored HIV test kits in the HTC counsellors' rooms or in the PMTCT nurse's room. One facility kept HIV test kits in both the stores and the HTC counsellors' rooms. Overall, the management of HIV test kits in the pharmacy stores was better with 86% of the pharmacy stores maintaining and updating stock cards on a regular basis. Only 65% of HTC counsellors that stored test kits in the counselling and testing rooms maintained stock cards, while the percentage that actually routinely used and updated the stock cards was even less at 40%.

J. TRANSPORT

Fundamental to the success of a health logistics system is the ability to reliably move commodities through the supply chain so they are available for use at health facilities when needed. As part of the assessment, respondents were asked who is responsible for transporting supplies to their facilities. 70% of the facilities visited collected their HIV test kits from a higher level facility, while 30% of facilities had the test kits delivered by the RMS. Since most of the facilities visited collect their HIV test kits, they receive them the same day, but those relying on the RMS received their test kit orders between 2 weeks to one month after ordering.

K. AVAILABILITY OF HIV TEST KITS AT HEALTH FACILITIES

The stock status at the Regional Medical Stores was reflective of the shortages of HIV test kits currently experienced countrywide. All three Regional Medical Stores were stocked out of at least one test kit on the day of the visit.

- RMS North was stocked out of all three HIV test kits on the day of the visit.
- RMS Central was stocked out of two HIV test kits (Uni-Gold and Bioline) on the day of the visit
- RMS South was stocked out of one HIV test kit (Bioline) on the day of the visit.

The product that has been most frequently stocked out in the last 12 complete months prior to the assessment visit was Bioline. Uni-Gold was the product identified from stock records as the least often stocked out. All three Regional Medical Stores reported stockouts of at least one product for more than 82 days at a time.

A number of facilities reported that they had to close outreach services or discontinue testing for quality control due to the shortage of test kits. Seven of the 20 facilities visited were stocked out of at least one HIV test kit on the day of the visit. The duration and frequency of stock outs at the facilities could only be measured at those facilities where stock cards were available and routinely updated and as such, may reflect underreporting of stockouts. Only three facilities had not experienced any stock outs over the last six months, while there was a wide variation in the number of days stocked out for each of the rapid assay HIV test kits. Bioline was stocked out for an average period of 55 days over the last six months, Determine for an average of 16 days, and Uni-Gold for an average of seven days. The most common reason cited for stockouts was the absence of test kits at the Regional Medical Stores. Repeated stockouts of HIV test kits at the facility level reflects general, systemic supply chain issues that need to be addressed at every level of the system.

L. CHALLENGES TO SCALE-UP OF HIV TESTING AND COUNSELLING SERVICES

Factors influencing the rate of scale-up of HIV testing and counselling services and consequently, the demand for HIV test kits as cited by health facility staff interviewed during the assessment include;

- the rapid scale up of HIV testing services in general, especially through PMTCT which is "scaling-up daily", and
- increased support for outreach activities through mobile units and door-to-door services.

On the other hand, other findings from the supply chain assessment indicated several challenges to scaling-up of HIV testing and counselling services. 65% of the staff interviewed at the health facilities identified the availability of HIV test kits as the major constraint to scale-up of HIV testing and counselling services, while 45% reported the availability of staff and the capacity of staff to perform HIV testing and counselling as significant constraints to scale-up. Other challenges reported included inadequate space in the waiting area; unreliable transport; and the need for coordination between pharmacy technicians and HIV coordinators to ensure availability of HIV test kits at HIV testing sites following training activities.

IV. QUANTIFICATION METHODOLOGY

A. FORECAST PERIOD FOR THE QUANTIFICATION

Once in country, the Ministry of Health HIV and AIDS Department requested the USAID | DELIVER PROJECT consultants to adjust the period of the quantification of HIV test kit requirements and cost estimates to coincide with the next two GOM fiscal years FY 2008 (July 1, 2008 – June 30, 2009) and FY 2009 (July 1, 2009 – June 30, 2010). Therefore, the full period of the quantification was extended from April 2008 through June 2010 to include all shipments that would need to be planned and funded within this time period. This assumes that, given the 10 month lead time in Malawi for disbursement of funds, procurement, and delivery of the test kits, the amounts of funding needed for procurement will made available in April and October of each year for UNICEF to initiate timely procurements for shipments to arrive at established intervals in February and August of the following year. Please see the attached *Appendix K. Timeline for Funding and Procurement of HIV Test Kits* and *Appendix L. Timeline for Ordering and Scheduling Shipments of HIV Test Kits* attached to this report.

B. TYPES OF DATA AND SOURCES OF DATA

The quantification team collected and examined three different types of data:

1. Logistics data (consumption, stock on hand and losses/adjustments) collected at facilities and from the Logistics MIS where available,
2. Service statistics data (numbers of clients tested, number of positive results, and number of discordant results) collected at facilities and as reported through the HMIS,
3. Target data provided by the Ministry of Health and data included in the Global Fund RCC proposal.

The logistics data on HIV test kits was found to be wanting in that facilities do not regularly collect and report consumption data (the quantities of individual HIV tests used) nor stock on hand data on the quantities of HIV test kits in stock. Whereas the district level facilities did report on the quantities of test kits issued to health centers, the data quality was such that the information could not be used for decision-making nor for informing the forecasting assumptions. In some cases, facilities would intermittently record and report the unit of issue as test kits, and at other times as number of tests. This did not allow for meaningful analysis and use of the data for the quantification. In addition, as Malawi is now moving away from a parallel to a serial testing algorithm and planning significant scale-up of HIV testing services, any available data on past consumption of HIV tests would not be representative of future demand and would not capture the rate of scale-up expected.

Therefore, service statistics data was collected, analyzed and adjusted to estimate the number of people that were tested in 2006 and 2007, and target data provided by the MOH was used to inform the forecasting assumptions for determining the testing targets for 2008-2010.

C. GENERAL FORECASTING ASSUMPTIONS

Multiple assumptions need to be made at different steps in the quantification methodology to arrive at the forecasted number of people to be tested and the quantities of each of the brands of HIV tests to be used. Throughout the quantification workshop, when data was unavailable or of insufficient quality for estimating the quantities of HIV tests needed over the next two year period, informed assumptions were arrived at through consultation with stakeholders and through analysis, discussion and consensus amongst the workshop participants selected to participate in the quantification. The specific data used and the assumptions agreed upon at each point in the forecasting step of the quantification process are documented below.

1. Types and brands of HIV test kits included in the quantification

The HIV testing products quantified include the three rapid assay HIV test kits currently in use in Malawi:

- Screening Test = Determine HIV 1/2
- Confirmatory Test = Uni-Gold HIV test, and
- Tiebreaker Test = SD Bioline HIV 1/2 3.0

It was assumed that these three rapid assay tests will be used in accordance with the recently revised national testing algorithm which has been changed from a parallel to a serial testing algorithm and is expected to go into effect starting May 1, 2008.

The test kits used for quality control, sentinel surveillance and other surveys include mainly long ELISA test kits:

- Vironostika Uniform II HIV 1/2 plus 0 (Organon ELISA) as the first screening test,
- Enzygnost Anti HIV 1/ HIV 2 plus (Behring ELISA) as the confirmatory test, and
- small quantities of Murex Antigen/Antibody tests being used for training and re-testing purposes.

The decision to change the selection of test kits used in Malawi to introduce a new test kit, the Kehua Bioengineering (KHB) HIV (1+2) rapid test of Chinese manufacture, and to change the national testing algorithm has yet to be made. It is anticipated that these policy decisions may be made in the next 3-4 months. The average lead time for funding disbursement and procurement of HIV test kits until delivery to the country is 10 months. Before the new HIV test kits arrive in the country, there will need to be an orientation and training of HIV testing providers on the use of the new test kits and the revised testing algorithm. Considering the timing of the above processes collectively, the quantification team and the MOH HIV and AIDS Department agreed that it did not seem feasible to introduce the new HIV test kit and testing algorithm before the next 12-14 months. At the time that the new HIV test kit is introduced, it will be necessary to re-examine the forecast assumptions and revise the quantification methodology.

2. Purposes of testing in Malawi

It is necessary to estimate the number of people that will be tested for each purpose of testing for each year of the quantification for two reasons. First, to be able to capture the growth in HIV testing and counseling which may vary across the different purposes of testing, and second, to account for the different HIV prevalence rates for the different populations being tested in the next step of the quantification.

In Malawi, HIV testing is conducted for the following purposes of testing that were included in the quantification. Each purpose of testing is defined within the Malawi context.

a. HIV Testing and Counseling (HTC)

HTC in Malawi includes all testing through traditional client-initiated Voluntary Counseling and Testing services, facility-based Provider-Initiated Testing and Counseling (PITC), community-based testing provided through mobile units, outreach sites and home-based door-to-door testing. HTC also includes the additional testing that occurs during the annual HIV testing week that will be in September this year. (20% of the total number of people tested per year is estimated to be tested during the HIV testing week and in the weeks immediately following).

b. Prevention of Mother-to-Child Transmission of HIV (PMTCT)

Refers to testing of pregnant women and their partners who access HIV testing and counseling through ANC clinics and labor wards. PMTCT also includes referral of HIV positive pregnant women and their partners for other HIV prevention, care and treatment services.

c. Testing of HIV-Exposed Infants

This refers to testing of HIV-exposed infants born of HIV positive mothers with a rapid assay test when they reach 18 months of age when the mother's HIV antibodies are no longer circulating in the infant's bloodstream. This does not include testing for Early Infant Diagnosis with a rapid assay test that may occur between 9 and 18 months for those infants identified under this initiative. At the time of the quantification, it was considered that the relatively small quantities of HIV tests that would be needed for Early Infant Diagnosis would be covered by the HIV test kits available for other purposes of testing.

d. Blood Safety

This refers to screening and testing of blood donors and testing of blood and blood products for HIV infection to ensure the safety of the blood supply for transfusion. In Malawi, central, district, mission and rural hospitals that do not receive a sufficient supply of blood bags from the Malawi Blood Transfusion Service (MBTS) use rapid assay HIV tests to test blood donors for blood collection. A different testing algorithm for testing blood donors is followed when using rapid assay tests. A single, screening test is conducted and, on the basis of the result, the blood is either discarded if sero-positive or stored for use if sero-negative. No confirmatory test is conducted for blood safety.

At this point in the forecasting step, the quantities of the HIV screening test (Determine HIV 1/2) that will be needed for each year (2008, 2009 and 2010) were calculated based on the number of people expected to be tested for each of the purposes of testing (assuming one HIV test is used for each person tested).

3. Determine the HIV prevalence for each purpose of testing

The next step is to determine the HIV prevalence of the population being tested for each purpose of testing, and to apply this percentage to the total number of people to be tested for each purpose of testing to arrive at the number of confirmatory tests (Uni-Gold HIV tests) that will be needed for re-testing of all positive blood samples.

This is the critical step for calculating the quantities of the confirmatory test (in this case, the Uni-Gold HIV tests), that will be needed for testing in a serial testing algorithm.

4. Determine the discordance rate between the screening and the confirmatory test results

The discordance rate between the number of positive results from the initial screening test and the confirmatory test results will determine the quantity of the tiebreaker tests that will be needed. In this case, it is the Bioline HIV 1/ 2 3.0 rapid tests that will be used as the tiebreaker test when there is discordance between the Determine and the Uni-Gold test results under the new serial HIV testing algorithm.

In Malawi, the national AIDS laboratory at CHSU reports a low 0.6% discordance rate based on studies conducted on discordant results. Consensus was reached within the quantification team to use a 2% discordance rate to estimate the need for the tiebreaker tests and to also account for possible underestimation due to the relatively higher stockout rates for Bioline observed in the country at the time of the quantification. The 2% discordance rate was assumed to be the same for all purposes of testing and was applied to the estimated number of positive results for each purpose of testing to calculate the quantities of the tiebreaker test that would be required for all purposes of testing.

This is the critical step for calculating the quantities of the tiebreaker test (in this case, the Bioline HIV 1 /2 3.0 rapid test), that will be needed for testing in a serial testing algorithm.

5. Wastage rate

Wastage is understood to be wastage that is expected through normal handling and use of HIV tests at the point of use. Wastage may occur due to spillage, contamination or damage of the test during testing, and may also include quantities of HIV tests that are found to be defective, or quantities used for re-testing due to errors in the testing procedure. Based on consultation and discussion within the quantification team, a 2% wastage rate for Malawi was agreed upon. This wastage rate was then applied to the aggregated total quantities of the three HIV tests needed for all the purposes of testing to calculate the additional quantities of each of the three brands of HIV tests that will be needed to account for wastage.

6. Other uses of HIV tests accounted for in the quantification

Other uses of HIV tests that were included in this quantification for Malawi that had not been considered in earlier quantifications but proved to be consuming large quantities of rapid HIV tests included:

a. Quality Control

Quality control procedures which require additional use of HIV tests in Malawi include:

- Use of rapid assay tests for routine testing of positive and negative laboratory controls and each time a new kit is opened. This is to ensure the quality of the HIV tests themselves.
- Use of rapid assay tests for testing panels of known blood samples sent to HIV testing facilities from CHSU to test the proficiency of all cadres of staff that are conducting HIV testing. This is to ensure the quality of the performance of the testing.
- Use of long ELISAs for re-testing of 1 in 20 (5%) of all blood samples tested at all HTC sites. Samples for re-testing are submitted to the central hospitals for re-testing as Dried Blood Spot (DBS) samples.

b. Training

The quantities of HIV tests needed for training are based on the total number of health care workers (HCWs) scheduled to be trained in HIV testing during each year of the quantification

period. The number of HCWs to be trained is then multiplied by the number of each brand of HIV test to be provided per participant in each training session to familiarize themselves with the tests and to conduct several tests during the training to reach a minimum level of proficiency.

c. Sentinel surveillance, surveys and research studies

Specific quantities of long ELISA tests will be needed for HIV sentinel surveillance, behavioral surveillance, the demographic health survey and a few community-based research projects, as well as for internal training activities planned at CHSU that will be conducted over the next two GOM fiscal years. The quantities of the long ELISA tests needed have been calculated based on survey or study protocols which prescribe the site selection, sample size and the procedures for collection and testing of blood samples. This data was provided by CHSU for the quantification.

7. Separate forecasts prepared for each of the three regions of the country

Because the proportion of the HIV testing services being provided and the HIV prevalence rates vary significantly across the three regions of the country, three separate forecasts were prepared to estimate the HIV testing targets and expected HIV prevalence rates by purpose of testing for the North, the Central and the South Regions for 2008, 2009 and 2010. In the latter steps of the quantification, separate PipeLine databases were created for each region to calculate the total HIV test kit requirements and to develop an individualized supply plan with the specific quantities of each brand of HIV test kit needed for each region.

D. SUMMARY OF FORECASTING ASSUMPTIONS BY PURPOSE OF TESTING

For all diagnostic purposes of testing i.e. HTC, PMTCT, HIV-exposed infants and blood safety, it was assumed that each person tested would be tested only once within the forecast period (2008 – 2010); that only one screening test would be used for each person tested; that all positive blood samples would be re-tested with only one confirmatory test; and that any discordant results would be tested with only one tiebreaker test. For the other uses of HIV tests, such as for quality control, training, sentinel surveillance, surveys and other types of studies, the quantities of HIV tests needed are calculated differently based on quality control procedures, the number of HIV tests to be provided for each health care worker trained, or study protocols.

The specific data inputs and forecasting assumptions for all purposes of testing and uses of HIV tests that were incorporated into the quantification methodology are described in detail below and in the series of tables presented throughout this section of the report and in *Appendix G. HIV Testing Forecasting Assumptions* attached at the end of the report.

1. Total Number of People Tested and Testing Targets

The summary of service statistics and target data that was used to estimate the current volume of HIV testing in the country and the testing targets used as the basis for forecasting the quantities of HIV tests needed for the quantification exercise is presented below in *Table 4. Estimated Number of People Tested for HIV and Testing Targets, by Year.*

TABLE 4. Estimated Number of People Tested for HIV and Testing Targets, by Year[1]

No. Tested 2006-2007				Testing Targets 2008-2010					
	Actual 2006	**Estimated 2007**	**% Increase**	**2008**	**% Increase**	**2009**	**% Increase**	**2010**	**% Increase**
HTC *	661,000	930,000	40.7%	1,300,000	39.8%	1,500,000	15.4%	1,700,000	13.3%
PMTCT	137,000	284,884	107.9%	350,000	22.9%	480,000	37.1%	550,000	14.6%
HIV Testing Week	84,000 (12.7%)	187,860 (20.2%)		300,000 (23.1%)		350,000 (23.2%)		375,000 (22.1%)	

* The total number of people tested for HTC includes the number tested for PMTCT and the number tested during the HIV Testing Week for the same year.

2. Estimated Number of People to be Tested by Region and by Purpose of Testing

As Malawi consists of three regions with varying degrees of service delivery capacity, volume of HIV testing and counselling taking place, and different HIV prevalence rates, it was important to forecast the quantities of HIV tests needed separately for each region. Therefore, the country's total testing targets were broken down further to reflect these regional differences. Data on the percentage of the total number of people tested in the country and HIV prevalence rates by region were taken from the 2006 Situational Analysis (*Report of a Country-Wide Survey of HIV and AIDS Services in Malawi for*

[1] Service statistics data from the Report of a Country-Wide Survey of HIV and AIDS Services in Malawi for the Year 2006. Testing Targets provided by the MOH HIV and AIDS Department

the Year 2006) and were applied to the total testing targets by year to arrive at the forecasted number of people to be tested for each purpose of testing by region for 2008, 2009 and 2010 as presented in Table 5. below.

TABLE 5. Estimated No. People to be Tested by Region and by Purpose of Testing 2008, 2009 and 2010

	January - December 2008					
REGION	**%**	**No. Tested**	**HTC**	**PMTCT**	**Exposed Infants**	**Blood Safety**
North	15%	195,000	135,034	45,000	1,966	13,000
Central	36%	468,000	344,883	108,000	4,717	10,400
South	49%	637,000	480,979	147,000	6,421	2,600
TOTAL No. Tested	100%	1,300,000	960,896	300,000	13,104	26,000

	January - December 2009					
REGION	**%**	**No. Tested**	**HTC**	**PMTCT**	**Exposed Infants**	**Blood Safety**
North	15%	225,000	140,680	72,000	4,320	8,000
Central	36%	540,000	350,432	172,800	10,368	6,400
South	49%	735,000	484,088	235,200	14,112	1,600
TOTAL No. Tested	100%	1,500,000	975,200	480,000	28,800	16,000

	January - December 2010					
REGION	**%**	**No. Tested**	**HTC**	**PMTCT**	**Exposed Infants**	**Blood Safety**
North	15%	255,000	157,480	82,500	7,020	8,000
Central	36%	612,000	390,752	198,000	16,848	6,400
South	49%	833,000	538,968	269,500	22,932	1,600
TOTAL No. Tested	100%	1,700,000	1,087,200	550,000	46,800	16,000

3. HIV Testing and Counseling (HTC)

HTC is defined as all Provider-initiated Testing and Counselling; Client-initiated Counselling and Testing (VCT); all testing provided through Mobile Units, Outreach Sites, and Home-based Door-to-Door testing; and the HIV testing week. It was noted that Malawi conducted a very successful HIV testing and counselling week where, through community mobilization, a large number of the 'worried well" presented themselves for HIV testing and counselling. Data on HIV testing over the past two years from the 2006 Situational Analysis and the NAC HIV testing week report indicates that over 20% of the testing per annum is carried out within the testing week. The prevalence for HTC was therefore arrived at by comparing the prevalence of the HIV testing week as the lowest prevalence, while that of Provider-initiated Testing and Counselling as the highest prevalence.

TABLE 6. HIV Prevalence for HTC and PMTCT, Adjusted by Region

		HIV Prevalence [1]	HIV Prevalence [1]	HIV Prevalence [1]
REGION	**% Tested**	**HTC 2006 ***	**HTC 2007**	**PMTCT****
North	15%	15%	30%	10.2%
Central	36%	19%	34%	10.7%
South	49%	27%	42%	20.5%
TOTAL	100%	20%	37%	12.0%

* Situational Analysis 2006

** HIV and Syphilis Sero-Survey 2007

[1] The HIV prevalence rate for people tested through HTC in each region was adjusted by +15% from the prevalence reported in the 2006 Situational Analysis to reflect the expected rise in the number of positive test results as Provider-initiated Testing and Counseling expands to include more symptomatic patients referred for testing from STI Clinics, TB Clinics, In-patient Wards and Out-Patient Departments

Since it is assumed that Provider-initiated Testing and Counselling is going to play a bigger role as services become more integrated and STI clinics are included in providing testing and counselling, the quantification team arrived at an average prevalence of 37% for the country -an increase of 15% over the 2006 Situational Analysis. This takes into account that the clients seen in integrated hospital settings, especially those referred from STI clinics, will have a higher HIV prevalence.

