



REPORT

Review Meeting of the National Laboratory System

Ethiopian Health and Nutrition Research Institute

September 2010

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Acronyms

AIDS	Acquired Immune-Deficiency Syndrome
ART	Antiretroviral Treatment
AWD	Acute Watery Diarrhea
CSF	Cerebro-Spinal Fluid
DBS	Dried Blood Spot
DST	Drug Susceptibility Testing
DTS	Dried Tube Specimens
EFY	Ethiopian Fiscal Year
EHNRI	Ethiopian Health and Nutrition Research Institute
EID	Early Infant Diagnosis
EQA	External Quality Assessment
HIV	Human Immunodeficiency Virus
IQC	Internal Quality Controls
LIS	Laboratory Information System
MoH/FMoH	(Federal) Ministry of Health
QA	Quality Assurance
RLCBD	Regional Laboratory Capacity Building Directorate

Introduction

The Ethiopian Health and Nutrition Research Institute (EHNRI) invited to the Annual Meeting of the National Laboratory System in Adama from June 28-30, 2010. This year, in addition to Regional Laboratories, HAPCO, CDC, and laboratory-related partners, invitees included the Federal Ministry of Health's programs on HIV, TB and malaria, Regional Health Bureaus, and select Hospitals.

The meeting was structured to combine both the Annual Review Meeting and the Annual Joint Planning Meeting led by the Regional Laboratory Capacity Building Directorate (RLCBD) of EHNRI. In addition to a general review of the National Laboratory System, some important topics were selected as 'Focus Areas,' such as Referral Linkage, Laboratory Support for Public Health Emergencies, DNA PCR testing for Early Infant Diagnosis, and Accreditation. For each Focus Area, EHNRI had conducted an assessment and presented evidence-based findings. Following presentations, attendees were divided into smaller groups for discussion focusing on Laboratory Support for Public Health Emergency, Referral Linkage and Early Infant Diagnosis, and Supply Chain Management.

The Review Meeting was well-received by attendees and discussions throughout the three days were very lively. Regional Joint Planning activities will be further discussed and finalized in the regions. At the same time specific action items for follow-up agreed upon at the meeting by EHNRI and partners will be followed up through the National Laboratory Technical Working Group.

This report provides an overview of the meeting attendees and attending institutions, presentation topics and content, and discussion topics along with resulting action items.

Institutions Represented

EHNRI values the presence of the following institutions at the 2010 National Review Meeting:

- Abt Associates
- Adama Hospital
- Adama Regional Lab
- Addis Ababa Regional Lab
- Afar Regional Health Bureau
- ALERT Hospital
- Amhara Regional Health Bureau
- Axum St. Mary Hospital
- Bahir Dar Regional Lab
- CDC-Ethiopia
- Clinton Health Access Initiative
- Columbia University ICAP
- DACA (FMHACA)
- Dessie Regional Lab
- Dire Dawa Regional Health Bureau
- Federal Ministry of Health
- Gambella Regional Health Bureau
- Harari Regional Health Bureau
- I-TECH
- JHU TSEHAI
- Jimma University Hospital
- Management Sciences for Health
- Metu Karl Hospital
- Oromia Regional Health Bureau
- SNNP Regional Health Bureau
- St. Paul Hospital
- St. Peter Hospital
- Supply Chain Management Systems
- Tigray Regional Health Bureau
- Tigray Regional Lab

Meeting Attendees

EHNRI acknowledges the involvement of the following participants:

Name	Institution	Position
Abdulselem Ahmed	I-TECH	Regional Lab Coordinator
Abebe Belay	ALERT	
Abel Yitbareg	EHNRI	
Adem Yesuf	Dessie Regional Lab	Process Owner
Adisu Kebede	EHNRI	Quality Officer
Adugna Amare	Bahir Dar Regional Health Bureau	Officer
Alemayehu Nigatu	SCMS	Lab Manager
Alie Husene	HAPCO	
Alefiyah Shambhoora	CHAI	Drug Access Team
Almaz Kenfie	Gonder University Hospital	Manager
Andargachew Goshu	ALERT Hospital	Lab Head
Andualem Mekonnen	EHNRI	Team Coordinator
Aregay G/Kidan	EHNRI	Maintenance
Dr Bereket H/Giorgis	ICAP	Program Director
Berhe Kalayu	Gambela RL	Lab Head
Dr. Betru Tekle	HAPCO	Director General
Bikila Bayissa	DACA	Lab Directorates
Birhanu Hurisa	EHNRI	
Birru Shigute	Oromia RHB	Program Officer
Chernet Gurum	Adama Hospital Lab	Lab Head
Daba Muleta	Adama Regional Lab	Lab Head
Dr. Dadi Jima	EHNRI	Deputy Director