4. Prevention of Mother-to-Child Prevention of HIV and Testing of HIV-Exposed Infants

The goal of the PMTCT program as articulated in the GF RCC Proposal is to offer PMTCT services to 80% of all HIV positive pregnant and lactating women by 2010 (of an estimated 600,000 pregnant women per year). The target numbers in the Global Fund RCC Proposal therefore reflect the volume of testing expected to be conducted at an estimated 546 ANC clinics as PMTCT services are further integrated into maternity, postnatal care and under-five clinics. The HIV prevalence of pregnant women varied from region to region according to the 2007 sentinel surveillance reports. The quantification team therefore used the reported HIV prevalence rates for PMTCT as 10.2% for the North Region, 10.7% for the Central Region and 20.5% for the South Region respectively.

It was assumed that HIV-exposed infants would also be tested in PMTCT settings with those over 18 months of age requiring the use of a screening and a confirmatory test. In order to establish the number of HIV-exposed infants likely to test positive at 18 months to determine the quantities of confirmatory tests that would be needed, it would have been necessary to determine:

- the number of women testing positive who deliver live infants,
- the number of women receiving Nevirapine single-dose prophylaxis,
- the number of infants who obtained ARV prophylaxis
- the number of women on HAART while breastfeeding
- those infants alive at 18 months
- the mode of feeding for the infants and the prevalence of HIV transmission across the feeding methods.

The Ministry of Health with the help of partners has carried out a pilot study of Early Infant Diagnosis using polymerase chain reaction testing technique (PCR) and so far has tested 5,000 infants through PMTCT services. The pilot is to be rolled out in the coming years as a national strategy. Since data from the pilot has yet to be collated, it was not possible to estimate the prevalence of HIV-exposed infants at 18 months and therefore, the use of the second, confirmatory test. As the target number for HIV-exposed infants constituted less than 1% of the total population receiving testing and counselling, it was assumed that the quantities of the confirmatory test (Uni-Gold HIV test) needed would be covered in the quantities of HIV tests being forecasted for all other purposes of testing.

5. Blood Safety

The Malawi Blood Transfusion Service (MBTS) located in Blantyre aspires to provide 100% of the blood requirements for the country with blood units shipped to all central and district hospitals countrywide. At present the total demand for blood for transfusion purposes has not been measured, however currently the demand for blood is not being met by the MBTS as several district and mission hospitals are still testing blood donors using rapid assay test using Determine as the single screening test in a serial algorithm. The MBTS plans to increase the number of blood units collected by 10,000 every year for the target period 2008 to 2010. It is therefore foreseen that the amount of testing for blood safety using rapid tests would decrease significantly over the coming years. As a baseline, the HTSS Diagnostics Unit of the MOH reported 36,000 donors screened outside the MBTS: the breakdown per region reflected geographical proximity to the central testing laboratory in Blantyre with only 10% of the rapid testing done in the South Region, 40% in the Central Region and 50% in the North Region.

As the testing algorithm for blood safety requires the use of a single rapid assay test, it was not necessary to use the HIV prevalence of blood donors screened in hospital settings to calculate quantities of confirmatory tests needed.

6. Wastage Rate

A certain amount of wastage is expected to occur through normal handling and use of HIV tests at the point of use due to spillage, contamination or damage of the test during testing, and may include quantities of HIV tests that may be found to be defective, or quantities used for re-testing due to errors in the testing procedure. Based on consultation and discussion within the quantification team, a 2% wastage rate for Malawi was agreed upon. At this point in the forecasting step, the 2% wastage rate was applied to the total quantities needed of each of the

HIV tests in the testing algorithm (Determine, Uni-Gold and Bioline) for each purpose of testing to calculate the total quantities needed to meet the testing targets for 2008, 2009 and 2010.

The methodology for estimating the number of positive results that will require the use of a confirmatory test and the number of discordant results that will require a tiebreaker test is presented below in *TABLE 7. Estimated No. to be Tested, No. of Positive Results and No. of Discordant Results by Purpose of Testing for 2008, 2009 and 2010*.

TABLE 7. Estimated No. to be Tested, No. of Positive Results and No. of Discordant Results by Purpose of Testing for 2008, 2009 and 2010

	Jan - Dec 2008				Jan - Dec 2009				Jan - Dec 2010			
Purpose of Testing	Estimated No. Tested	No. Positive	HIV Prevalence	Discordance Rate (2.0%)	Estimated No. Tested	No. Positive	HIV Prevalence	Discordance Rate (2.0%)	Estimated No. Tested	No. Positive	HIV Prevalence	Discordance Rate (2.0%)
HTC [1]	910,896	337,032	37.0%	6,741	975,200	360,824	37.0%	7,216	1,087,200	402,264	37.0%	8,045
PMTCT [2]	350,000	42,000	12.0%	840	480,000	57,600	12.0%	1,152	550,000	66,000	12.0%	1,320
Exposed Infants [3]	13,104	-		-	28,800	-		-	46,800	-		-
Blood Safety [4]	26,000				16,000				16,000			
Sub-Total	1,300,000	379,032		7,581	1,500,000	418,424		8,368	1,700,000	468,264		9,365
Wastage Rate (2.0%)	26,000	7,581		152	30,000	8,368		167	34,000	9,365		187
TOTAL	1,326,000	386,612		7,732	1,530,000	426,792		8,536	1,734,000	477,629		9,553

[1] HTC = all Provider Initiated Testing and Counseling; Client Initiated Counseling and Testing (VCT); and all testing provided through Mobile Units, Outreach Sites, and Home Based Door-to-Door testing

[2] PMTCT = Estimated No. of Pregnant Women tested for HIV in ANC Clinics, Labor Wards; No. of Partners tested

[3] Exposed Infants = No. of Exposed Infants tested for HIV at 18 months. (It has not been possible to determine what the prevalence rate/number of positive results would be for Exposed Infants at 18 months. Since the quantities of Uni-Gold needed for testing positive Exposed Infants at 18 months would represent less than 1% of the total quantities of Uni-Gold needed for the program, it was assumed that this need for Uni-Gold HIV tests will be covered within the general HIV test kit supply).

[4] Blood Safety = Estimated No. of blood donors screened for HIV at central, district, mission and rural hospitals not covered by MBTS

Other Uses of HIV Tests

At this point in the forecasting step of the quantification, the additional quantities of rapid assay HIV tests needed for quality control and for training, and the long ELISA tests needed for sentinel surveillance, behavioral surveillance, the demographic health survey and other community-based testing projects were estimated based on the data inputs and forecasting assumptions documented below and in *Appendix G. HIV Testing Forecasting Assumptions* attached to this report.

7. Quality Control

Malawi runs an impressive quality control program which was found to be in evidence at the facilities visited. The majority of sites reported running positive and negative laboratory controls provided by CHSU. In addition, the quantification team found records of panels of blood samples sent to the majority of the labs for quality control testing by HIV testing staff at the facility. It is then the responsibility of the lab in charge to ensure every counsellor runs the positive and negative laboratory controls and tests the five blood samples in the panel. The number of HIV tests used for these types of QC have previously not been quantified or recorded and as such, the quantification team had to use existing protocols to arrive at estimates for the quantities of HIV tests needed for Quality Control.

The quantification team identified 35 high volume facilities in the country which included all MACRO sites, Lighthouse Trust supported sites, all central hospitals, 10 high volume CHAM facilities, and 14 district hospitals all reaching an estimated 127 testing sites. Each high volume site reported running positive and negative laboratory controls on a daily basis and would therefore need approximately 66,000 tests of Determine and Uni-Gold each.

10 district hospitals, with approximately three testing sites each were identified. Each testing site would need to run weekly controls over at each testing site. Cumulatively this amounts to 3,120 HIV tests needed per year for medium volume facilities.

Low volume facilities were estimated at 550 facilities where laboratory controls would be done every two weeks. The use of HIV tests for laboratory controls in this way was estimated at 14,456 tests of Determine and Uni-Gold each per year.

As all cadres of staff at HIV testing sites are expected to test panels of known blood samples for quality control, the quantification team assumed that the 2,500 staff trained in HTC so far were all actively counselling and testing. Given the quarterly distribution of the panels from CHSU, this means that each HTC counselor, lab technician or other HIV testing staff would test four panels of 5 known blood samples per year. In addition, as part of the quality control testing, HTC staff are expected to run positive and negative laboratory controls for the Determine and the Uni-Gold tests for each panel of five samples. Assuming that three of the five known blood samples would have a positive result, this would then require at least 70,000 Determine tests and 50,000 Uni-Gold tests per year for the external quality assurance. See *TABLE 8. Total Quantities of HIV Tests Required for Quality Control* below and in *Appendix G. HIV Testing Forecasting Assumptions* attached to this report.

TABLE 8. Total Quantities of HIV Tests Required for Quality Control

	Jan - Dec 2008		Jan - Dec 2009		Jan - Dec 2010	
	Determine	**Uni-Gold**	**Determine**	**Uni-Gold**	**Determine**	**Uni-Gold**
High Volume Testing Sites	66,040	66,040	66,040	66,040	66,040	66,040
Medium Volume Testing Sites	3,120	3,120	3,120	3,120	3,120	3,120
Low Volume Testing Sites	14,456	14,456	14,456	14,456	14,456	14,456
External Quality Assurance	70,000	50,000	70,000	50,000	70,000	50,000
Total	**153,616**	**133,616**	**153,616**	**133,616**	**153,616**	**133,616**

8. Training

The targets for training were obtained from consultations with the various stakeholders as well as from the National AIDS Commission, (NAC) that funds the decentralized district trainings. The Global Fund RCC proposal contains provision for the training of 420 HTC Counsellors and 1,800 PMTCT Counsellors over 6 years. At the time of the consultancy, NAC was working on the 2008-2009 workplan and as such, projections for district trainings had not yet been prepared. It is therefore assumed that NAC will at least fund the same level of training for each year of the quantification period using both the Global Fund and other sources of financing.

The national curriculum for training in HIV testing states that for each participant to be considered competent in HIV testing, they should at least have used five Determine tests, three Uni-Gold tests and three Bioline HIV 1/2 tests per participant in each 3-week training class. The estimates of the number of staff expected to be trained to conduct HIV testing in the upcoming years came from the MOH, NGO and other partner organizations themselves based on their training plans for the next two years. See *Tables 9-1*. and *9-2.* and *Table 9. Total Quantities of HIV Tests Required for Training per Year, by Region* below.

TABLE 9-1. Number of HCWs to be Trained by Partner in 2008, 2008 and 2010

No. of HCWs to be Trained by Partner	**Jan - Dec 2008**	**Jan – Dec 2009**	**Jan - Dec 2010**
Laboratory Technicians (trained through HTSS Diagnostics)	100	100	100
HTC/PMTCT District level training	1,690	1,690	1,690
CHAI	42	42	0
Lighthouse Trust	160	160	160
MACRO	160	180	200
Total No. HCWs to be Trained	**2,152**	**2,172**	**2,150**

TABLE 9-2. Quantity of HIV Tests per HCW Trained and Total Quantities of HIV Tests Required for Training, by Partner and per Year

Jan - Dec 2008			Jan - Dec 2009			Jan - Dec 2010		
Determine	**Uni-Gold**	**Bioline**	**Determine**	**Uni-Gold**	**Bioline**	**Determine**	**Uni-Gold**	**Bioline**
5 Tests/ HCW	*3 Tests/ HCW*	*3 Tests/ HCW*	*5 Tests/ HCW*	*3 Tests/ HCW*	*3 Tests/ HCW*	*5 Tests/ HCW*	*3 Tests/ HCW*	*3 Tests/ HCW*
500	300	300	500	300	300	500	300	300
8,450	5,070	5,070	8,450	5,070	5,070	8,450	5,070	5,070
210	126	126	210	126	126	0	0	0
800	480	480	800	480	480	800	480	480
800	480	480	900	540	540	1,000	600	600
10,760	**6,456**	**6,456**	**10,860**	**6,516**	**6,516**	**10,750**	**6,450**	**6,450**

TABLE 9. Total Quantities of HIV Tests Required for Training per Year, by Region

		Jan - Dec 2008			Jan - Dec 2009			Jan - Dec 2010		
REGION	**%**	**Determine**	**Uni-Gold**	**Bioline**	**Determine**	**Uni-Gold**	**Bioline**	**Determine**	**Uni-Gold**	**Bioline**
North	**15%**	1,614	968	968	1,629	977	977	1,613	968	968
Central	**36%**	3,874	2,324	2,324	3,910	2,346	2,346	3,870	2,322	2,322
South	**49%**	5,272	3,163	3,163	5,321	3,193	3,193	5,268	3,161	3,161
TOTAL No. HIV Tests Required	**100%**	**10,760**	**6,456**	**6,456**	**10,860**	**6,516**	**6,516**	**10,750**	**6,450**	**6,450**

9. Long ELISA Tests for Sentinel Surveillance, Behavioral Surveillance, Demographic Health Survey and Community-based Projects

The National AIDS Laboratory at CHSU uses long ELISAs to conduct HIV testing for a variety of purposes. In general, Vironostika is used as the first screening test while Enzygnost is used as the confirmatory test. The purposes of testing and the sample targets as provided by CHSU are summarized below:

a. Dried Blood Spot: Re-testing 1 in 20 (5%) of all blood samples from all HTC sites. Collected as DBS and submitted for re-testing at central hospitals.
   Protocol: Vironostika used as the initial screening test while Enzygnost is used as the confirmatory test for positive results.
b. Behavioral Surveillance: Conducted every 2 years, 3,000 - 6,000 samples tested each year
   Protocol: Vironostika used as the initial screening test while Enzygnost is used as the confirmatory test for positive results. 10% of all tests are re-tested using both Vironostika and Enzygnost for quality control.
c. Demographic Survey to be conducted in 2009: Target is 12,000 samples
   Protocol: Vironostika used as the initial screening test while Enzygnost is used as the confirmatory test for positive results.10% of all tests are re-tested using both Vironostika and Enzygnost for quality control.
d. Sentinel Surveillance: Conducted every 2 years, 4,000 - 6,000 samples tested each year.
   Protocol: Vironostika used as the initial screening test while Enzygnost is used as the confirmatory test for positive results.10% of all tests are re-tested using both Vironostika and Enzygnost for quality control.
e. Community-based Testing (4 Projects): 1,500 - 3,000 tests/year

The final results of the estimates of the quantities of long ELISA tests needed by CSHU are presented in *Table 10. Total Quantities of Long ELISA Tests Required for Quality Control, Sentinel Surveillance, Behavioral Surveillance, Demographic Health Survey and Community-based Projects for 2008, 2009.*

TABLE 10. Total Quantities of Long ELISA Tests Required for Quality Control, Sentinel Surveillance, Behavioral Surveillance, Demographic Health Survey and Community-based Testing Projects for 2008, 2009 and 2010

	QC DBS	Jan - Dec 2008			QC DBS	Jan - Dec 2009			QC DBS	Jan - Dec 2010		
	5% of No. Tested per Year	Vironostika	Enzygnost	Murex Ag/Ab	5% of No. Tested per Year	Vironostika	Enzygnost	Murex Ag/Ab	5% of No. Tested per Year	Vironostika	Enzygnost	Murex Ag/Ab
Dried Blood Spot	1,300,000	65,000	15,925		1,500,000	75,000	18,375		1,700,000	85,000	20,825	
(Re-testing 1 in 20 blood												
samples from all HTC sites)												
Behavioral Surveillance		4,400	400							5,500	500	
(Conducted every 2 years,												
3,000 - 6,000 samples tested												
each year)												
Demographic Survey						13,200	1,200					
(to be conducted in 2009)												
Sentinel Surveillance						6,600	600					
(Conducted every 2 years,												
4,000 - 6,000 samples tested												
each year)												
Community Based												
Testing (4 Projects)												
(1,500 - 3,000 tests/year)		2,000	2,000			2,000	2,000			2,000	2,000	
Training/Re-Testing with				500				500				500
Murex Ag/Ab												
(~ 500 tests/year)												
SUB-TOTAL												
No. HIV Tests Required		71,400	18,325	500		96,800	22,175	500		92,500	23,325	500
No. Kits Required		**124**	**96**	**2**		**169**	**116**	**2**		**161**	**122**	**2**
Training		2,000	2,000			2,000	2,000			2,000	2,000	
(2,000 samples tested with both												
Vironostika and Enzygnost												
No. Tests per Kit		576	192			576	192			576	192	
No. Kits Required		**4**	**11**			**4**	**11**			**4**	**11**	
TOTAL No. Tests Required		73,400	20,325			98,800	24,175			94,500	25,325	
TOTAL No. Kits Required		**128**	**107**	**2**		**173**	**127**	**2**		**165**	**133**	**2**

The final results of the forecast of the quantities of HIV tests required for all purposes of testing and uses of HIV tests for 2008, 2009 and 2010 are aggregated and presented in *Table 11. Total Quantities of HIV Tests Required for All Purposes of Testing and Uses of HIV Tests for 2008, 2009 and 2010*.

TABLE 11. Total Quantities of HIV Tests Required for All Purposes of Testing and Uses of HIV Tests for 2008, 2009 and 2010

	Jan - Dec 2008			Jan - Dec 2009			Jan - Dec 2010		
	Determine (100 tests/kit)	Uni-Gold (20 tests/kit)	Bioline (30 tests/kit)	Determine (100 tests/kit)	Uni-Gold (20 tests/kit)	Bioline (30 tests/kit)	Determine (100 tests/kit)	Uni-Gold (20 tests/kit)	Bioline (30 tests/kit)
All Purposes of Testing	1,326,000	403,018	8,060	1,530,000	447,492	8,950	1,734,000	501,141	10,023
Quality Control [5]	153,616	133,616		153,616	133,616		153,616	133,616	
Training [6]	10,760	6,456	6,456	10,860	6,516	6,516	10,750	6,450	6,450
TOTAL No. HIV Tests	1,490,376	543,090	14,516	1,694,476	587,624	15,466	1,898,366	641,207	16,473
TOTAL No. HIV Test Kits	14,905	27,156	485	16,946	29,382	517	18,985	32,062	551
TOTAL No. Kits/Month	1,242	2,263	40	1,412	2,449	43	1,582	2,672	46

[5] Quality Control : includes use of rapid tests for positive and negative laborotory controls and for quality control testing of known blood samples by HTC staff.

[6] Training: includes all planned training in HIV Testing and Counseling offered through the MOH and multiple partner organizations (HTSS Diagnostics, Districts, NGOs, FBOs, NGOs)

E. ANALYSIS OF HIV TESTING FORECASTING ASSUMPTIONS

The results of the data analysis indicate that PMTCT is set to grow aggressively and contribute close to 30% of those tested through the provision of opt-out testing and the expansion of testing to the maternity wards, post-natal care and under-five clinics. In addition, if all facilities continue to adhere to the internal and external quality control procedures as prescribed by CHSU, the number of HIV test kits used for this purpose will be significant at between 9-10%.

TABLE 12. Analysis of HIV Testing Forecasting Assumptions

	Jan - Dec 2008		Jan - Dec 2009		Jan - Dec 2010	
Purpose of Testing	**Proportion (%) Tested**	**Estimated No. Tested/ No. Tests Needed**	**Proportion (%) Tested**	**Estimated No. Tested/ No. Tests Needed**	**Proportion (%) Tested**	**Estimated No. Tested/ No. Tests Needed**
HTC	61.1	910,896	57.6	975,200	57.27	1,087,200
PMTCT	23.5	350,000	28.3	480,000	28.97	550,000
Exposed Infants	0.9	13,104	1.7	28,800.0	2.47	46,800.00
Blood Safety	1.7	26,000	0.9	16,000.0	0.84	16,000.00
Sub-Total	**87.2**	**1,300,000**	**88.5**	**1,500,000**	**89.55**	**1,700,000**
Wastage Rate (2.0%)	1.7	26,000	1.8	30,000	1.8	34,000
Quality Control	10.3	153,616	9.1	153,616	8.1	153,616
Training	0.7	10,760	0.6	10,860	0.6	10,750
TOTALS		**1,490,376**		**1,694,476**		**1,898,366**

V. QUANTIFICATION RESULTS

In the following steps of the quantification, the total quantities of HIV tests required for all the purposes of testing and other uses of HIV tests are first converted from the quantity of individual HIV tests required, to the number of HIV test kits required by rounding up to the nearest kit size for each of the brands of HIV tests quantified, Determine (100 tests/kit); Uni-Gold HIV test (20 tests/kit); and Bioline (30 tests/kit) as indicated in *Table 8. Total Quantities of HIV Tests Required for All Purposes of Testing and Uses of HIV Tests for 2008, 2009 and 2010* in *Appendix G. HIV Testing Forecasting Assumptions* attached at the end of this report.

The total quantities of HIV test kits are then adjusted to take into account the stock status in the country and any planned shipments that are already on order and expected to be received at the time of the quantification. Other factors taken into consideration in finalizing the total HIV test kit requirements to be procured in the next two GOM fiscal years included:

- The stock on hand of each brand of HIV test at each RMS at the time of the quantification,
- The estimated monthly consumption of each brand of HIV test over the period of the quantification based on the forecasted quantities of HIV test kits for all purposes of testing and uses of HIV tests for each year 2008, 2009 and 2010,
- The lead time for funding, procurement and delivery of HIV test kits from the time the MOH places an order and a request for funding, until the shipment of HIV test kits is received in the country and distributed to the RMSs,
- The agreed upon buffer stock level to cover any unexpected shipment delays or surges in consumption of HIV test kits,
- The quantities of each HIV test kit needed to maintain the established maximum and minimum stock levels at the facility level and the regional level to avoid shortages and stockouts,
- The quantities of HIV test kits already on order.

All of the data entry and the parameters of the logistics system for HIV test kits (maximum and minimum levels based on the lead times and buffer stocks) and the planned shipments with shipment quantities and delivery schedules were entered into the PipeLine databases that were for each of the three regions and then aggregated to provide the total HIV test kit requirements and costs for the period of the quantification from April 2008 to June 2010.

Several additional assumptions were made with regard to the procurement and delivery of commodities:

- UNICEF will continue to be the procurement agent for the Global Fund for the near future.
- The average Shipping/Freight Costs are 17% (varies based on the weight and volume of the shipments) plus the UNICEF handling fee 4% which adds up to an average Shipping/Freight/Handling Cost of 21% which was added to cost of the products
- The lead-time for the disbursement request, release of funds, procurement and delivery of commodities as it currently exists with UNICEF as the procurement agent is 10 months for normal orders.
- The lead-time for emergency orders is 4 months.
- Based on the normal lead-time, the maximum and minimum stock levels that should be maintained by the system are18 months and 12 months resThe desired end year stock level was set us an average of 17 months.

A. HIV TEST KIT REQUIREMENTS, SHIPMENT RECEIPT DATES AND COSTS FOR FY 2008 AND FY 2009

Despite the fact that UNICEF has procured test kits that will arrive in country within the next two months with funding from UNITAID and the Global Fund, an emergency order of HIV test kits is urgently required to arrive in country within the next 4 months. The emergency order should arrive in August 2008, in time for the HIV testing week scheduled for September, and to fill the supply pipeline to cover the 10 month lead time such that subsequent orders of test kits for the next two year period can be made on a regular basis. The total quantities of HIV test kits needed and the cost estimates are summarized in Table 13.,14., and 15. below and in *Appendix H. HIV Test Kit Requirements, Shipment Receipt Dates and Cost Estimates by Region and for All Regions for FY 2008 and FY 2009* and in *Appendix J. Total Commodity Costs, Funding Commitments and Funding Gaps for FY 2008 and FY 2009*.

Based on the results of the quantification, the MOH should place an emergency order and request for disbursement of funds to the Global Fund in April 2008 for UNICEF to procure a shipment of HIV test kits to arrive in country by August 2008 in time for the September 2008 HIV testing week. This is based on the four month lead time needed for an emergency shipment as reported by UNICEF.

Table 13. below indicates the specific quantities, shipment dates and cost for each of the brands of HIV test kits to be funded and procured for the MOH as an emergency order in April 2008.

TABLE 13: HIV Test Kit Requirements and Costs for Emergency Order to be Procured in April 2008 for Shipment to Arrive in August 2008

Supplier	Product	Receive Date	Quantity	Product Costs	Freight Costs	Total Costs
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	31-Aug-08	120	$17,280	$3,629	$20,909
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	31-Aug-08	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	31-Aug-08	130	$56,160	$11,794	$67,954
UNICEF-GF	Bioline HIV ½ (30 tests/kit)	31-Aug-08	240	$5,760	$1,210	$6,970
UNICEF-GF	Chase buffer (2.5ml bottle)	31-Aug-08	1,100	$1,100	$231	$1,331
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	31-Aug-08	10,600	$848,000	$178,080	$1,026,080
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	31-Aug-08	30,000	$1,122,900	$235,809	$1,358,709
					TOTAL	**$2,482,475**

In addition, given the 10 month lead time for regularly scheduled shipments, the MOH should also place the order and the request for disbursement of funds from the Global Fund in April 2008 for the next regularly scheduled shipment of HIV test kits to arrive in country by February 2009 – thus allowing six months for approval and disbursement of funds by the Global Fund, and four months for procurement and delivery of the HIV test kits by UNICEF and individual suppliers.

Table 14. below indicates the quantities, shipment dates and cost for each of the brands of HIV test kits to be funded and procured for the MOH that should also be ordered in April 2008 as a regularly scheduled shipment to arrive by February 2009, as well as the quantities, shipment dates and cost of each of the brands of HIV test kits that should be ordered in October 2008 for the shipments to arrive by August 2009. See *Appendix K. Timeline for Funding and Procurement of HIV Test Kits* and *Appendix L. Timeline for Ordering and Scheduling Shipments of HIV Test Kits* attached at the end of this report.

TABLE 14. HIV Test Kit Requirements and Costs FY 2008 (July 2008 - June 2009) ALL REGIONS

(Assumes MOH submits disbursement requests to Global Fund in April 08 and October 08 so that funding is available for UNICEF to initiate procurements in October 08 and April 09 of FY 2008 for shipments that will arrive in Feb 09 and August 09)

Supplier	Product	Receive Date	Quantity	Product Costs	Freight Costs	Total Costs
FHI*	Bioline HIV 1/2 (30 tests/kit)	30-Nov-08	68	$1,632	$343	$1,975
FHI*	Determine HIV 1/2 (100 tests/kit)	30-Nov-08	404	$32,320	$6,787	$39,107
FHI*	Uni-Gold HIV Test (20 tests/kit)	30-Nov-08	605	$22,645	$4,755	$27,401
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	28-Feb-09	40	$5,760	$1,210	$6,970
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	28-Feb-09	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	28-Feb-09	61	$26,352	$5,534	$31,886
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	28-Feb-09	80	$1,920	$403	$2,323
UNICEF-GF	Chase buffer (2.5ml bottle)	28-Feb-09	600	$600	$126	$726
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	28-Feb-09	3,900	$312,000	$65,520	$377,520
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	28-Feb-09	5,680	$212,602	$44,647	$257,249
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	31-May-09	114	$49,248	$10,342	$59,590
FHI	Bioline HIV 1/2 (30 tests/kit)	31-May-09	68	$1,632	$343	$1,975
FHI	Determine HIV 1/2 (100 tests/kit)	31-May-09	404	$32,320	$6,787	$39,107
FHI	Uni-Gold HIV Test (20 tests/kit)	31-May-09	605	$22,645	$4,755	$27,401
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	31-Aug-09	89	$12,816	$2,691	$15,507
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	31-Aug-09	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II	31-Aug-09	47	$20,304	$4,264	$24,568

	Plus O (576 tests/kit)					
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	31-Aug-09	280	$6,720	$1,411	$8,131
UNICEF-GF	Chase buffer (2.5ml bottle)	31-Aug-09	600	$600	$126	$726
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	31-Aug-09	11,600	$928,000	$194,880	$1,122,880
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	31-Aug-09	25,000	$935,750	$196,508	$1,132,258
					TOTAL	**$3,178,344**

** FHI shipments scheduled to arrive in November 2008 and May 2009 (within GOM FY 2008) were assumed will be funded and procured in time by FHI to meet these shipment receipt dates.*

Shipments to arrive in FY 2009 (July 2009 – June 2010) will need to have the six monthly quantifications updated and the MOH order and request for funding disbursement submitted to the Global Fund by April 2009 and October 2009 to ensure adequate timing for the shipments to arrive by the scheduled shipment dates in February 2010 and August 2010. See *Appendix K. Timeline for Funding and Procurement of HIV Test Kits* and *Appendix L. Timeline for Ordering and Scheduling Shipments of HIV Test Kits* attached at the end of this report.

TABLE 15. HIV Test Kit Requirements and Costs FY 2009 (July 2009 - June 2010)
ALL REGIONS

(Assumes MOH submits disbursement requests to Global Fund in April 09 and October 09 so that funding is available for UNICEF to initiate procurements in October 09 and April 10 of FY 2009 for shipments that will arrive in Feb 2010 and August 2010)

Supplier	Product	Receive Date	Quantity	Product Costs	Freight Costs	Total Costs
FHI	Bioline HIV 1/2 (30 tests/kit)	30-Nov-09	68	$1,632	$343	$1,975
FHI	Determine HIV 1/2 (100 tests/kit)	30-Nov-09	404	$32,320	$6,787	$39,107
FHI	Uni-Gold HIV Test (20 tests/kit)	30-Nov-09	605	$22,645	$4,755	$27,401
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	28-Feb-10	40	$5,760	$1,210	$6,970
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	28-Feb-10	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	28-Feb-10	60	$25,920	$5,443	$31,363
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	28-Feb-10	140	$3,360	$706	$4,066
UNICEF-GF	Chase buffer (2.5ml bottle)	28-Feb-10	600	$600	$126	$726
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	28-Feb-10	6,700	$536,000	$112,560	$648,560
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	28-Feb-10	7,320	$273,988	$57,537	$331,525
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	31-Aug-10	100	$14,400	$3,024	$17,424
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	31-Aug-10	1	$432	$91	$523

UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	31-Aug-10	140	$60,480	$12,701	$73,181
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	31-Aug-10	520	$12,480	$2,621	$15,101
UNICEF-GF	Chase Buffer solution (2.5ml bottle)	31-Aug-10	600	$600	$126	$726
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	31-Aug-10	21,000	$1,680,000	$352,800	$2,032,800
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	31-Aug-10	35,520	$1,329,514	$279,198	$1,608,711
					TOTAL	**$4,840,680**

** FHI shipments scheduled to arrive in November 2009 (within GOM FY 2009) were assumed will be funded and procured in time by FHI to meet these shipment receipt dates.*

B. GLOBAL FUND RCC PROPOSAL BUDGET, YEAR 1, 2, AND 3

TABLE 16. Global fund RCC Proposal Budget for Year 1, 2 and 3

Global Fund RCC Proposal Budget

	Year 1	Year 2	Year 3
Bioline	$1,200,000	$1,200,000	$1,440,000
KHB	$180,000	$180,000	$216,000
Uni-Gold	$75,600	$75,600	$90,720
14%	$203,784	$203,784	$244,541
TOTAL	**$1,659,384**	**$1,659,384**	**$1,991,261**

It should be noted that different assumptions were used in developing the GF RCC proposal budget vs. the assumptions used in the national quantification of HIV test kit requirements and costs conducted in April 2008. The GF RCC proposal is based on selection and procurement of different HIV test kits and use of a different HIV testing algorithm than what is currently the practice in the country. Moreover, the GF RCC proposal budget also underestimates the procurement and distribution costs at 9% and 5% respectively for a total of 14%, but current shipping, freight and handling costs are an average 21% depending on weight and volume of the shipment (including the UNICEF handling fee of 4%).

If the selection of HIV test kits to be procured changes and the national testing algorithm is revised according to the GF RCC proposal, then a new quantification will need to be conducted to reflect these changes to estimate the quantities required of each of the brands of HIV test kits, and to adjust the cost estimates and the funding that will be required to support the planned scale-up of HIV testing and counseling over the next two fiscal years.

C. TOTAL COMMODITY COSTS, FUNDING COMMITMENTS AND FUNDING GAPS FOR FY 2008 AND FY 2009

After completing the quantification exercise, the total commodity costs for the April 2008 – June 2010 time period amounted to US$10,501,500. This includes procurement of the total quantities needed to address the immediate shortages and stockouts of HIV test kits and to fill the supply pipeline to reach and maintain the established maximum and minimum stock levels needed to cover the lead times and to maintain a buffer stock to avoid shortages and stockouts through the end of FY 2009. A comparison of the funding commitments to the total estimated commodity costs for the period revealed a US$6,977,286 funding gap at the time of the quantification.

The final results of the quantification also indicated the need for an emergency order estimated at US $2,482,475 to be placed by the MOH in April 2008 to ensure arrival of a shipment in August 2008 to ameliorate the ongoing stockouts and interruptions in HIV testing services, and for the MOH to be able to meet the needs for the HIV testing week in September 2008. At the time of the quantification, there was no identified funding source to be able to procure this emergency shipment in April 2008. In addition, the MOH also needs to submit a regular order and request for disbursement of funds to the Global Fund in April 2008 to ensure delivery by February 2009 (10 months later) in time to maintain the ongoing HIV testing services and to support the GOM plans to scale-up HIV testing and counselling services in 2009.

TABLE 17. Total Commodity Costs, Funding Commitments and Funding Gaps for FY 2008 and FY 2009

	Funding Already Committed as of April 2008 [1]	Total Cost April 2008 Emergency Shipment [2]	Total Cost FY 2008 (July 2008 - June 2009)	Total Cost FY 2009 (July 2009 - June 2010)	TOTAL FUNDING REQUIRED April 08, FY 2008 & FY 2009
Total Commodity Costs	**$1,944,124**	**$2,482,475**	**$3,178,344**	**$4,840,680**	**$10,501,500**
Funding Commitments					
Global Fund Rd 2	$1,430,602	$0	$0	$0	$0
Global Fund RCC	$0	$0	$1,659,384	$1,659,384	$3,318,768
CDC	$12,960	$0	$0	$0	$0
FHI	$68,483	$0	$136,965	$68,483	$205,448
UNITAID [3]	$432,079	$0	$0	$0	$0
AXIOS	$0	$0	$0	$0	$0
UNICEF	$0	$0	$0	$0	$0
Other	$0	$0	$0	$0	$0
Funding Gap	**($0)**	**$2,482,475**	**$1,381,995**	**$3,112,814**	**$6,977,284**

[1] Includes GF Rd 2 and UNITAID funded shipments that have already been ordered and are expected to arrive in April and May 2008.

Also assumes CDC and FHI funded HIV test kits are already funded and planned to arrive in April and May 2008. Therefore, these amounts of already committed funding have not been included in the Total Funding Required for FY 2008 and FY 2009

[2] The emergency shipment to be ordered in April 2008 assumes a 4 month lead time until arrival in country. A shipment is needed to arrive in country by August 2008 to fill the supply pipeline to cover the 10 month lead time until the next regularly scheduled shipment arrives in Feb 2009, and to meet the expected increase in demand for HIV test kits during the HIV testing week in Sept 2008.

[3] At the time of the quantification, it was not known what proportion of the UNITAID commitment of US$3.7 million for PMTCT for FY 2008 and FY 2009 might be allocated for procurement of HIV test kits, nor how soon these funds could be mobilized and made available for procurement

VI. RECOMMENDATIONS

A. SHORT-TERM RECOMMENDATIONS

The following short-term recommendations should be acted upon within the six month period following this supply chain assessment and the national quantification of HIV test kit requirements.

1. Selection, Registration and Use of HIV Test Kits

If the national HIV testing algorithm is changed to include the selection of new HIV test kit(s) (e.g. if KHB is approved as the screening test) or if a change in the testing protocols is approved (e.g. a different test kit is selected to be used as the confirmatory or the tiebreaker test), then

- A new quantification exercise will need to be conducted to include the new brand(s) of HIV test kits to be procured and, if the testing protocol also changes, to adjust the forecast of the quantities of each of the HIV test kits that will be required. The quantification should capture the expected timeframe for arrival of the new test kits to be able to plan for phase-out of the stocks of the test kits being replaced, and to phase-in the quantities of the new HIV test kits that are being procured in order to avoid expiries or stockouts during the transition period. This will require frequent and close monitoring and updating of the three PipeLine databases for each region of the country to effectively coordinate the incoming shipment delivery schedules and quantities with the ongoing consumption and stock levels of the HIV test kits in the country.
- The timing of the procurement and distribution of any new brand(s) of HIV test kits should be coordinated to ensure prior registration and approval of the new HIV test kit(s) in the country before shipments arrive, and to allow time for revision and dissemination of the new HIV testing algorithm and for training providers in the use of the new HIV test kit(s) and the new HIV testing protocol before the new test kits are distributed to facilities. It is important for HTC staff at the health facilities to have received official guidance regarding implementation of the new HIV testing algorithm and to have been trained on how to use the new tests to avoid delays in using the new test kits and losing time on the shelf life once they have arrived in the country.

2. Quantification and Procurement of HIV Test Kits

- A routine review and update of the quantification data and assumptions is required every six months or sooner if major changes in the forecasting assumptions occur before six months from the last quantification. This is particularly true for programs that are scaling up services in which future demand for services and consumption of commodities may be changing rapidly. An example would be if the proposed changes in the selection of HIV test kits and the testing algorithm mentioned under point 1. above occurs before the next quantification of HIV test kits is scheduled, then a new quantification would have to be conducted at the time the new guidelines become effective.
- Future quantifications should cover the HIV test kit requirements for the next full two year period and should be coordinated with the GOM fiscal years to be able to undertake timely resource mobilization for any funding gaps identified, and to coordinate the timing of procurements and supplier shipment delivery schedules to ensure a continuous supply of HIV test kits to the country and to maintain the stock levels between the established maximum and minimum stock levels. Please refer to *Appendix K. Timeline for Funding and Procurement of HIV Test Kits* of this report for a diagram describing the process and the timeline for submission of MOH orders and

requests for funding disbursements, and for procurement and receipt of shipments to be followed to ensure that funding is available for timely procurement and receipt of commodities to avoid stock outs in the future.

- Current stock levels of HIV test kits in the country are low so that even when the scheduled shipments already on order arrive in April and May 2008, an emergency order will still need to be placed immediately to fill the supply pipeline to cover the 10 month lead time until the next shipment arrives in February 2009, and to meet the increased demand for HIV test kits anticipated during the HIV testing week in September.

- Collecting and reporting data on the number of people tested for the different purposes of testing (VCT, PITC, PMTCT, home-based testing, quality control etc) on the facility HTC Register should be strengthened, not only to improve reporting rates, but to be able to inform and improve the accuracy of future quantifications of HIV test kits in which the methodology recognizes that the different populations tested through the different types of HIV testing services have different HIV prevalence rates, and that significant quantities of HIV tests are used for non-diagnostic purposes of testing such as quality control and training.

3. Funding for Procurement of HIV Test Kits

- The MOH HIV and AIDS Department should address the funding gaps for procurement of HIV test kits over the next two GOM fiscal years identified through this quantification exercise. Efforts should be coordinated with the National AIDS Commission and other stakeholders to mobilize the additional resources needed to address the current shortages and stockouts of test kits and to fill the in-country supply pipeline to cover the 10 month lead time to be able to maintain ongoing services and to support the MOH's planned scale-up of HIV testing and counseling.

4. Ordering and Distribution of HIV Test Kits According to Established Maximum and Minimum Stock Levels

- Maximum and minimum stock levels for HIV test kits at the RMSs and the health facility level have already been established according to the Standard Operating Procedures for the logistics system developed for essential medicines, contraceptives and HIV test kits. While the established maximum and minimum stock levels were reviewed and re-enforced during the quantification workshop, it was clear from the field visits to RMSs and health facilities that much technical support, monitoring and supervision is needed to strengthen capacity of health facility and RMS staff in ordering and distribution of HIV test kits according to the maximum/ minimum stock levels and for the RMSs to be able to effectively monitor the stock status of HIV test kits in the region.

5. Storage and Distribution

A goal of the Ministry of Health is to achieve integrated storage and distribution of HIV test kits together with essential medicines and contraceptives. In some facilities, HIV test kits are being stored and managed in the pharmacy stores, while in others, test kits are being stored and managed in the laboratories. As described in the findings of this report, different mechanisms currently exist for delivery and/or collection of HIV test kits between RMSs and facilities.

- A concerted effort is needed to provide ongoing monitoring, supervision and support to RMSs and health facilities to standardize storage, reporting and ordering of HIV test kits at pharmacy

stores, and to unify the distribution system for HIV test kits from RMSs along with other non-pharmaceutical products and pharmaceutical products.

6. Logistics Management Information System (LMIS)

- The existing LMIS forms for collecting and reporting logistics data should be revised and standardized to include all of the rapid assay and ELISA HIV test kits currently in use.
- Ongoing monitoring, supervision and support is required to strengthen facility staff knowledge and skills on how to collect and report the data on HIV test kits on the integrated Monthly LMIS forms for essential drugs, contraceptives and HIV test kits.
- Program and facility level staff from both the NGO and mission sectors should be included in training, monitoring and supervision of the MOH logistics system for management of HIV test kits. Especially since the contributions of these sectors towards HIV testing and counseling are likely to be quite significant in the future.
- The MOH training curriculum for HIV testing and counseling staff should include a component on basic logistics principles and the existing Standard Operating Procedures for facility reporting and ordering of HIV test kits.
- The RMSs should have a computerized program installed, like the Supply Chain Manager software program currently in use in many districts, or other software program that allows them to enter and analyze LMIS data and orders received from the health facilities and the districts, and to monitor the stock status of HIV test kits in the region.

B. MEDIUM-TERM RECOMMENDATIONS

The following general recommendations are offered for consideration and implementation over the next one to two year period to strengthen overall supply chain management of HIV test kits to improve the availability of HIV test kits for the people that wish to know their sero-status and for the MOH HIV and AIDS Department to be able to achieve the planned scale-up of HIV testing and counseling services in the country.

1. Implement a medium-term, two year planning period for quantification, resource mobilization and supply planning for HIV test kits

The MOH should adopt a medium-term, two year period for quantification, resource mobilization and procurement planning for HIV test kits and this should be incorporated into overall program planning and budgeting for the MOH HIV and AIDS Department.

2. Develop a medium-term workplan for continuing to build technical capacity in quantification and overall supply chain management in the country

While capacity building took place through the close collaboration and participation of MOH program managers, technical officers, laboratory and pharmacy technicians and others throughout the field data collection and the quantification workshop, (see *Appendix F. HIV Test Kit Quantification Workshop Agenda and List of Participants*), further technical assistance in quantification of HIV test kits will be required before the MOH HIV and AIDS Department will be able to independently conduct

a national quantification exercise following the quantification methodology presented and modeled during this technical assistance. Additional training and technical support will also be needed for MOH staff at the program level and at the RMSs to fully master the use of the PipeLine software tool for estimating the total HIV test kit requirements and costs, developing a national supply plan for coordinating the different funding sources and suppliers with the timing of the procurements and supplier delivery schedules, and for ongoing monitoring of the stock status of the HIV test kit supply in the country. In addition,

- Capacity building in supply chain management of HIV test kits should be incorporated with management of other health commodities that may be managed through the same supply chains.
- Capacity building and strengthening activities should include stakeholders from the policy and program management levels as well as commodity managers and service providers from the RMS and facility levels.

3. Develop a national HIV AND AIDS Commodity Security Strategy

Develop a national HIV and AIDS commodity security strategy to promote policies and plans for securing long-term financing for procurement of commodities and for improving overall supply chain management of HIV test kits as well as other HIV-related commodities in the country.

This would include establishment of an HIV and AIDS commodities technical working group comprised of representatives from donor agencies, MOH and other government entities, technical assistance partners, and other key stakeholders. A few key activities of this proposed HIV AND AIDS commodities technical working group would be to meet at least quarterly to:

- Share information and update all members on the status of planned shipments and the stock status (months of stock on hand) of HIV test kits and other HIV-related commodities in the country. A simple reporting format for informing stakeholders on the consumption and stock levels of commodities in each of the regions could be developed for this purpose.
- Plan, coordinate and review the annual quantification exercise and the six-monthly review and update of the quantification data inputs, assumptions and results.
- Verify the amounts and timing of funding commitments for procurement of commodities each time the quantification is reviewed and updated.
- Coordinate resource mobilization efforts for procurement of commodities when needed.
- Identify the needs for continued technical capacity building in supply chain management, make recommendations and advocate for resources and technical assistance when needed.

VII. NEXT STEPS

The following are specific actions to be taken immediately following the national quantification exercise that have already been communicated to the MOH HIV and AIDS Department in an earlier draft version of this technical report.

In order to ensure the supply of HIV test kits needed to support the ongoing provision of HIV testing and counselling and to be able to respond to the planned scale up of HIV testing services in Malawi, the MOH HIV and AIDS Department will need to:

- Identify all potential and actual funding sources for procurement of HIV test kits for the national HIV testing program for the next two fiscal years. The list of actual and potential funding sources at the time of the quantification included the Global Fund, UNITAID, UNICEF as a separate funding source, FHI, AXIOS donation program, CDC, and CHAI.
- For each funding source, confirm the specific amounts and the timing of the funding commitments for procurement of HIV test kits for the next two fiscal years July 2008 – June 2009 and June 2009 – July 2010. Take into consideration the funding disbursement schedules and past experience to verify when funding will actually be available to initiate procurement.
- Confirm which HIV test kits and what quantities of HIV test kits will be donated or delivered directly as in-kind contributions to the program over the next two fiscal years. This would include, for example, quantities of Determine HIV 1/2 test kits donated by AXIOS.
- Compare the Total Commodity Costs with the amounts and the timing of the Funding Commitments for procurement of HIV test kits for each fiscal year to verify the Funding Gaps and begin mobilization of the needed resources to be able to undertake timely procurement of the HIV test kit requirements for each year. (Please see *Appendix I. Total Commodity Costs and Funding Required April 2008 and FY08 & FY09*)
- The MOH should place an emergency order and request for disbursement of funds to the Global Fund in April 2008 for UNICEF to procure a shipment of HIV test kits to arrive in country by August 2008 in time for the September 2008 HIV testing week. This is based on the four month lead time needed for an emergency shipment as reported by UNICEF.

  Table 13. reproduced below indicates the specific quantities, shipment dates and cost for each of the brands of HIV test kits to be funded and procured for the MOH as an emergency order in April 2008

TABLE 13: HIV Test Kit Requirements and Costs for Emergency Order to be Procured in April 2008 for Shipment to Arrive in August 2008

Supplier	Product	Receive Date	Quantity	Product Costs	Freight Costs	Total Costs
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	31-Aug-08	120	$17,280	$3,629	$20,909
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	31-Aug-08	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	31-Aug-08	130	$56,160	$11,794	$67,954
UNICEF-GF	Bioline HIV ½ (30 tests/kit)	31-Aug-08	240	$5,760	$1,210	$6,970
UNICEF-GF	Chase buffer (2.5ml bottle)	31-Aug-08	1,100	$1,100	$231	$1,331
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	31-Aug-08	10,600	$848,000	$178,080	$1,026,080
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	31-Aug-08	30,000	$1,122,900	$235,809	$1,358,709
					TOTAL	**$2,482,475**

- In addition, given the 10 month lead time for regularly scheduled shipments, the MOH should also place the order and the request for disbursement of funds from the Global Fund in April 2008 for the next regularly scheduled shipment of HIV test kits to arrive in country by February 2009 – thus allowing six months for approval and disbursement of funds by the Global Fund, and four months for procurement and delivery of the HIV test kits by UNICEF and individual suppliers.
- Table 14. below indicates the quantities, shipment dates and cost for each of the brands of HIV test kits to be funded and procured for the MOH that should also be ordered in April 2008 as a regularly scheduled shipment to arrive by February 2009, as well as the quantities, shipment dates and cost of each of the brands of HIV test kits that should be ordered in October 2008 for the shipments to arrive by August 2009.

TABLE 14. Total HIV Test Kit Requirements and Costs FY 2008 (July 2008 - June 2009) ALL REGIONS

(Assumes MOH submits disbursement requests to Global Fund in April 08 and October 08 so that funding is available for UNICEF to initiate procurements in October 08 and April 09 of FY 2008 for shipments that will arrive in Feb 09 and August 09)

Supplier	Product	Receive Date	Quantity	Product Costs	Freight Costs	Total Costs
FHI*	Bioline HIV 1/2 (30 tests/kit)	30-Nov-08	68	$1,632	$343	$1,975
FHI*	Determine HIV 1/2 (100 tests/kit)	30-Nov-08	404	$32,320	$6,787	$39,107
FHI*	Uni-Gold HIV Test (20 tests/kit)	30-Nov-08	605	$22,645	$4,755	$27,401
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	28-Feb-09	40	$5,760	$1,210	$6,970
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	28-Feb-09	1	$432	$91	$523

UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	28-Feb-09	61	$26,352	$5,534	$31,886
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	28-Feb-09	80	$1,920	$403	$2,323
UNICEF-GF	Chase buffer (2.5ml bottle)	28-Feb-09	600	$600	$126	$726
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	28-Feb-09	3,900	$312,000	$65,520	$377,520
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	28-Feb-09	5,680	$212,602	$44,647	$257,249
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	31-May-09	114	$49,248	$10,342	$59,590
FHI	Bioline HIV 1/2 (30 tests/kit)	31-May-09	68	$1,632	$343	$1,975
FHI	Determine HIV 1/2 (100 tests/kit)	31-May-09	404	$32,320	$6,787	$39,107
FHI	Uni-Gold HIV Test (20 tests/kit)	31-May-09	605	$22,645	$4,755	$27,401
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	31-Aug-09	89	$12,816	$2,691	$15,507
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	31-Aug-09	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	31-Aug-09	47	$20,304	$4,264	$24,568
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	31-Aug-09	280	$6,720	$1,411	$8,131
UNICEF-GF	Chase buffer (2.5ml bottle)	31-Aug-09	600	$600	$126	$726
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	31-Aug-09	11,600	$928,000	$194,880	$1,122,880
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	31-Aug-09	25,000	$935,750	$196,508	$1,132,258
					TOTAL	**$3,178,344**

** FHI shipments scheduled to arrive in November 2008 and May 2009 (within GOM FY 2008) were assumed will be funded and procured in time by FHI to meet these shipment receipt dates.*

- Shipments to arrive in FY 2009 (July 2009 – June 2010) will need to have the six monthly quantifications updated and the MOH order and request for funding disbursement submitted to the Global Fund by April 2009 and October 2009 to ensure adequate timing for the shipments to arrive by the scheduled shipment dates in February 2010 and August 2010.

TABLE 15. Total HIV Test Kit Requirements and Costs FY 2009 (July 2009 - June 2010) ALL REGIONS

(Assumes MOH submits disbursement requests to Global Fund in April 09 and October 09 so that funding is available for UNICEF to initiate procurements in October 09 and April 10 of FY 2009 for shipments that will arrive in Feb 2010 and August 2010)

Supplier	Product	Receive Date	Quantity	Product Costs	Freight Costs	Total Costs
FHI	Bioline HIV 1/2 (30 tests/kit)	30-Nov-09	68	$1,632	$343	$1,975
FHI	Determine HIV 1/2 (100 tests/kit)	30-Nov-09	404	$32,320	$6,787	$39,107
FHI	Uni-Gold HIV Test (20 tests/kit)	30-Nov-09	605	$22,645	$4,755	$27,401

UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	28-Feb-10	40	$5,760	$1,210	$6,970
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	28-Feb-10	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	28-Feb-10	60	$25,920	$5,443	$31,363
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	28-Feb-10	140	$3,360	$706	$4,066
UNICEF-GF	Chase buffer (2.5ml bottle)	28-Feb-10	600	$600	$126	$726
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	28-Feb-10	6,700	$536,000	$112,560	$648,560
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	28-Feb-10	7,320	$273,988	$57,537	$331,525
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	31-Aug-10	100	$14,400	$3,024	$17,424
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	31-Aug-10	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	31-Aug-10	140	$60,480	$12,701	$73,181
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	31-Aug-10	520	$12,480	$2,621	$15,101
UNICEF-GF	Chase Buffer solution (2.5ml bottle)	31-Aug-10	600	$600	$126	$726
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	31-Aug-10	21,000	$1,680,000	$352,800	$2,032,800
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	31-Aug-10	35,520	$1,329,514	$279,198	$1,608,711
					TOTAL	**$4,840,680**

** FHI shipments scheduled to arrive in November 2009 (within GOM FY 2009) were assumed will be funded and procured in time by FHI to meet these shipment receipt dates.*

Please refer to the following Appendices attached to this report for further information and guidance.

- *Appendix H. HIV Test Kit Requirements, Shipment Dates and Cost Estimates by Region and for All Regions for FY 2008 and FY 2009*
- *Appendix I. Total Commodity Costs, Funding Commitments and Funding Gaps by Fiscal Year*
- *Appendix J. Global Fund RCC Proposal Budget, Year 1, 2, and 3*
- *Appendix K. Timeline for Funding and Procurement of HIV Test Kits*
- *Appendix L. Timeline for Ordering and Scheduling Shipments of HIV Test Kits*

PLEASE NOTE THE FOLLOWING CORRECTION:

Since the price of the 2.5 ml bottle of chase buffer solution when procured separately from the Determine HIV 1/2 test kits could not be verified at the time the quantification exercise was being conducted, an illustrative price of US$1.00 was used. Inquiries since the quantification exercise have confirmed the current price as US $5.00 per 2.5 ml bottle. Therefore, the cost estimates will need to be adjusted to reflect this significantly higher price which may impact the MOH's decision to procure this product.

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APPENDICES

APPENDIX A. FIELD ASSESSMENT AND QUANTIFICATION DATA COLLECTION TEAM

Field Assessment and Quantification Data Collection Team Members
19th March and 24th – 28th March, 2008

Name	Title	Organization
NORTH REGION		
Samuel Chirwa	Senior Logistics Officer	MOH, HTSS Pharmaceuticals Unit
Frank Chilambadzuka	Pharmacy Technician	CMS Procurement DRP
Amanda Mwirotsi	Technical Advisor	John Snow, Inc./Logistics Services
CENTRAL REGION		
Evance Moyo	Assistant LMIS Associate	USAID | DELIVER PROJECT, JSI Malawi
Manondo Msefula	Resident Logistics Advisor	USAID | DELIVER PROJECT, JSI Malawi
SOUTH REGION		
Lucius Ng'omang'oma	HTC Officer	MOH, HIV and AIDS Department
Claudia Allers	Senior Technical Advisor	USAID | DELIVER PROJECT, John Snow, Inc

APPENDIX B. LIST OF STAKEHOLDERS AND PERSONS INTERVIEWED

List of Stakeholders and Persons Interviewed		
NAME	**TITLE**	**ORGANIZATION**
Dr. Kelita Kamoto	Head	MOH, HIV and AIDS Department
Philip Moses	HIV/AIDS Advisor	MOH, HIV and AIDS Department/FHI
Lucius Ng'omang'oma	HTC Officer	MOH, HIV and AIDS Department
Eric Schouten	HIV Coordinator	MOH, HIV and AIDS Department
Michael Eliya	National PMTCT Coordinator	MOH, PMTCT Program
Peggy Chibuwe	PMTCT Technical Advisor	MOH, PMTCT Program
Emmanuel Saka	M & E Officer	MOH, PMTCT Program/Early Infant Diagnosis
Simon Makombe	ART Officer	MOH, HIV and AIDS Department
Amon Nkhata	ART Officer	MOH, HIV and AIDS Department
Francis Chafulumira	Director	MOH, HTSS Pharmaceuticals Unit
Samuel Chirwa	Senior Logistics Officer	MOH, HTSS Pharmaceuticals Unit
Dorica Chirwa	Logistics Officer	MOH, HTSS Pharmaceuticals Unit
Reuben Mwenda	Deputy Director	MOH, HTSS Diagnostics Unit
James Kandulu	EMLS Regional Supervisor	MOH, HTSS Diagnostics Unit
Edwin Chifandale	Laboratory Technician	Kamuzu Central Hospital
Semu Bangelo	Pharmacy Technician	Michinji District Health Office
Charles Abondo	Senior Mgmt Consultant	GLOCOMS/CMS
Miriam Chipimo	Project Officer	UNICEF
Caesar Mudondo	Procurement Officer	UNICEF
Ben Chilima	Director, Quality Assurance	Community Health Services Unit (CHSU)
Dr. Bridon M'Baya	Medical Director	Malawi Blood Transfusion Service (MBTS)
Florence Kayambo	Head, Policy Support and Development	National AIDS Commission (NAC)
Bridget Chibwana	Director, Policy and Programmes	National AIDS Commission (NAC)
Washington Kaimvi	Director, Finance & Administration	National AIDS Commission (NAC)
Wellington E. Limbe	Director	MACRO
Bruno Nanthuru	Branch Manager	MACRO
Frank Chilambadzuka	Pharmacy Technician	Central Medical Stores (CMS) Procurement
Oliver Chipaka Phiri	Regional Manager	Banja La Mtsogolo (BLM)
George Macheka	Director of Operations	Banja La Mtsogolo (BLM)
Elias Chasukwa	HIV/AIDS Coordinator	Christian Health Association of Malawi (CHAM)
Veronica Chipeta Chirwa	Programme Manager, Laboratory Services	Clinton Foundation HIV/AIDS Initiative (CHAI)
Alex Mwase	Procurement Analyst	Clinton Foundation HIV/AIDS Initiative (CHAI)
Matt Boxshall	Management Advisor	Lighthouse Trust
Jayne Waweru	Country Director	USAID | DELIVER PROJECT, JSI Malawi
Elias Mwalabu	LMIS Associate	USAID | DELIVER PROJECT, JSI Malawi
Manondo Msefula	Resident Logistics Advisor	USAID | DELIVER PROJECT, JSI Malawi
Evance Moyo	Assistant LMIS Associate	USAID | DELIVER PROJECT, JSI Malawi
Emily Hughes	HIV/AIDS Advisor	USAID | MALAWI
Kate Wolf (for Matt Barnhart)	Malaria CTO (HIV Cluster Lead)	USAID | MALAWI USAID | MALAWI

APPENDIX C. LIST OF FACILITIES VISITED

List of Facilities Visited 19th March and 24th – 28th March, 2008

Region	No.	District	Facility Name	Type
South	1.	Balaka	Ncherezo	CBO
	2.	Mangochi	Mangochi District Hospital	Public
	3.	Chikwawa	Illovo Health Centre	Public
	4.	Chiradzulu	Mikolongwe DAPP	NGO
	5.	Blantyre	Queens Central Hospital	Public
	6.	Blantyre	Regional Medical Store	Public
Central	1.	Lilongwe	MACRO Stand Alone [Pilot Site]	NGO
	2.	Lilongwe	Kawale Health Centre [Pilot Site]	Public/UNC project
	3.	Lilongwe	St. Gabriel Hospital	CHAM
	4.	Lilongwe	Area 18 Health Centre	Public
	5.	Lilongwe	Regional Medical Store	Public
	6.	Lilongwe	Partners In Hope	Private
	7.	Lilongwe	UNC Project, Stand Alone	Public
	8.	Kasungu	Kasungu District Hospital	Public
	9.	Salima	Salima District Hospital	Public
	10.	Dedza	Maonde Health Centre	Public
North	1.	Nkhatabay	Nkhatabay District Hospital	Public
	2.	Mzimba	Mzuzu Central Hospital	Public
	3.	Mzimba	Ekwendeni Hospital	CHAM
	4.	Rumphi	Bolero Rural Hospital	Public
	5.	Karonga	Karonga District Hospital	Public
	6.	Mzimba	Reiply Clinic	Private
	7.	Mzimba	Regional Medical Store	Public
TOTAL	**23**			

APPENDIX D. FACILITY LEVEL DATA COLLECTION TOOL

Facility Level Questionnaire

HIV Test Kit Quantification

Ministry of Health
MALAWI

Period of Data Collection

19th – 28th March, 2008

List of Health Facilities to be Visited for the HIV Test Kit Quantification

Region	No.	District	Facility Name	Type
South	**1.**	Balaka	Ncherezo	CBO
	2.	Mangochi	Mangochi District Hospital	Public
	3.	Chikwawa	Illovo Health Centre	Public
	4.	Chiradzulu	Mikolongwe DAPP	NGO
	5.	Blantyre	Queens Central Hospital	Public
	6.	Blantyre	Regional Medical Store	Public
Central	**1.**	Lilongwe	MACRO Stand Alone [Pilot Site]	NGO
	2.	Lilongwe	Kawale Health Centre [Pilot Site]	Public/UNC project
	3.	Lilongwe	St. Gabriel Hospital	CHAM
	4.	Lilongwe	Area 18 Health Centre	Public
	5.	Lilongwe	Regional Medical Store	Public
	6.	Lilongwe	Partners In Hope	Private
	7.	Lilongwe	UNC Project, Stand Alone	Public
	8.	Lilongwe	Kamuzu Central Hospital (TBD)	Public
	9.	Kasungu	Kasungu District Hospital	Public
	10.	Salima	Salima District Hospital	District Hospital
	11.	Dedza	Maonde Health Centre	Public
North	**1.**	Nkhatabay	Nkhatabay District Hospital	Public
	2.	Mzimba	Mzuzu Central Hospital	Public
	3.	Mzimba	Ekwendeni Hospital	CHAM
	4.	Rumphi	Bolero Rural Hospital	Public
	5.	Karonga	Karonga District Hospital	Public
	6.	Mzimba	Reiply Clinic	Private
	7.	Mzimba	Regional Medical Store	Public
TOTAL	**24**			

Questionnaire Guidelines

I. Information about Interview	Record the date of the interview and list the names of the interviewers.
II. Facility Identification	Ask to speak to the person in-charge of the facility. Write the name of the facility and the location. Record the location, facility type, facility code and characteristics using the codes provided for each question. Write the code number of the responses in the boxes on the right
III. Introduction	Use the text here to guide your introduction and explain the purpose of the assessment to facility staff. Request permission to conduct the interviews and record the information regarding the interviewee(s) titles and functions. For sections IV. through IX. of the questionnaire, record responses by clearly circling either the number or letter that corresponds to the interviewee's response. Questions with letters may have multiple responses; questions with numbers have only a single response; others require the interviewer to write the interviewees' responses.
IV. HIV Testing Program Information	Interview the Facility In-Charge and other staff about the HIV testing services provided at the facility
V. HIV Testing Algorithm	Confirm if the HIV testing algorithm is a parallel or a serial algorithm, the testing algorithm for each purpose of testing, and the brand of HIV test kit used at each step in the algorithm.
VI. Data Collection and Reporting on HIV Testing Services	Review the forms and registers used for collecting and reporting data on HIV testing services at the facility. Ask to see the registers and reports for the most recent 12 month period. Record in the questionnaire the No. Clients/Patients Tested, No. Positive Results and No. Discordant Results for each of the 12 months.
VII. Data Collection and Reporting on Quantities Used (Consumption) and Stock on Hand	Review the forms and registers used for collecting and reporting logistics data on consumption, losses/adjustments and stock on hand data at the facility. Ask to see the registers and reports for the most recent 12 month period. Record in the questionnaire the monthly consumption of each brand of HIV test kit for each of the 12 months.
VIII. Ordering	Record interviewee's responses to the questions in this section.
IX. Distribution/Transport	Record interviewee's responses to the questions in this section.
X. Supervision	Record interviewee's responses to the questions in this section.
XI. Use of Stock Card, Stock on Hand on Day of Visit	Observe the inventory control records, do a physical count to determine if the bin cards are updated, and identify any quantities of expired product.
XII. End Interview	Ask the interviewee/s if they want to ask any questions or offer any comments or suggestions. Thank them for their time and for the information.
XIII. After the Interview	Interviewer to record any additional comments/observations and provide a brief analysis of findings from the facility visit

I. INFORMATION ABOUT INTERVIEW

Date of Visit: _____ / _____ / _____
Day Month Year

Time Started: _____

Interviewer(s): Name / Title / Organization

1) _____

2) _____

3) _____

4) _____

5) _____

II. FACILITY IDENTIFICATION

Name of the Facility: _____

Facility location:

Region: _____

District: _____

Urban/Rural: _____

Facility Type:

Central Hospital _____ Stand Alone site _____

Mental Hospital _____ Mobile Unit _____

District Hospital _____ Outreach Site _____

Health Centre _____ Home Based Door-to-Door _____

Regional Medical Stores _____

Other (specify): _____

III. Introduction

Ask for the person in-charge of the facility and show the letter of introduction/authorization from the MOH, HIV/AIDS Unit. Introduce all team members and ask facility representatives to introduce themselves.

Explain the objectives of the quantification and the purpose of the visit to the facility today:

Good day and thank you for agreeing to receive us today. My name is _____. My colleague(s) and I are here at the request of the Ministry of Health. We are assisting the HIV and AIDS Department to conduct a quantification of HIV test kits required for the national program. We are visiting selected health facilities throughout the country to collect data for the quantification. The purpose of the visit today is to learn about the HIV testing services being offered at this facility, to collect data on the number of clients/patients being tested and the number that are positive, and to learn how the supply of HIV test kits at this facility is being ordered and managed. This is not a supervisory visit and the performance of individual staff members is not being evaluated. The results of this visit will provide information for the national quantification of HIV test kits.

Explain how the team would like to conduct the interviews:
With your permission, we would first like to speak with staff members who can provide information on the HIV testing services being provided at this facility. Explain that the interviewers may need to separate to collect information about the different HIV testing services being provided and how the HIV test kits are being managed if testing is being conducted at various locations within the facility e.g. HTC Counseling Room, ANC/PMTCT Clinic, Laboratory, or VCT Stand Alone. Ask the Facility In-Charge and other staff members if they have any questions at this time before proceeding with the interview questions.

Questions 1.- 9. are most relevant for the Facility-In Charge. For the remainder of the questionnaire, ask the In-Charge to identify staff members who can answer further questions about the HIV testing services and commodities at the facility.

No.	IV. HIV Testing Program Information	Code Classification	Go To
1.	Name and Title of person interviewed for this section	Name: _____ Title: _____	
2.	Number of years and months you have worked at this facility?	Years: _____ Months: _____	

3.	How long have HIV testing and counseling services been offered at this facility?	Years: _____ Months: _____	
4.	What are the main purposes for which HIV testing is being provided at this facility? *(Circle all that apply. HTC refers to all forms of Provider Initiated Testing and Counseling and Client Initiated Counseling and Testing/VCT)*	HTC.....A PMTCT .....B Early Infant Diagnosis……..C Clinical Diagnosis ..... D Blood Safety ..... F Sentinel Surveillance ..... G Quality Control (external)……H Training .....I HIV testing campaign……..J Blood donor drive .....K Other……..W	
5.	Which cadres of staff are qualified to perform HIV testing and counseling at this facility? (*Check (√) all that apply)*		

Cadres of staff qualified to perform HIV testing and counseling				
(√)	**CADRE**	**Number**	**Full Time**	**Part Time**
	Clinical Officer			
	Nurse/Counselor			
	PMTCT Nurse			
	Laboratory Technician			
	Laboratory Assistant			
	HTC Counselor			
	Health Surveillance Assistant (HSA)			
	Other (specify)			

6.	How many days per week do staff provide HIV testing and counseling services?	

7.	Where is HIV testing taking place at this facility? *(Circle all that apply)*	Laboratory .....A ANC Clinic.....B HTC Counseling & Testing Room .. C STI Clinic ..... D TB Clinic.....E In-Patient Ward .....F Out Patient Dept……..G Mobile Unit ..... H Outreach site .....I Home based/Door to Door……..J Other (specify)..... ….W	
8.	Where are the HIV test kits stored at this facility? *(Circle all that apply)*	Pharmacy Stores .....A Laboratory Stores .....B ANC Clinic..... C HTC Testing & Counseling Room .. D STI Clinic .....E TB Clinic..... F In-Patient Ward ..... G Out Patient Dept ..... H Other (specify)..... W	If Other, go to 9.
9.	If other, why are HIV test kits stored at other locations? *(Circle all that apply)*	Space Constraints……A Temperature Constraints ……B Security……..C Other (specify)……..W	

Ask to speak to staff member(s) responsible for performing HIV testing and for collecting and reporting data on the number of clients/patients tested and the results of the testing (negative, positive, discordant results).

No.	V. HIV Testing Algorithm	Code Classification	Go To/ Comments
10.	a. Name and title of person interviewed for this section.	Name: _____ Title: _____	
	Number of years and months you have worked at this facility?	Years: _____ Months: _____	
	b. Name and title of person interviewed for this section.	Name: _____ Title: _____	

	Number of years and months you have worked at this facility?	Years: _____ Months: _____	
	c. Name and title of person interviewed for this section.	Name: _____ Title: _____	
	Number of years and months you have worked at this facility?	Years: _____ Months: _____	

11. Which type of testing algorithm (Parallel or Serial) and what is the HIV testing algorithm followed for each purpose of testing at this facility? *(Note "P" for Parallel and "S" for Serial testing algorithm, and write the brand of HIV test used as the Screening, the Confirmatory and the Tiebreaker test for each purpose of testing)*

	Testing Algorithm		**Screening Test**	**Confirmatory Test**	**Tiebreaker Test**
Purpose of Testing	**P**	**S**	**(Brand Name)**	**(Brand Name)**	**(Brand Name)**
HTC					
PMTCT					
Early Infant Diagnosis					
Lab/Clinical Diagnosis					
Blood Safety					
Sentinel Surveillance					
Quality Control					
Training					
Other					

No.	VI. Data Collection and Reporting on HIV Testing Services	Code Classification	Go To/ Comments
12.	Where do you record the number of patients/clients tested and the test results on a daily basis? *(Write the name of the form and ask to see the register for the last 12 months, March 2007 to February 2008)*		
13.	Which form do you use for reporting to the higher level on the number of people tested and the test results at this facility? *(Write the name of the form and ask to see the reports for the last 12 months, March 2007 to February 2008)*		
14.	For each purpose of testing, what was the Total No. of Clients/Patients Tested; the No. of Positive Results; and the Total No. of Discordant Results at this facility over the past 12 months?		

15.

HTC			
March 07 – Feb 08	**No. Clients/ Patients Tested**	**No. Positive Results**	**No. Discordant Results**
March 2007			
April 2007			
May 2007			
June 2007			
July 2007			
August 2007			
September 2007			
October 2007			
November 2007			
December 2007			
January 2008			
February 2008			
TOTAL			

16.

PMTCT			
March 07 – Feb 08	**No. Pregnant Women Tested**	**No. Positive Results**	**No. Discordant Results**
March 2007			
April 2007			
May 2007			
June 2007			
July 2007			
August 2007			
September 2007			
October 2007			
November 2007			
December 2007			
January 2008			
February 2008			
TOTAL			

17.

Early Infant Diagnosis			
March 07 – Feb 08	**No. Clients Tested**	**No. Positive Results**	**No. Discordant Results**
March 2007			
April 2007			
May 2007			
June 2007			
July 2007			
August 2007			
September 2007			
October 2007			
November 2007			
December 2007			
January 2008			
February 2008			
TOTAL			

18.

Lab/Clinical Diagnosis			
March 07 – Feb 08	**No. Blood Donors Screened**	**No. Positive Results**	**No. Discordant Results**
March 2007			
April 2007			
May 2007			
June 2007			
July 2007			
August 2007			
September 2007			
October 2007			
November 2007			
December 2007			
January 2008			
February 2008			
TOTAL			

19.

Blood Safety			
March 07 – Feb 08	**No. Blood Donors Screened**	**No. Positive Results**	**No. Discordant Results**
March 2007			
April 2007			
May 2007			
June 2007			
July 2007			
August 2007			
September 2007			
October 2007			
November 2007			
December 2007			
January 2008			
February 2008			
TOTAL			

20.

Sentinel Surveillance			
March 07 – Feb 08	**No. Blood Samples Tested**	**No. Positive Results**	**No. Discordant Results**
March 2007			
April 2007			
May 2007			
June 2007			
July 2007			
August 2007			
September 2007			
October 2007			
November 2007			
December 2007			
January 2008			
February 2008			
TOTAL			

21.

Quality Control			
March 07 – Feb 08	**No. Blood Samples Tested**	**No. Positive Results**	**No. Discordant Results**
March 2007			
April 2007			
May 2007			
June 2007			
July 2007			
August 2007			
September 2007			
October 2007			
November 2007			
December 2007			
January 2008			
February 2008			
TOTAL			

22.

Training			
March 07 – Feb 08	**No. Tests per HCW Trained**	**No. Tests per HCW Trained**	**No. Tests per HCW Trained**
March 2007			
April 2007			
May 2007			
June 2007			
July 2007			
August 2007			
September 2007			
October 2007			
November 2007			
December 2007			
January 2008			
February 2008			
TOTAL			

23. What are the greatest challenges to scaling up HIV Testing Services?

(Interviewer to check (√) responses 1. through 5. and note staff comments below.)

Availability of HIV Testing Supplies…1
Availability and capacity of staff ……..2
Adequate space for testing and counseling…….……..
3 Laboratory capacity ……...4
Other (specify) ……..5

	After asking the questions in section VI. above, ask to speak to staff member(s) responsible for managing the HIV test kit supply and for collecting and reporting data on the quantities of HIV tests used (consumption) and the stock on hand at the facility.		
No.	**VII. Data Collection and Reporting on Quantities of HIV Tests Used (Consumption) and Stock on Hand**	**Code Classification**	**Go To/ Comments**
24.	Name and title of person interviewed for this section.	Name: _____ Title: _____	
25.	Number of years and months you have worked at this facility?	Years: _____ Months: _____	
26.	Where do you record information on the quantities of HIV tests used? (Consumption) *(Write an X for all that apply)*		

	Daily Register	Lab Register	Stores Ledger	Stock Card	Other	Not Recorded	
HTC Counseling Room							
ANC/PMTCT Clinic							
Laboratory							
VCT Stand Alone							
Other							

27.	Where do you record information on the quantities of HIV tests in stock? (Stock on Hand - SOH). *(Write an X for all that apply)*		

	Daily Register	Lab Register	Stores Ledger	Stock Card	Other	Not Recorded	
HTC Counseling Room							
ANC/PMTCT Clinic							
Laboratory							
VCT Stand Alone							
Other							

NOTE: *If the person performing HIV tests is not responsible for compiling and submitting facility reports on consumption and stock levels of HIV tests, interviewer will need to ask to speak to the appropriate person to answer the following questions about reporting in this section.*

28.	Do you report consumption and SOH information to the higher level? *(If yes, interviewer note to which higher level DHO; RMS; CMS; Other).*	Yes ..... 1 DHO ___ RMS ___ CMS ___ Other ___ No 0	If no, go to 34.

29.	What report forms do you use for reporting to the higher level (*ask to see a copy of the report, write the name of the report to the right).*		
30.	Verify the type of data collected on the LMIS forms. (Circle all that apply)	Beginning balance……. A Quantity Received since last Report/Order ……. B Quantity Used…….…… C Losses/Adjustments ……. D Ending balance…….. E Quantity Requested F Other …….... W	
31.	How often is the LMIS report sent to the higher level?	Monthly ……...…… A Quarterly …….. ……. B Semi-annually …… C Annually…… …….. D Other …….... W	
32.	When was the last time you submitted the report on consumption and stock on hand of HIV test kits to the higher level?	Never .....1 Within the last month .....2 2 months ago .....3 3 months ago .....4 More than 3 months ago 5	
33.	How often is this report supposed to be submitted to the higher level?	Monthly ……...…… A Quarterly …….. ……. B Semi-annually …… C Annually…… …. D Other …….... W	

34.	Do you receive reports on the quantities of HIV tests used (consumption) and the quantities of HIV tests in stock (stock on hand) from lower level health facilities? (*If Yes, note from which lower level e.g. RMS: DHO; HC; Other)*	Yes .....1 RMS ___ DHO ___ HC ___ Other ___ No 0	➔ If no, go to 37.
35.	How many of these facilities submitted their reports for the last reporting period?	No. of Health Facilities ……. [ ]	
36.	How many health facilities are supposed to submit reports on HIV test kits to this facility?	No. of Health Facilities ……. [ ]	
No.	**VIII. Ordering**	**Code Classification**	**Go To/ Comments**
37.	Who determines the quantities of HIV test kits to order for this facility? *(Circle all that apply.)*	Clinical Officer ..... A Nurse/Counselor ..... B Laboratory Technician ..... C Laboratory Assistant ..... D PMTCT Nurse ..... E VCT Counselor.....F Pharmacy Technician..... G Other (specify)..... H Facility does not order..... G	➔Go to 44.
38.	How are the order quantities determined? *(ask interviewee to explain the formula used to arrive at the order quantity and note here)*	Formula .....1 Don't know .....2 Other means (specify) ……3	
39.	Are the orders for HIV test kits submitted together with the report? *(Does the order have to be submitted on the same form as the report?)*	Yes……...1 No……....0	
40.	Where did you send your orders to?	DHO…….……A Regional Medical Stores… …… B Central Medical Stores…….....C MOH HIV/AIDS Unit……...D MOH HTSS Logistics Officer……...E Others …….……W	

41.	How often does the health facility place orders for HIV test kits? *(Circle all that apply)*	Weekly ..... A Monthly ..... B Quarterly ..... C Semi-annually ..... D Annually..... E Other ..... W	
42.	Do you receive the quantities of HIV test kits that you order?	Always.....1 Sometimes .....2 Never 3	
43.	How many emergency orders for HIV test kits were placed in the last 6 months?	None .....0 1 .....1 2 .....2 3 .....3 More than 3.....4 DK.....5	

No.	IX. Distribution/Transport	Code Classification	Go To/ Comments
44.	Who is responsible for transporting HIV test kits to your facility? *(Circle all that apply, specify which higher level if applicable.)*	Local supplier delivers ..... A Higher level delivers ..... B RMS ____ DHO ____ Other _____ This facility collects ..... C Other (specify) ..... W	
45.	What type of transportation is most often used for HIV test kits?	RMS vehicle .....1 Facility vehicle .....2 Public transportation .....3 Private vehicle .....4 Motorcycle .....5 Bicycle .....6 On foot .....7 Other (specify) 8	

46.	On average, approximately how long does it take from the time the health facility places an order - until the HIV test kits are received?	Less than 2 weeks .....1 2 weeks to 1 month .....2 Between 1 and 2 months .....3 More than 2 months 4	
No.	**X. Supervision**	**Code Classification**	**Go To/ Comments**
47.	When did you receive your most recent supervision visit for the HIV testing program? Check visitors book, if necessary.	Never received .....1 Within the last month .....2 Within the last 3 months .....3 Within the last 6 months 4 More than 6 months ago .....5 Other (specify) 9	
48.	Did your last supervision visit include a review of how the HIV test kits are being managed at this facility? (e.g., review of stock cards, reports, physical stock count, removal/ disposal of expired stock, storage conditions)?	Yes .....1 No 0	
49.	What are the greatest challenges to scaling up HIV Testing Services? (Interviewer to check (√) responses 1. through 5. and note staff comments below.)	Availability of HIV testing supplies…….. A Availability and capacity of staff….. B Adequate space for testing and counseling…….. C Laboratory Capacity……. D Other (specify)……..……... W	

Thank you for your time and information. You have been very helpful. Our remaining questions will require looking at products in the storeroom and speaking with the person who oversees the main store where HIV test kits are managed.

When in the Store Room, if with a different person, start with question 50., but if with the same person from previous session, go to question 51.

No.	XI. Use of Stock Card, Stock on Hand on Day of Visit	Code Classification	Go To
50.	a. Name and title of person interviewed for this section.	Name: _____ Title: _____	
	Number of years and months you have worked at this facility?	Years: _____ Months: _____	
	b. Name and title of person interviewed for this section.	Name: _____ Title: _____	
	Number of years and months you have worked at this facility?	Years: _____ Months: _____	
	c. Name and title of person interviewed for this section.	Name: _____ Title: _____	
	Number of years and months you have worked at this facility?	Years: _____ Months: _____	
51.	Who is the person responsible for managing the HIV test kits in this storeroom?	Clinical Officer..... 1 Laboratory Technician..... 2 PMTCT Nurse ..... 3 HTC Counselor ..... 4 Pharmacy Technician ……..…5 Other (specify)……..6	
52.	Interviewer ask to see where the products are stored and to see the stock cards. Do stock cards record the smallest unit of count? *(individual HIV tests, not kits)*	Yes ..... 1 No 0	
53.	Review the stock cards or other records the facility may use for recording stock balances and stock transactions. Complete Table 1. below.		

INSTRUCTIONS:

Column:

1. Name of each HIV testing product that will be counted
2. Unit of count for the product is individual tests, not kits. Note if smallest unit of count is not used on the stock card.

Note*:* Columns 1 and 2 should be filled out before questionnaires are printed.

3. Whether or not the product is available, is this facility supposed to manage this product? Answer Y for Yes or N if No.
4. Check if the stock card (or other logistics data sources) is available for each product, answer Y for Yes or N for No. If another type of record is used e.g. stores ledger, please note in the comments section, and continue to gather consumption data using another type of logistics data record.
5. Check if the stock card has been updated within the last 30 days, answer Y for Yes or N for No. Note: If the balance was 0 the last time the stock card was updated and the facility has not received any re-supply of HIV test kits, consider the stock card up-to-date.
6. Record the balance on the stock card.
7. Record if the facility has had any stockouts of the product during the last six complete months before the day of the visit, answer Y for Yes or N if No. A 0 in the balance column of the stock card within the last six months will signify a stockout.
8. Record how many times the product stocked out during the last six complete months before the day of the visit according to the stock card.
9. Record the total number of days the product was stocked out during the last six complete months before the day of the visit (in this case, 1st September 2007 to 28th February 2008).
10. Reason/s for Stockout. Note: For any product that experienced a stockout in the last six complete months and up to the day of the visit, please note the number corresponding to the reason for stockout (by product).
11. Record if the facility is experiencing a stockout of the product on the day of the visit, *according to the physical inventory*, answer Y for Yes or N if No.
12. Record the quantity of each HIV testing product in stock in the storeroom. Count the number of HIV tests remaining in any opened boxes.
13. Count all expired products on the day of the visit. Record the total quantity expired of each product.

TABLE 1. Use of Stock Cards and Stock on Hand on Day of Visit

Location of Storeroom: _____

Product	Unit of Count	Managed at this facility? (Y/N)	Stock card available? (Y/N)	Stock card updated? (Y/N)	Balance on stock card	Stock out most recent 6 months? (Y/N)	Number of Stockouts (most recent 6 months)	Total No. Days Out of Stock	Reason for stock out. (List reason/s below)*	Stock out today? (YN)	Physical inventory (in store room)	Total Quantity Expired
1	2	3	4	5	6	7	8	9	10 *	11	12	13
Determine	Test											
Uni-Gold	Test											
Bioline	Test											
	Test											
	Test											
	Test											

*** 10. Reason/s for Stockout:**

a). Did not receive order;

b). Did not order on time;

c). Do not know how to order;

d). Did not receive the quantity ordered;

e). Stock out at the central level,

f). Transportation not available for delivery;

g) Other

Location of Storeroom: _____

Product	Unit of Count	Managed at this facility? (Y/N)	Stock card available? (Y/N)	Stock card updated? (Y/N)	Balance on stock card	Stock out most recent 6 months? (Y/N)	Number of Stockouts (most recent 6 months)	Total No. Days Out of Stock	Reason for stock out. (List reason/s below)*	Stock out today? (YN)	Physical inventory (in store room)	Total Quantity Expired
1	2	3	4	5	6	7	8	9	10 *	11	12	13
Determine	Test											
Uni-Gold	Test											
Bioline	Test											
	Test											
	Test											
	Test											

*** 10. <u>Reason/s for Stockout:</u>**

a). Did not receive order;

b). Did not order on time;

c). Do not know how to order;

d). Did not receive the quantity ordered;

e). Stock out at the central level,

f). Transportation not available for delivery;

g) Other

Location of Storeroom: _____

Product	Unit of Count	Managed at this facility? (Y/N)	Stock card available? (Y/N)	Stock card updated? (Y/N)	Balance on stock card	Stock out most recent 6 months? (Y/N)	Number of Stockouts (most recent 6 months)	Total No. Days Out of Stock	Reason for stock out. (List reason/s below)*	Stock out today? (YN)	Physical inventory (in store room)	Total Quantity Expired
1	2	3	4	5	6	7	8	9	10 *	11	12	13
Determine	Test											
Uni-Gold	Test											
Bioline	Test											
	Test											
	Test											
	Test											

*** 10. <u>Reason/s for Stockout:</u>**

a). Did not receive order;

b). Did not order on time;

c). Do not know how to order;

d). Did not receive the quantity ordered;

e). Stock out at the central level,

f). Transportation not available for delivery;

g) Other

Location of Storeroom: _____

Product	Unit of Count	Managed at this facility? (Y/N)	Stock card available? (Y/N)	Stock card updated? (Y/N)	Balance on stock card	Stock out most recent 6 months? (Y/N)	Number of Stockouts (most recent 6 months)	Total No. Days Out of Stock	Reason for stock out. (List reason/s below)*	Stock out today? (YN)	Physical inventory (in store room)	Total Quantity Expired
1	2	3	4	5	6	7	8	9	10 *	11	12	13
Determine	Test											
Uni-Gold	Test											
Bioline	Test											
	Test											
	Test											
	Test											

*** 10. <u>Reason/s for Stockout:</u>**

a). Did not receive order;

b). Did not order on time;

c). Do not know how to order;

d). Did not receive the quantity ordered;

e). Stock out at the central level,

f). Transportation not available for delivery;

g) Other

XII. Ask the person(s) interviewed if they have any questions, comments or suggestions.

Interviewee Comments:

XIII. Thank the person(s) interviewed for their time and their contribution to helping the program achieve its objectives. Assure them that the results of the interview and the data collected will be used to inform the quantification of HIV test kit requirements for the national HIV/AIDS programme.

Time Ended: _____

---------- **END OF QUESTIONNAIRE** ----------

Additional Interviewer Comments:

Brief Analysis of Findings from the Facility Visit:

APPENDIX E. REGIONAL MEDICAL STORES DATA COLLECTION TOOL

Regional Medical Store Questionnaire

HIV Test Kit Quantification

Ministry of Health
MALAWI

Period of Data Collection

19th – 28th March, 2008

Questionnaire Guidelines

I. Information about Interview	Record the date of the interview and list the names of the interviewers.
II. Facility Identification	Note the time the visit started on arrival at the facility. Ask to speak to the person in-charge of the facility. Write the name of the facility and the location. Record the location and facility type.
III. Introduction	Use the text here to guide your introduction and explain the purpose of the visit to facility staff. Request permission to conduct the interviews and record the information regarding the interviewee(s) titles and functions. For sections IV. through IX. of the questionnaire, record responses by clearly circling either the number or letter that corresponds to the interviewee's response. Questions with letters may have multiple responses; questions with numbers have only a single response; others require the interviewer to write the interviewees' responses.
IV. Receipt and Storage of HIV Test Kits at the Regional Medical Store	Record interviewee's responses to the questions in this section.
V. Distribution of HIV Test Kits to Health Facilities	Record interviewee's responses to the questions in this section.
VI. Ordering HIV Test Kits for the RMS and for Health Facilities	Record interviewee's responses to the questions in this section. Ask to see a Health Facility order.
VII. Reporting on Quantities Issued and Stock on Hand at the RMS	Review the forms and registers used for collecting and reporting logistics data on issues, losses/adjustments and stock on hand data at the regional medical store.
VIII. Reporting on Consumption and Stock on Hand at Health Facilities	Review the forms and registers used by Health Facilities for collecting and reporting logistics data on consumption, losses/adjustments and stock on hand data to the RMS.
IX. Use of Stock Card, Quantity Received, Quantity Issued, and Days Out of Stock	Ask to see medical store records for the most recent 12 month period. Record in the questionnaire the monthly issues of each brand of HIV test kit for January 2007 – March 2008
X. End Interview	Ask the interviewee/s if they want to ask any questions or offer any comments or suggestions. Thank them for their time and for the information.
XI. After the Interview	Interviewer to record any additional comments/observations and provide a brief analysis of findings from the facility visit

I. INFORMATION ABOUT INTERVIEW

Date of Visit: _____ / _____ / _____
Day Month Year

Time Started: _____

Interviewer(s): Name / Title / Organization

1)_____

2)_____

3)_____

4)_____

5)_____

II. FACILITY IDENTIFICATION

Name of the Facility: _____

Facility location:

Region: _____

District: _____

Urban/Rural: _____

Facility Type:

Central Hospital _____ Stand Alone site _____

Mental Hospital _____ Mobile Unit _____

District Hospital _____ Outreach Site _____

Health Centre _____ Home Based Door-to-Door _____

Regional Medical Stores _____

Other (specify): _____

III. Introduction

Ask for the person in-charge of the facility and show the letter of introduction/authorization from the MOH, HIV/AIDS Unit. Introduce all team members and ask facility representatives to introduce themselves.

Explain the objectives of the quantification and the purpose of the visit to the facility today:

Good day and thank you for agreeing to receive us today. My name is _____. My colleague(s) and I are here at the request of the Ministry of Health. We are assisting the HIV and AIDS Department to conduct a quantification of HIV test kits required for the national program. We are visiting selected health facilities throughout the country to collect data for the quantification. The purpose of the visit today is to learn how the supply of HIV test kits at this facility are being ordered and managed. This is not a supervisory visit and the performance of individual staff members is not being evaluated. The results of this visit will provide information for the national quantification of HIV test kits.

Explain how the team would like to conduct the interviews:
With your permission, we would first like to speak with staff members who can provide information on the storage, management and distribution of HIV test kits at this medical store. We would like to collect specific information on the stock on hand and distribution of HIV test kits. Ask the Facility In-Charge and other staff members if they have any questions at this time. Proceed to interview the appropriate staff.

No.	IV. Receipt and Storage of HIV Test Kits at the Regional Medical Store	Code Classification	Go To
54.	Name and Title of person interviewed for this section	Name: _____ Title: _____	
55.	Number of years and months you have worked at this medical store?	Years: _____ Months: _____	
56.	Who is the person responsible for managing the HIV test kits in this medical store?	Medical Stores Manager.....…….....…1 Specific commodity manager (specify)..2 Other (specify) 3	

57.	Which brands of HIV test kits are stored and distributed by this medical store?	**Brand of HIV Test Kit** — **Code No.** Determine HIV- 1/2 — 01 Uni-Gold HIV Test — 02 SD Bioline HIV-1/2 3.0 — 03 Other: _____ — 04 Other: _____ — 05 Other: _____ — 06 Other: _____ — 07	
58.	Where does this medical store receive or collect its HIV test kits from?	Supplier…….… A CMS Lilongwe…..….. ……..….. B Airport…… C Other (specify)…… W	
59.	Who is responsible for transporting HIV test kits to this medical store from the higher level? *(Circle all that apply)*	Supplier vehicle…...…… A CMS Central vehicle……. B RMS vehicle…… C Private vehicle…..……. D Other (explain)……... W	
60.	Which mode of transportation is used for delivery or collection of the HIV test kits from the higher level?	Supplier vehicle…...……..… A CMS Central vehicle……. B RMS vehicle ……..…… C Private vehicle…..……. D Other (explain)……... W	
61.	How often does this medical store receive HIV test kits?	Monthly ……...…… A Quarterly ……. ……. B Semi-annually …… C Annually……. D Other (explain)……... W	
62.	Where are the HIV test kits stored in this medical store? *(list all locations where HIV test kits are stored in this medical store)*	_____ A _____ B _____ C	

63.	What constraints, if any, have you experienced in storage of HIV test kits in this medical store? *(please explain)*	Space constraints…… A Temperature constraints ……. B Shelving/racking…… C Other (explain)……... W	
No.	**V. Distribution of HIV Test Kits to Health Facilities**	**Code Classification**	**Go To**
64.	Which type and which level of health facilities does this medical store distribute HIV test kits to?	Central Hospitals...…...……. A Mental Hospitals….. ……. B District Hospitals……..…… C Health Centres……..……. D NGOs……..……... E CBO/Mission Hospitals…..... F Private Hospital/Clinic……... G Other (specify)……...…… W	
65.	How many health facilities does this medical store distribute HIV test kits to?	No. of Health Facilities ……. [ ]	
66.	Are HIV test kits distributed together with other health commodities e.g. essential drugs?	Yes……..1 No…….....2 Sometimes (explain)……....3	
67.	What mode of transportation is used to distribute the HIV test kits to the lower level health facilities?	Supplier vehicle……...……. A RMS vehicle……..……. B Private vehicle…… C Public Transport……. D Health Facilities collect……... E Other (specify)……... G	
68.	How often does this medical store distribute HIV test kits to the lower level health facilities?	Monthly ……..…… A Quarterly …….. ……. B Semi-annually …… C Annually……. D Other (explain)……... W	
69.	On average, how long does it take from the time the health facility places an order at the medical store - until the HIV test kits are received at the health facility?	Less than 2 weeks…..…… A 2 weeks to 1 month ….……. B Between 1 and 2 months…..… C More than 2 months……. D Other (explain)……... W	

70.	For health facilities that come to collect their HIV test kits, what mode of transport is used to collect the HIV test kits from the medical store?	RMS vehicle……..……. A Private vehicle…… B Health Facility vehicle……. C Public transport……... D Other (specify)……... G	
71.	What constraints, if any, have you experienced in the distribution of HIV test kits from this medical store to the health facilities? *(please circle all that apply)*	Availability of vehicles…..… A Vehicle maintenance…….. …. B Availability of drivers …… C Availability of petrol……... D Other (explain)……... W	
No.	**VI. Ordering HIV Test Kits for the RMS and Health Facilities**	**Code Classification**	**Go To/ Comments**
72.	Who determines the quantities of HIV test kits to be ordered/resupplied to this medical store? *(Circle all that apply.)*	CMS Lilongwe……... A This RMS……. B MOH HIV/AIDS Unit…….… C MOH HTSS…….. D MOH PMTCT Program…….. E Other……..…….. W Don't Know……... DK	
73.	How are the order quantities for resupply of HIV test kits to the medical store determined? *(ask interviewee to explain the formula used to arrive at the order quantity and note here)*	Formula .....1 Don't know .....2 Other means (specify) ……3	
74.	How often does this medical store place orders for HIV test kits? *(Circle all that apply)*	Weekly …… A Monthly …….…… B Quarterly …….. ……. C Semi-annually …… D Annually…….. E Other ……... W	
75.	Does this medical store always receive the quantities of HIV test kits that were ordered? *(If no, please explain)*	Yes …….. 1 No …….. 2	

76.	Who determines the quantities of HIV test kits that the medical store issues to the health facilities? *(Circle all that apply.)*	Health Facility .....1 Regional Medical Store.....2 Distribution list given by higher level.....3 Other (specify).....4	
77.	How are the order quantities for resupply to the health facilities determined? *(ask interviewee to explain the formula used to arrive at the order quantity and note here)*	Formula .....1 Don't know .....2 Other means (specify) ……3	
78.	Are the health facility orders for HIV test kits submitted together with a report? (Does the order have to be submitted on the same form as the report?)	Yes……..1 No……....0	
79.	Ask to see an example of an Order for HIV test kits from a Health Facility. (V*erify if the form is for both Reporting and Ordering).*	Order form only…… A Report and Order form…… B	
80.	What data is recorded on the Report/Order form? *(circle all that apply)*	Beginning balance……. A Quantity Received since last Report/Order ……. B Quantity Used…… C Losses/Adjustments ……. D Ending balance…….. E Quantity Requested F Other ……... W	
81.	How often do the health facilities place orders for HIV test kits? *(Circle all that apply)*	Weekly …… A Monthly ……..…… B Quarterly …….. ……. C Semi-annually …… D Annually…….. E Other ……... W	
82.	How many facilities received HIV test kits from this medical store in the last month (February 2008)? *(review distribution list to verify number of health facilities)*	No. of Health Facilities ……... [ ]	

83.	How many health facilities are supposed to receive their HIV test kits from this medical store? *(Review/verify list of total number of health facilities that should be re-supplied by this medical store)*	No. of Health Facilities …….	
84.	Is there an established procedure for health facilities to place an emergency order? *(If yes, please explain)*	Yes……..1 No……....0 Don't know ……DK	
No.	**VII. Reporting on Quantities Issued and Stock on Hand at the RMS**	**Code Classification**	**Go To/ Comments**
85.	Do you report data on the Quantities of HIV test kits Issued and the Stock on Hand at this medical store to a higher level?	Yes .....1 No 0	If no, go to 39.
86.	Where do you send this report to?	Lilongwe Central Medical Store….. A MOH/HTSS Logistics Officer…….. B MOH HIV/AIDS Unit……..…… C MOH PMTCT Program……. D Other (specify)……... W	

87.	What report forms do you use for reporting to a higher level? (*ask to see a copy of the report)*		
88.	Interviewer please verify the type of data collected on the LMIS report forms		
A.	Received	Yes……..1 No……..0	
B.	Issues	Yes……..1 No……..0	
C.	Usage (consumption)	Yes……..1 No……....0	
D.	Stock on Hand	Yes……..1 No…….. 0	
E.	Losses/Adjustments	Yes……..1 No ……..0	
F.	None of the above	Yes……..1 No……..0	

89.	How often is this LMIS report sent to the higher level?	Monthly …… A Quarterly …….. ……. B Semi-annually …… C Annually…….. D Other ……... W	
90.	When was the last time you submitted the LMIS report on the Quantities Issued and Stock on Hand of HIV test kits at this medical store?	Never .....1 Within the last month .....2 2 months ago .....3 3 months ago .....4 More than 3 months ago 5	
91.	How often is this LMIS report supposed to be submitted to the higher level?	Monthly …… A Quarterly …….. ……. B Semi-annually …… C Annually……. D Other ……... W	
No.	**VIII. Reporting on Consumption and Stock on Hand at Health Facilities**	**Code Classification**	**Go To/ Comments**
92.	Do you receive reports on the quantities of HIV tests used (consumption) and the quantities of HIV tests in stock (stock on hand) from the lower level health facilities that you distribute to?	Yes .....1 No 0	➔ If no, go to 44.
93.	If yes, which type of health facilities does the medical store receive the LMIS reports from?	Central Hospital...……. A Mental Hospital….. ……. B District Hospital…… C Health Centre……. D NGO ……... E CBO/Mission Hospital……... F Private Hospital/Clinic……... G Other (specify)…… W	
94.	How many health facilities submitted their reports for the last reporting period?	No. of Health Facilities ……. [ ]	
95.	How many lower level health facilities are supposed to submit LMIS reports on consumption and stock on hand of HIV tests to this medical store?	No. of Health Facilities ……. [ ]	

96.	What does the medical store do with the data on consumption and stock on hand of HIV tests reported by the health facilities? *(please explain)*		

No.	IX. Use of Stock Card, Quantity Received, Quantity Issued, and Days Out of Stock from January 2007 March 2008	Code Classification	Go To
97.	Name and title of person interviewed for this section.	Name: _____ Title: _____	
98.	Number of years and months you have worked at this facility.	Years: _____ Months: _____	
99.	Review the stock cards or other records for recording stock balances and stock transactions		
100.	Complete Table 1. Use of Stock Cards and Stock on Hand on the Day of the Visit		
101.	Record the Quantity Received, the Quantity Issued and the Days Out of Stock for each brand of HIV test kit for each month from January 2007 – March 2008 in the attached Tables.		

TABLE 1. Use of Stock Cards and Stock on Hand on Day of Visit

INSTRUCTIONS:

Column:

14. Name of each HIV testing product that will be counted
15. Unit of Count for the product – whole HIV test kits for the Medical Store, number of individual tests for the Health Facility

Note*:* Columns 1 and 2 should be filled out before questionnaires are printed.

16. Whether or not the product is available, is this facility supposed to manage this product? Answer Y for Yes or N if No.
17. Check if the stock card (or other logistics data sources) is available for each product, answer Y for Yes or N for No. If another type of record is used e.g. stores ledger, please note in the comments section, and continue to gather issues data using another type of logistics data record.
18. Check if the stock card has been updated within the last 30 days, answer Y for Yes or N for No. Note: If the balance was 0 the last time the stock card was updated and the facility has not received any re-supply of HIV test kits, consider the stock card up-to-date.
19. Record the balance on the stock card.
20. Record if the facility is experiencing a stockout of the product on the day of the visit, *according to the physical inventory*, answer Y for Yes or N if No.
21. Record the quantity of each brand of HIV test kit in stock in the Medical Store.
22. Count the number of expired HIV test kits on the day of the visit. Record the total quantity expired of each product.

TABLE 1. Use of Stock Cards and Stock on Hand on Day of Visit

Product	Unit of Count *	Managed at this facility? (Y/N)	Stock card available? (Y/N)	Stock card updated? (Y/N)	Balance on stock card	Stock Out today? (YN)	Physical Inventory	Total Quantity Expired
1	2	3	4	5	6	7	8	9
Determine	Kit of 100							
Uni-Gold	Kit of 20							
Bioline	Kit of 30							
	Kit							
	Kit							
	Kit							

Unit of Count at Medical Stores is Kits, not individual Tests.

		Jan 07	Feb 07	Mar 07	Apr 07	May 07	Jun 07	July 07	Aug 07	Sep 07	Oct 07	Nov 07	Dec 07	Jan 08	Feb 08	Mar 08					
HIV Test Kits Received																					
Determine	Kit of 100																				
Uni-Gold	Kit of 20																				
Bioline	Kit of 30																				
HIV Test Kits Issued																					
Determine	Kit of 100																				
Uni-Gold	Kit of 20																				
Bioline	Kit of 30																				

		Jan 07	Feb 07	Mar 07	Apr 07	May 07	Jun 07	Jul 07	Aug 07	Sep 07	Oct 07	Nov 07	Dec 07	Jan 08	Feb 08	Mar 08					
Days Out of Stock																					
Determine	Kit of 100																				
Uni-Gold	Kit of 20																				
Bioline	Kit of 30																				
Reason for stock out																					

Reason/s for Stockout:

a). Did not receive order;

b). Did not order on time;

c). Do not know how to order;

d). Did not receive the quantity ordered;

e). Stock out at the central level,

f). Transportation not available for delivery;

g) Other (specify)

X. Ask the person(s) interviewed if they have any questions, comments or suggestions

Interviewee Comments/Suggestions:

XI. Thank the person(s) interviewed for their time and their contribution to helping the program achieve its objectives. Assure them that the results of the interview and the data collected will be used to inform the quantification of HIV test kit needs for the national HIV/AIDS programme.

Time Ended:

---------- **END OF QUESTIONNAIRE** ----------

Interviewer Comments:

Brief Analysis of Findings from the Medical Store Visit:

APPENDIX F. HIV TEST KIT QUANTIFICATION WORKSHOP AGENDA AND LIST OF PARTICIPANTS

Ministry of Health
MALAWI

HIV Test Kit Quantification Workshop

Crossroads Hotel, Nyasa Room
31st March – 4th April, 2008

Lilongwe, MALAWI

WORKSHOP AGENDA		
MONDAY **31st March 2008**		
08:30 – 09:00	Introduction to Workshop	
09:00 – 10:30	Session I. Overview of Malawi HIV Test Kit Supply Chain	
10:30 – 10:45	BREAK	
10:45 – 12:30	Session II. Review of the Quantification Process	
12:30 – 1:30	LUNCH	
1:30- 3:00	Session III. Forecasting Methodology for HIV Test Kits	
	▪ Types and sources of data ▪ Forecasting methods ▪ Forecasting HIV test kits by purpose of testing	
3:00 – 3:15	BREAK	
3:30 – 4:30	Session III. Forecasting Methodology for HIV Test Kits	
	▪ Review and analysis of data collection on HIV test kits ▪ Challenges in availability and quality of data ▪ Scavenger Hunt	
TUESDAY **1st April 2008**		
08:30 – 10:30	Session IV. Forecasting Data and Assumptions by Purpose of Testing ▪ Estimated number of people to be tested, by purpose of testing ▪ HIV prevalence, by purpose of testing ▪ Quantity of HIV test kits needed for Quality Control, Training, Wastage	
10:30 – 10:45	BREAK	
10:45 – 12:30	Session IV. Forecasting Data and Assumptions by Purpose of Testing	
	▪ Continued	
12:30 – 1:30	LUNCH	
1:30 – 3:00	Session IV. Forecasting Data and Assumptions by Purpose of Testing	
	▪ Continued	
3:00 – 3:15	BREAK	
3:15 – 4:30	Session IV. Forecasting Data and Assumptions by Purpose of Testing	
	▪ Estimate final forecast quantities of HIV test kits needed for all purposes of testing ▪ Apply monthly scale-up rate for each year of the forecast	
WEDNESDAY **2nd April 2008**		
08:30 – 10:30	Session V. Estimating Total Program Requirements	
	▪ Next step in the quantification process ▪ Review of basic Logistics Concepts and Terminology ▪ Maximum/Minimum Inventory Control System ▪ How to calculate Months of Stock on Hand	

WORKSHOP AGENDA		
	▪ How to calculate Order Quantity	
10:30 – 10:45	BREAK	
10:45 – 12:30	Session V. Estimating Total Program Requirements	
	▪ Define logistics system design for HIV test kits for Malawi	
12:30 – 1:30	LUNCH	
1:30 – 2:30	Session VI. Introduction to PipeLine software for monitoring national stock status and planning shipment delivery schedules	
	▪ Review PipeLine inputs and outputs ▪ Install PipeLine CDs	
2:30 – 3:00	Session VII. Hands On Data Entry and Analysis in PipeLine	
	▪ Create HIV test kit database for Malawi; ▪ Enter all data inputs; monthly forecast quantities; ▪ Analysis of months of stock; ▪ Plan shipments	
3:00 – 3:15	BREAK	
3:15 – 4:30	Session VII. Hands on Data Entry and Analysis in PipeLine	
	▪ Create HIV test kit database for Malawi; ▪ Enter all data inputs; monthly forecast quantities; ▪ Analysis of months of stock; ▪ Plan shipments	
THURSDAY 3rd April 2008		
08:30 – 09:30	Session VII. Hands on Data Entry and Analysis in PipeLine	
	▪ Finalize data entry and analysis in PipeLine	
09:30 – 10:30	Session VIII. Determine Total Program Requirements for HIV Test Kits for April 2008- March 2010	
10:30 – 10:45	BREAK	
10:45 – 12:30	Session IX. Develop a Two-Year Supply Plan for Procurement and Delivery of HIV Test Kits from April 2008- March 2010	
12:30 – 1:30	LUNCH	
1:30 – 2:30	Session X. Review of PipeLine Outputs and Reports	
2:30 – 3:00	Session XI. Prepare Cost Estimate of Total HIV Test Kit Requirements for April 2008 – March 2010	
3:00 – 3:15	BREAK	
3:15 – 4:30	Session XII. Funding analysis for procurements of HIV test kits for April 2008 – March 2010	
FRIDAY 4th April 2008		
8:30 – 10:00	Session XIII. Finalize and Present Quantification Results	
10:15 – 10:30	BREAK	
10:30 – 12:00	Session XIV. Review Key Findings and Recommendations	
12:00 – 12:30	Closing Remarks	
12:30-1:30	LUNCH	

Ministry of Health
MALAWI

HIV Test Kit Quantification Workshop

Crossroads Hotel, Lilongwe
31st March - 4th April, 2008

List of Participants

No.	NAME	TITLE	ORGANIZATION	Mobile	E-mail
1.	Bruno Nanthuru	Branch Manager	MACRO	09 948 152	bananthuru@yahoo.com
2.	Edwin Chifandale	Laboratory Technician	Kamuzu Central Hospital	08 688 064	
3.	Manondo Msefula	Resident Logistics Advisor	USAID | DELIVER PROJECT, JSI Malawi	08 852 304	mmsefula@jsimw.com
4.	Lucius Ng'omang'oma	HTC Officer	MOH, HIV and AIDS Department	08 342 529	lngomangoma@yahoo.com
5.	Michael Eliya	National PMTCT Coordinator	MOH, PMTCT Program	09 735 118	michaeleliya@yahoo.com
6.	Simon Makombe	ART Officer	MOH, HIV and AIDS Department	08 865 193	simondmakombe@yahoo.com
7.	James Kandulu	EMLS Regional Supervisor	MOH, HTSS Diagnostics Unit	08 868 928	emlscentral@malawi.net
8.	Dorica Chirwa	Logistics Officer	MOH, HTSS Pharmaceuticals Unit	08 367 402	doricas@gmail.com
9.	Amon Nkhata	ART Officer	MOH, HIV and AIDS Department	08 876 277	amonnkhata@yahoo.co.uk
10.	Semu Bangelo	Pharmacy Technician	Michinji District Health Office	09 456 843	semubangelo@yahoo.com.uk
11.	Frank Chilambadzuka	Pharmacy Technician	CMS Procurement DRP	09 266 521	FrankChilambadzuka@yahoo.com
12.	Evance Moyo	Assistant LMIS Associate	USAID | DELIVER PROJECT, JSI Malawi	09 557 390	emoyo@jsimw.com
13.	Caesar Mudondo	Procurement Specialist	UNICEF	09 497 337	cmudondo@unicef.org
14.	Samuel Chirwa	Senior Logistics Officer	MOH, HTSS Pharmaceuticals Unit	09 552 977	schirwa@gmail.com
15.	Elias Mwalabu	LMIS Associate	USAID | DELIVER PROJECT, JSI Malawi	08 876 210	emwalabu@jsimw.com
16.	Philip Moses	HIV/AIDS Advisor	MOH, HIV and AIDS Department	08 525 796	pfmoses@malawi.net
17.	Claudia Allers	Senior Technical Advisor	USAID | DELIVER PROJECT, John Snow, Inc	001 703 310 5064	callers@jsi.com
18.	Amanda Mwirotsi	Technical Advisor	John Snow, Inc./Logistics Services	254 733 529 029	amandaombeva@pscms.co.ke

APPENDIX G. HIV TESTING FORECASTING ASSUMPTIONS

(Please see Appendix G. MALAWI HIV Test Kit Forecast Tables in Excel attached)

APPENDIX H. HIV TEST KIT REQUIREMENTS, SHIPMENT RECEIPT DATES AND COST ESTIMATES FOR FY 2008 AND FY 2009

HIV Test Kit Requirements and Costs for Emergency Order in April 2008 for Shipment to Arrive in Country by August 2008

ALL REGIONS

(Assumes four month lead time for funding, procurement and delivery of an emergency order for shipment to arrive by August 2008)

Supplier	Product	Receive Date	Quantity	Product Costs	Freight Costs	Total Costs
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	31-Aug-08	120	$17,280	$3,629	$20,909
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	31-Aug-08	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	31-Aug-08	130	$56,160	$11,794	$67,954
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	31-Aug-08	240	$5,760	$1,210	$6,970
UNICEF-GF	Chase buffer (2.5ml bottle)	31-Aug-08	1,100	$1,100	$231	$1,331
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	31-Aug-08	10,600	$848,000	$178,080	$1,026,080
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	31-Aug-08	30,000	$1,122,900	$235,809	$1,358,709
					TOTAL	**$2,482,475**

HIV Test Kit Requirements and Costs FY 2008 (July 2008 - June 2009)
ALL REGIONS

(Assumes MOH submits disbursement requests and orders to Global Fund in April 08 and in October 08 so that funding is available for UNICEF to initiate procurements 6 months later, in October 08 and April 09 of FY 2008, for shipments that will arrive in Feb 09 and Aug 09)

Supplier	Product	Receive Date	Quantity	Product Costs	Freight Costs	Total Costs
FHI	Bioline HIV 1/2 (30 tests/kit)	30-Nov-08	68	$1,632	$343	$1,975
FHI	Determine HIV 1/2 (100 tests/kit)	30-Nov-08	404	$32,320	$6,787	$39,107
FHI	Uni-Gold HIV Test (20 tests/kit)	30-Nov-08	605	$22,645	$4,755	$27,401
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	28-Feb-09	40	$5,760	$1,210	$6,970
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	28-Feb-09	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	28-Feb-09	61	$26,352	$5,534	$31,886
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	28-Feb-09	80	$1,920	$403	$2,323
UNICEF-GF	Chase buffer (2.5ml bottle)	28-Feb-09	600	$600	$126	$726
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	28-Feb-09	3,900	$312,000	$65,520	$377,520
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	28-Feb-09	5,680	$212,602	$44,647	$257,249
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	31-May-09	114	$49,248	$10,342	$59,590
FHI	Bioline HIV 1/2 (30 tests/kit)	31-May-09	68	$1,632	$343	$1,975
FHI	Determine HIV 1/2 (100 tests/kit)	31-May-09	404	$32,320	$6,787	$39,107
FHI	Uni-Gold HIV Test (20 tests/kit)	31-May-09	605	$22,645	$4,755	$27,401
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	31-Aug-09	89	$12,816	$2,691	$15,507
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	31-Aug-09	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	31-Aug-09	47	$20,304	$4,264	$24,568

UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	31-Aug-09	280	$6,720	$1,411	$8,131
UNICEF-GF	Chase buffer (2.5ml bottle)	31-Aug-09	600	$600	$126	$726
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	31-Aug-09	11,600	$928,000	$194,880	$1,122,880
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	31-Aug-09	25,000	$935,750	$196,508	$1,132,258
					TOTAL	**$3,178,344**

HIV Test Kit Requirements and Costs FY 2009 (July 2009 - June 2010)
ALL REGIONS

(Assumes MOH submits disbursement requests to Global Fund in April 09 and October 09 so that funding is available for UNICEF to initiate procurements 6 months later, in October 09 and April 10 of FY 2009, for shipments that will arrive in Feb 10 and August 10)

Supplier	Product	Receive Date	Quantity	Product Costs	Freight Costs	Total Costs
FHI	Bioline HIV 1/2 (30 tests/kit)	30-Nov-09	68	$1,632	$343	$1,975
FHI	Determine HIV 1/2 (100 tests/kit)	30-Nov-09	404	$32,320	$6,787	$39,107
FHI	Uni-Gold HIV Test (20 tests/kit)	30-Nov-09	605	$22,645	$4,755	$27,401
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	28-Feb-10	40	$5,760	$1,210	$6,970
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	28-Feb-10	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	28-Feb-10	60	$25,920	$5,443	$31,363
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	28-Feb-10	140	$3,360	$706	$4,066
UNICEF-GF	Chase buffer (2.5ml bottle)	28-Feb-10	600	$600	$126	$726
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	28-Feb-10	6,700	$536,000	$112,560	$648,560
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	28-Feb-10	7,320	$273,988	$57,537	$331,525

UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	31-Aug-10	100	$14,400	$3,024	$17,424
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	31-Aug-10	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	31-Aug-10	140	$60,480	$12,701	$73,181
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	31-Aug-10	520	$12,480	$2,621	$15,101
UNICEF-GF	Chase Buffer solution (2.5ml bottle)	31-Aug-10	600	$600	$126	$726
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	31-Aug-10	21,000	$1,680,000	$352,800	$2,032,800
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	31-Aug-10	35,520	$1,329,514	$279,198	$1,608,711
					TOTAL	**$4,840,680**

APPENDIX I. GLOBAL FUND RCC PROPOSAL BUDGET: YEAR 1, 2 AND 3

Global Fund RCC Proposal Budget (as of April 2008)

	Year 1	Year 2	Year 3
Bioline	$1,200,000	$1,200,000	$1,440,000
KHB	$180,000	$180,000	$216,000
Uni-Gold	$75,600	$75,600	$90,720
14%*	$203,784	$203,784	$244,541
TOTAL	**$1,659,384**	**$1,659,384**	**$1,991,261**

*** Procurement costs estimated at 9% of product cost**
Distribution costs estimated at 5% of product cost

It should be noted that different assumptions were used in developing the GF RCC proposal budget vs. the assumptions used in the national quantification of HIV test kit requirements and costs conducted in April 2008. The GF RCC proposal is based on selection and procurement of different HIV test kits and use of a different HIV testing algorithm than what is currently the practice in the country. Moreover, the GF RCC proposal budget also underestimates the procurement and distribution costs at 9% and 5% respectively for a total of 14%, but current shipping, freight and handling costs are an average 21% depending on weight and volume of the shipment (including the UNICEF handling fee of 4%).

If the selection of HIV test kits to be procured changes and the national testing algorithm is revised according to the GF RCC proposal, then a new quantification will need to be conducted to reflect these changes to estimate the quantities required of each of the brands of HIV test kits, and to adjust the cost estimates and the funding that will be required to support the planned scale-up of HIV testing and counseling over the next two fiscal years.

APPENDIX J. TOTAL COMMODITY COSTS, FUNDING COMMITMENTS AND FUNDING GAPS FOR FY2008 AND FY2009

Total Commodity Costs, Funding Commitments and Funding Gaps for FY 2008 and FY 2009

	Funding Already Committed as of April 2008 [1]	Total Cost April 2008 Emergency Shipment [2]	Total Cost FY 2008 (July 2008 - June 2009)	Total Cost FY 2009 (July 2009 - June 2010)	TOTAL FUNDING REQUIRED April 08, FY 2008 & FY 2009
Total Commodity Costs	**$1,944,124**	**$2,482,475**	**$3,178,344**	**$4,840,680**	**$10,501,500**
Funding Commitments					
Global Fund Rd 2	$1,430,602	$0	$0	$0	$0
Global Fund RCC	$0	$0	$1,659,384	$1,659,384	$3,318,768
CDC	$12,960	$0	$0	$0	$0
FHI	$68,483	$0	$136,965	$68,483	$205,448
UNITAID [3]	$432,079	$0	$0	$0	$0
AXIOS	$0	$0	$0	$0	$0
UNICEF	$0	$0	$0	$0	$0
Other	$0	$0	$0	$0	$0
Funding Gap	**($0)**	**$2,482,475**	**$1,381,995**	**$3,112,814**	**$6,977,284**

[1] Includes GF Rd 2 and UNITAID funded shipments that have already been ordered and are expected to arrive in April and May 2008.

Also assumes CDC and FHI funded HIV test kits are already funded and planned to arrive in April and May 2008. Therefore, these amounts of already committed funding have not been included in the Total Funding Required for FY 2008 and FY 2009

[2] The emergency shipment to be ordered in April 2008 assumes a 4 month lead time until arrival in country. A shipment is needed to arrive in country by August 2008 to fill the supply pipeline to cover the 10 month lead time until the next regularly scheduled shipment arrives in Feb 2009, and to meet the expected increase in demand for HIV test kits during the HIV testing week in Sept 2008.

[3] At the time of the quantification, it was not known what proportion of the UNITAID commitment of US$3.7 million for PMTCT for FY 2008 and FY 2009 might be allocated for procurement of HIV test kits, nor how soon these funds could be mobilized and made available for procurement.

APPENDIX K. TIMELINE FOR FUNDING AND PROCUREMENT OF HIV TEST KITS

TIMELINE FOR FUNDING AND PROCUREMENT OF HIV TEST KITS

April 08

Funding required to be available for procurement of emergency order of HIV test kits to arrive in August 2008, (assumes 4 month lead time for procurement and delivery of emergency order). This emergency shipment is needed to fill supply pipeline until next regularly scheduled shipment arrives in Feb 09 and to meet increased demand for HIV test kits during HIV testing week Sept 08.

MOH to submit order quantities and request for GF disbursement for shipment to arrive in Feb 09. (assumes 6 month lead time for approval and disbursement of GF funds and 4 month lead time for UNICEF procurement and delivery of shipment)

Aug 08

Emergency order requested in April 08 arrives Aug 08

Oct 08

GF funds approved and transferred to UNICEF to initiate procurement of shipment to arrive in Feb 09 (4 month lead time for procurement and delivery)

MOH to submit order quantities and request for GF disbursement for shipment to arrive in Aug 09. (assumes 6 month lead time for approval and disbursement of GF funds and 4 month lead time for UNICEF procurement and delivery of shipment)

Feb 09

Shipment requested in April 08 arrives Feb 09

April 09

GF funds approved and transferred to UNICEF to initiate procurement of shipment to arrive in Aug 09 (4 month lead time for procurement and delivery)

MOH to submit order quantities and request for GF disbursement for shipment to arrive in Feb 10. (assumes 6 month lead time for approval and disbursement of GF funds and 4 month lead time for UNICEF procurement and delivery of shipment)

Aug 09

Shipment requested in Oct 08 arrives Aug 09

Oct 09

GF funds approved and transferred to UNICEF to initiate procurement of shipment to arrive in Feb 10 (4 month lead time for procurement and delivery)

MOH to submit order quantities and request for GF disbursement for shipment to arrive in Aug 10. (assumes 6 month lead time for approval and disbursement of GF funds and 4 month lead time for UNICEF procurement and delivery of shipment)

Feb 10

Shipment requested in April 09 arrives Feb 10

APPENDIX L. TIMELINE FOR ORDERING AND SCHEDULING SHIPMENTS OF HIV TEST KITS

TIMELINE FOR ORDERING AND SCHEDULING SHIPMENTS OF HIV TEST KITS

April 08

Conduct physical count at all RMS. Update stock on hand and enter actual monthly consumption in PipeLine as of 31st March 08

Update status of any planned or ordered shipments.

Update HIV test kit forecast (April 08 to June 2010)

Update suppliers, prices and other product data in PipeLine

Enter monthly forecasted consumption into PipeLine (April 08 to June 2010)

Plan shipments to arrive Feb 09 (10 month Lead Time)

Submit 6 month order to UNICEF and request GF disbursement

Request Emergency Order to arrive in Aug 08 to fill pipeline and meet demand for HIV testing week in Sept 08

Aug 08

Emergency order arrives in Aug 08

Update status of shipments in PipeLine to "Received" with actual quantities of each product received

Verify stock on hand at all RMS as of 31st Jul 08

Update forecasted consumption with actual consumption over the last 4 months Apr 08 to July 08

Oct 08

Conduct physical count at all RMS. Update stock on hand and enter actual monthly consumption in PipeLine as of 30th Sept 08

Update status of any planned or ordered shipments.

Update HIV test kit forecast for Oct 08 to Dec 2010

Update suppliers, prices and other product data in PipeLine

Enter monthly forecasted consumption into PipeLine (Oct 08 to Dec 2010)

Plan shipments to arrive Aug 09 (10 month Lead Time)

Submit 6 month order to UNICEF and request GF disbursement

Feb 09

Shipments from April 08 order arrive

Update status of shipments in PipeLine to "Received" with actual quantities of each product received

Verify stock on hand at all RMS as of 31st Jan 09

Update forecasted consumption with actual consumption over the last 4 months Oct 08 to Jan 09

April 09

Conduct physical count at all RMS. Update stock on hand and enter actual monthly consumption in PipeLine as of 31st March 09

Update status of any planned or ordered shipments.

Update HIV test kit forecast for Apr 09 to Jun 2011

Update suppliers, prices and other product data in PipeLine

Enter monthly forecasted consumption into PipeLine (April 09 to June 2011)

Plan shipments to arrive Feb 10 (10 month Lead Time)

Submit 6 month order to UNICEF and request GF disbursement

Aug 09

Shipments from Oct 08 order arrive

Update status of shipments in PipeLine to "Received" with actual quantities received

Verify stock on hand at all RMS as of 31st Jul 09

Update forecasted consumption with actual consumption over the last 4 months April to July 09

Oct 09

Conduct physical count at all RMS. Update stock on hand and enter actual monthly consumption in PipeLine as of 30th Sept 09

Update status of any planned or ordered shipments.

Update HIV test kit forecast for Oct 09 to Dec 2011

Update suppliers, prices and other product data in PipeLine

Enter monthly forecasted consumption into PipeLine (Oct 09 to Dec 2011)

Plan shipments to arrive Aug 10 (10 month Lead Time)

Submit 6 month order to UNICEF and request GF disbursement

Feb 10

Shipments from April 09 order arrive

Update status of shipment in PipeLine to "Received" with actual quantities received

Verify stock on hand at all RMS as of 31st Jan 10

Update forecasted consumption with actual consumption over the last 4 months Oct 09 to Jan 10

APPENDIX M. STAKEHOLDER DEBRIEFING

Slide 1

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Ministry of Health
MALAWI

HIV Test Kit Supply Chain Assessment and Quantification

DEBRIEFING

Crossroads Hotel
4th April 2008
Lilongwe, MALAWI

Amanda Ombeva, Technical Advisor, John Snow, Inc./Logistics Services
Claudia Allers, Senior Technical Advisor, John Snow, Inc.

Slide 2

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Background and Purpose of the TA

Background

- Irregular and interrupted supply of HIV test kits restricting provision of HIV testing services and plans for scale-up
  - Incoming shipments to country
  - Distribution within in-country supply pipeline
- Change from parallel to serial testing algorithm
- Plans to shift procurement from UNICEF to CMS
- Government mandate to continue scale-up of integrated HTC services

Slide 3

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Background and Purpose of the TA

Request for technical assistance

- Conduct quantification of HIV test kit requirements for the MOH for the next two fiscal years FY08 and FY09 (July 1 - June 30)
- Include rapid assay HIV test kits and long ELISAs
- Build capacity in quantification of HIV test kits
  - Quantification methodology
  - Use of PipeLine software for monitoring national consumption and stock status and for supply planning
- Once in country, also asked to assess HIV test kit supply chain due to concern about suspected leakage of commodities

Slide 4

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Technical assistance activities

- Review, pilot and finalize data collection tools with the quantification team in Lilongwe
- Selection of health facilities for data collection and scheduling of field visits in all three regions
- Stakeholder interviews at central level
  - Policy-makers, program managers, donors, international partners, implementing institutions, information managers, procurement specialists and warehousing managers
- Field visits to RMSs and health facilities to interview staff and collect data for the quantification and the supply chain assessment

Slide 5

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Technical assistance activities (cont'd)

- HIV Test Kit Quantification Workshop 31st March – 4th April 2008
- Debriefing of preliminary results of supply chain assessment and quantification

Slide 6

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HIV Test Kit Quantification Workshop

Workshop Goal :

Build participants' capacity in quantification of HIV test kits to improve forecasting accuracy, timeliness of procurement, and coordination of shipment delivery schedules to ensure a continuous supply of quality HIV test kits to support the ongoing provision and planned scale-up of HIV testing services in the Ministry of Health.

Slide 7

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Workshop Objectives (1):

- Describe the supply chain for funding, procurement and distribution of HIV test kits in Malawi
- Understand the quantification process and how to conduct a national quantification of HIV test kits
- Gain knowledge and skills in forecasting and supply planning as key steps in the quantification of HIV test kits
- Prepare a medium-term forecast of HIV test kit needs to cover FY2008 and FY2009 (April 2008 – June 2010)
- Use PipeLine software to create a database for coordinating different sources of supply, monitoring national consumption and stock status of HIV test kits, and for planning shipment delivery schedules

Slide 8

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Workshop Objectives (2)

- Determine the total program requirements for HIV test kits for April 2008 – June 2010
- Propose a two-year supply plan for procurement and delivery of HIV test kits from April 2008-June 2010
- Prepare a cost estimate for HIV test kit requirements for April 2008 – June 2010
- Identify funding gaps for procurement of HIV test kits for April 2008 – June 2010
- Propose recommendations for
  - strengthening MOH capacity in quantification of HIV test kits
  - improving the quality and availability of data for quantification

Slide 9

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Quantification Workshop Sessions (1)

- 5-day workshop, 31st March – 4th April, 2008
- Quantification team included representatives from:
  - MOH HIV and AIDS Dept; HTSS Pharmaceuticals Unit; PMTCT Program; CMS; EMLS; UNICEF; and USAID | DELIVER - included laboratory technicians, pharmacy technicians, program managers, procurement specialists and logistics officers
- Consultative, consensus building approach
- Review and analysis of multiple sources and types of data and challenges in data quality to arrive at selection of data to use for the quantification

Slide 10

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Quantification Workshop Sessions (2)

- Discussion of program policies and plans
  - selection of HIV test kits; national testing algorithm; program scale-up plans
- Review of logistics concepts and terminology
- Design of Malawi logistics system for HIV test kits
  - lead times; buffer stock; order intervals; maximum/minimum stock levels; emergency order point
- Training in PipeLine software
  - created database for each of the three regions; entered system and product parameters; entered consumption and SOH assumptions

Slide 11

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Quantification Workshop Sessions (3)

- Aggregation of three regional databases to produce final quantification of Total Program Requirements and Cost Estimate
- Comparison of current funding commitments to total commodity and funding needs to determine funding gaps for FY 2008 and FY 2009
- Presentation of preliminary results from supply chain assessment and the quantification

Slide 12

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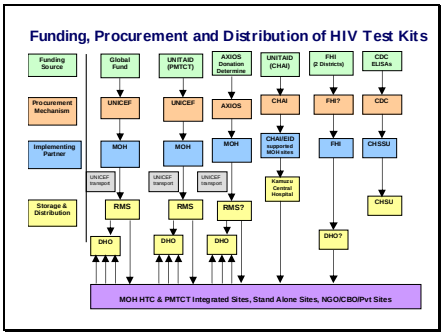
HIV Test Kit Supply Chain Assessment

Preliminary Findings

Slide 13



Slide 14

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Implementing Partners

- Banja La Mtsogolo (BLM)
- Christian Health Association of Malawi (CHAM)
- Malawi AIDS Counseling and Resources Organization (MACRO)
- Lighthouse Trust
- Partners in Hope
- University of North Carolina (UNC)
- Clinton HIV/AIDS Initiative (CHAI)
- Family Health International (FHI)
- Johns Hopkins University (JHU)
- CHSU

Slide 15

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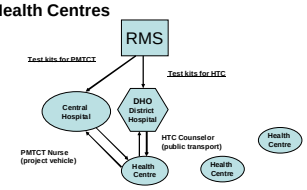
Distribution of HIV test kits from RMS to DHO to Health Centres



Slide 16

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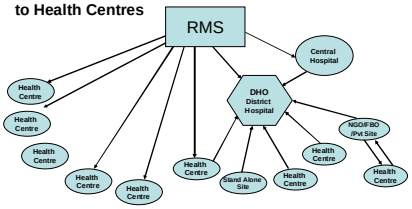
Distribution of HIV Test Kits from RMS to DHO to Health Centres



Slide 17

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Methodology

- HIV Test Kit LIAT adapted for data collection for the quantification and the supply chain assessment
- Areas of inquiry included
  - HIV testing algorithm
  - Service statistics on number of people tested and HIV prevalence
  - Logistics data on consumption and stock on hand of HIV test kits
  - Ordering
  - Distribution
  - Supervision
  - Stockkeeping practices and storage conditions

Slide 18

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Methodology …….Continued

- 1 day training for field data collection team
- Pilot visit by all data collectors at two sites in Lilongwe
- 1 week data collection for the assessment and the quantification
- Supervision to check for data quality and completeness
- Questionnaire data entry and editing in field
- Analysis in Excel spreadsheets

Slide 19

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Sample Characteristics

- 5 District Hospitals
- 3 Regional Medical Stores
- 2 Central Hospitals
- 4 Health Centres
- 20 facilities of which 12 are MOH health facilities, 2 CHAM facilities, 3 private facilities and 5 NGO facilities
- 12 of the 28 Districts were represented

Slide 20

What are the main purposes for which HIV testing is being provided at the facilities?

HTC	19
PMTCT	16
Early Infant Diagnosis	4
Clinical Diagnosis	9
Blood Safety	7
Sentinel Surveillance	1
Quality Control	14
Training	3
HIV testing campaign	10
Blood donor drive	3

Slide 21

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Staff providing HTC at facilities visited

Total number of staff	241
Percentage full-time staff	34%
Percentage part-time staff	66%

Slide 22

Where is HIV testing being performed at this facility?

Laboratory	10
ANC Clinic	9
HTC Counselling Room	18
STI Clinic	0
TB Clinic	2
In-Patient Ward	4
Mobile Unit	2
Outreach Site	8
Home Based/Door to Door	0
Out Patient Department	1
ART Site	4
MCH	1

Slide 23

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Findings on HIV testing algorithm

- 100% of all sites followed testing algorithm despite shortages of kits
- All labs had quality control systems in place and actively supervised the testing by all cadres of counsellors in the facilities

Slide 24

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Ordering

- Staff at only 25% of facilities knew how to calculate the order quantity for test kits using logistics data
- 30% of the health facilities did not know how to calculate order quantity at all, while the remainder used service statistics data to estimate test kit needs
- 80% of all sites order monthly while 20% do not have a fixed schedule for ordering
- 55% of facilities sometimes receive the quantity of HIV test kits ordered while 20% of facilities always received the quantities ordered
- 65% of facilities had placed emergency orders for test kits in the last 6 months

Slide 25

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Distribution

- 70% of facilities collected their test kits while 30% of facilities sometimes had the test kits delivered by the RMS
- Since most facilities collect their test kits, they receive them the same day, but those relying on the RMS received their test kit orders between 2 weeks to one month after ordering

Slide 26

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Challenges to Scale-up of HIV Testing and Counselling Services

- 65% of people interviewed reported **availability of testing supplies** as the greatest challenge to scaling up HIV testing services
- 45 % stated that **availability and capacity of staff** doing the testing would constitute a significant challenge

Slide 27

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Challenges to Scale-up of HIV Testing and Counselling Services

Other challenges mentioned included:

- Space for waiting area
- The speed of scale up, especially PMTCT which is scaling up daily
- Transport
- Support for outreach activities
- Coordination between pharmacy technicians and HIV coordinators to ensure availability of test kits after training

Slide 28

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HIV Test Kit Quantification: Methodology and Results

Slide 29

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Forecast according to each purpose of testing

Discussions with key informants and field visits identified the following main purposes of testing:

1. HTC which includes

   All Provider Initiated Testing and Counseling; Client Initiated Counseling and Testing (VCT); and all testing provided through Mobile Units, Outreach Sites, and Home Based Door-to-Door testing

1. PMTCT
2. Testing of HIV Exposed Infants
3. Blood Safety (outside MBTS)
4. Sentinel Surveillance and special surveys

Slide 30

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Forecast for other uses of HIV test kits

5. Quality Control
   - Routine use of laboratory controls
   - QC testing of panels of known blood samples by HTC staff
   - Re-testing of 5% of tested blood samples through DBS sent to CHSU
6. Training
7. Wastage

Slide 31

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Types of Data Used

- Logistics data (consumption of HIV tests by purpose of testing; stock on hand of each HIV test kit) reported by facilities to regions and adjusted for non-reporting
- Service statistics data (number of people tested and HIV prevalence by purpose of testing) reported by facilities to districts and to MOH, except for blood safety
- Program target data (estimated number of people to be tested) provided by MOH
- **BUT, all types of data did not exist for all purposes of testing**

Slide 32

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Forecasting Assumptions

1) Assume change from parallel to serial testing algorithm as of May 1, 2008, therefore
   - The quantity of confirmatory tests (Uni-Gold) is calculated based on expected HIV prevalence for each purpose of testing

2) The 3 regions in Malawi are unique in terms of % of total number of people being tested and HIV prevalence for each of the purposes of testing

Slide 33

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Forecasting Assumptions

3) Scale-up of integration of HIV testing services and referral of symptomatic patients through PITC will result in higher HIV prevalence rates, therefore
   - Assumed +15% increase in overall HIV prevalence of people tested through HTC

4) PMTCT will scale-up significantly but HIV prevalence will remain relatively constant

Slide 34

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Distribution of No. of People Tested and HIV Prevalence by Region

REGION	% Tested	HIV Prevalence HTC 2006 [1]	HIV Prevalence [2] HTC 2007	HIV Prevalence PMTCT [3]
North	15%	15%	30%	10.2%
Central	36%	19%	34%	10.7%
South	49%	27%	42%	20.5%
TOTAL	100%	20%	37%	12.0%

[1] Situational Analysis 2006
[2] HIV prevalence assumed to increase by +15% in 2007 and beyond due to higher prevalence of symptomatic patients being tested through PITC
[3] HIV and Syphilis Sero-Survey 2007

Slide 35

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Forecasting Assumptions

5) Total Target Number of people to be tested through HTC includes all purposes of testing i.e.
   1) HTC, PMTCT, HIV Exposed Infants, Blood Safety, HIV Testing Week
6) Estimated Total No. People Tested in 2007 = 930,000
7) Target No. People to be Tested for 2008 = 1.3 million, 2009 = 1.5 million, 2010 = 1.7 million
8) ~ 20% of total number of people tested per year are tested during the HIV testing week

Slide 36

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HIV Testing Targets 2008 - 2010

TARGETS	Actual 2006	2007	% Increase	2008	% Increase	2009	% Increase	2010	% Increase
HTC *	661,000	930,000	40.7%	1,300,000	39.8%	1,500,000	15.4%	1,700,000	13.3%
HIV Testing Week (% Total HTC)	84,300	187,860	20.2%	300,000	23.1%	350,000	23.3%	375,000	22.1%
PMTCT	137,996	284,884	106.4%	350,000	22.9%	480,000	37.1%	550,000	14.6%

* HTC = HTC + PMTCT + HIV Exposed Infants + Blood Safety + HIV Testing Week

Slide 37

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HIV Testing Targets by Region and by Purpose of Testing: Jan – Dec 2008

	January - December 2008					
REGION	%	No. Tested	HTC	PMTCT	Exposed Infants	Blood Safety
North	15%	195,000	127,534	52,500	1,966	13,000
Central	36%	468,000	326,883	126,000	4,717	10,400
South	49%	637,000	456,479	171,500	6,421	2,600
TOTAL No. Tested	100%	1,300,000	910,896	350,000	13,104	26,000

Slide 38

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HIV Testing Targets by Region and by Purpose of Testing: Jan – Dec 2009

	January - December 2009					
REGION	%	No. Tested	HTC	PMTCT	Exposed Infants	Blood Safety
North	15%	225,000	140,680	72,000	4,320	8,000
Central	36%	540,000	350,432	172,800	10,368	6,400
South	49%	735,000	484,088	235,200	14,112	1,600
TOTAL No. Tested	100%	1,500,000	975,200	480,000	28,800	16,000

Slide 39

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HIV Testing Targets by Region and by Purpose of Testing: Jan – Dec 2010

	January - December 2010					
REGION	%	No. Tested	HTC	PMTCT	Exposed Infants	Blood Safety
North	15%	255,000	157,480	82,500	7,020	8,000
Central	36%	612,000	390,752	198,000	16,848	6,400
South	49%	833,000	538,968	269,500	22,932	1,600
TOTAL No. Tested	100%	1,700,000	1,087,200	550,000	46,800	16,000

Slide 40

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Forecasting Assumptions

9) Use of HIV tests for performing positive and negative laboratory controls =
   - Daily for high volume testing sites, i.e. central hospitals, 10 CHAM facilities, 14 district hospitals, and others
   - Weekly for medium volume testing sites, i.e. 10 district hospitals
   - Every 2 weeks for low volume testing sites, i.e. ~556 health centres and other smaller facilities

** See MALAWI HIV Test Kit Forecast Tables 25-Apr-08 for Quantities Required for Quality Control*

Slide 41

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Forecasting Assumptions

10) Use of HIV tests for Quality Control

- Quarterly distribution of panels of 5 known blood samples to be tested by HTC counsellors at health facilities
- Each HTC counsellor assumed to test 4 panels per year
- 5 Determine tests and 3 Uni-Gold tests estimated to be needed for each panel
- 2 Determine HIV tests and 2 Uni-Gold HIV tests to be used as positive and negative laboratory controls for each panel
- Monthly collection of 5% of blood samples tested at each health facility to be sent as DBS to CHSU for re-testing with long ELISAs (Vironostika and Enzygnost)

** See MALAWI HIV Test Kit Forecast Tables 25-Apr-08 for Quantities Required for Quality Control*

Slide 42

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Forecasting Assumptions

11) Use of HIV tests for Training in HTC

- Estimated number of HCWs to be trained in 2008, 2009 and 2010 based on estimates from NAC supported training in Districts, HTSS Diagnostics Unit, MACRO, Lighthouse Trust and CHAI
- According to MOH training curriculum for HTC
  - 5 Determine HIV Tests per HCW trained
  - 3 Uni-Gold HIV tests per HCW trained
  - 3 Bioline HIV tests per HCW trained

Slide 43

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No. HCWs to be Trained to Provide HTC

	Jan – Dec 2008	Jan - Dec 2009	Jan - Dec 2010
Laboratory Technicians/ HTSS Diagnostics Unit	100	100	100
HTC/PMTCT Districts	1,690	1,690	1,690
CHAI	42	42	0
Lighthouse Trust	160	160	160
MACRO	160	180	200
Total No. HCWs to be Trained	**2,152**	**2,172**	**2,150**

Slide 44

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Quantity HIV Tests Required for Training: 2008 - 2010

		Jan - Dec 2008			Jan - Dec 2009			Jan - Dec 2010		
REGION	%	Determine	Uni-Gold	Bioline	Determine	Uni-Gold	Bioline	Determine	Uni-Gold	Bioline
North	15%	1,614	968	968	1,629	977	977	1,613	968	968
Central	36%	3,874	2,324	2,324	3,910	2,346	2,346	3,870	2,322	2,322
South	49%	5,272	3,163	3,163	5,321	3,193	3,193	5,268	3,161	3,161
TOTAL No. HIV Tests Required	100%	10,760	6,456	6,456	10,860	6,516	6,516	10,750	6,450	6,450

Slide 45

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Forecasting Assumptions

12) Application of 2% Wastage Rate to cover expected loss of HIV tests in handling due to:
- Damage, contamination, spillage
- Repeat testing due to errors in testing procedure

** See MALAWI HIV Test Kit Forecast Tables 25-Apr-08 for Quantities Required for All Purposes of Testing, All Uses of HIV Tests, and Wastage Rate for ALL REGIONS*

Slide 46

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Forecasting Assumptions

13) Lack of logistics data available on consumption and stock on hand from health facilities, therefore
- Assumed national consumption over past 12 months was issues data from all three RMSs
- Assumed national stock on hand in the country was aggregated stock on hand of HIV test kits at all three RMSs

** See PipeLine databases for each Region*

Slide 47

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Forecasting Assumptions

14) Average Shipping/Freight/Handling costs ~ 21% when procured by UNICEF
- Freight cost varies by volume and weight ~ 17%
- UNICEF handling fee = 4%

** See PipeLine databases for each Region, and Shipment Summary Tables by Product and Funding Required by Region and for ALL REGIONS*

Slide 48

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Estimating Total Program Requirements

- Quantities of HIV test kits estimated to meet demand for 2008, 2009 and 2010 (forecasted consumption)
- PLUS additional quantities needed to account for supply chain factors:
  - Lead time for funding disbursements, procurement and delivery (10 months)
  - Buffer stock (2 months)
  - Shipment Intervals (every 6 months)
  - Emergency Order Point (4 months)
  - Maximum/minimum stock levels at RMS and Health Facilities
- MINUS
  - Current Stock on Hand
  - Quantities on Order (UNITAID funded/GF funded)

** See PipeLine databases for each Region*

Slide 49

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Total Commodity Costs by Region and by Fiscal Year

Total Cost of Emergency Shipment by Region
APRIL 2008

Region	Total Cost
North	$376,165
Central	$801,833
South	$1,304,477
ALL REGIONS	$2,482,475

Total Cost Estimate by Region
FY08 (July 2008 - June 2009)

Region	Total Cost
North	$431,824
Central	$1,107,820
South	$1,638,700
ALL REGIONS	$3,178,344

Total Cost Estimate by Region
FY09(July 2009 – June 2010)

Region	Total Cost
North	$639,727
Central	$1,862,328
South	$2,338,625
ALL REGIONS	$4,840,680

** See Shipment Summary Tables by Product and Funding Required by Region and for All Regions*

Slide 50

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Need for Emergency Shipment

- To cover consumption of HIV test kits until next regular shipment estimated to arrive in February 2009 due to 10 month lead time (assumes MOH places order in April 2008)
- MOH will need to submit order quantities and funding request in April 2008 for emergency shipment to arrive in August 2008
- Assumes 4 month lead time for emergency shipment per UNICEF
- MOH will also need to submit order quantities in April 2008 for regular shipment to arrive in February 2009

Slide 51

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Quantities Required and Cost Estimate for Emergency Shipment for All Regions – APRIL 2008

Supplier	Product	Receive Date	QTY	Product Cost	Freight Cost	Total Cost
UNICEF-GF	Enzygnost Anti-HIV 1/2 Plus (192 tests/kit)	31-Aug-08	120	$17,280	$3,629	$20,909
UNICEF-GF	Murex Ag/Ab (480 tests/kit)	31-Aug-08	1	$432	$91	$523
UNICEF-GF	Vironostika HIV Uniform II Plus O (576 tests/kit)	31-Aug-08	130	$56,160	$11,794	$67,954
UNICEF-GF	Bioline HIV 1/2 (30 tests/kit)	31-Aug-08	240	$5,760	$1,210	$6,970
UNICEF-GF	Chase buffer (2.5ml bottle)	31-Aug-08	1,100	$1,100	$231	$1,331
UNICEF-GF	Determine HIV 1/2 (100 tests/kit)	31-Aug-08	10,600	$848,000	$178,080	$1,026,080
UNICEF-GF	Uni-Gold HIV Test (20 tests/kit)	31-Aug-08	30,000	$1,122,900	$235,809	$1,358,709
				TOTAL		$2,482,475

Slide 52

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Global Fund RCC Proposal Budget

	Year 1	Year 2	Year 3
Bioline	$1,200,000	$1,200,000	$1,440,000
KHB	$180,000	$180,000	$216,000
Uni-Gold	$75,600	$75,600	$90,720
+14% *	$203,784	$203,784	$244,541
TOTAL	$1,659,384	$1,659,384	$1,991,261

** GF Proposal estimates Procurement Costs = 9%, Distribution Costs = 5%*

Slide 53

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Commodity Costs, Funding Commitments and Funding Gaps as of April 2008

	Funding Already Committed as of April 2008 [1]		Total Cost April 2008 Emergency Shipment [2]	
Total Commodity Costs	**$1,944,124**		**$2,482,475**	
Funding Commitments				
Global Fund Rd 2	$1,430,602	(May 08)	$0	
Global Fund RCC	$0		$0	
CDC	$12,960	(April 08)	$0	
FHI	$68,483	(May 08)	$0	
UNITAID [2]	$432,079	(April 08)	$0	??
AXIOS	$0		$0	
UNICEF	$0		$0	
Other	$0		$0	
Funding Gap	**$0**		**$2,482,475**	

Slide 54

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Commodity Costs, Funding Commitments and Funding Gaps for GOM FY 2008 and FY 2009

	Funding Required FY 2008 (July 2008 – June 2009)		Funding Required FY 2009 (July 2009 – June 2010)	
Total Commodity Costs	**$3,178,344**		**$4,840,680**	
Funding Commitments				
Global Fund Rd 2	$0		$0	
Global Fund RCC	$1,659,384	GF RCC Year 1	$1,659,384	GF RCC Year 2
CDC	$0		$0	
FHI	$136,965	(Nov 08 & May 09)	$68,483	(Nov 09)
UNITAID [3]	$0	??	$0	??
AXIOS	$0		$0	
UNICEF	$0		$0	
Other	$0		$0	
Funding Gap	**$1,381,995**		**$3,112,814**	

Slide 55

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Total Commodity Costs, Funding Commitments and Funding Gaps for April 2008 and GOM FY08 and FY09

	TOTAL FUNDING REQUIRED April 2008, FY08 and FY09	
Total Commodity Costs	**$10,501,500**	
Total Funding Commitments		
Global Fund Rd 2	**$0**	
Global Fund RCC (Yr 1 & Yr 2)	**$3,318,768**	**$1,991,261?**
CDC	**$0**	(GF RCC Year 3?)
FHI	**$205,448**	
UNITAID [3]	**$0**	
AXIOS	**$0**	
UNICEF	**$0**	
Other	**$0**	
Total Funding Gap	**$6,977,284**	

For more information, please visit deliver.jsi.com.

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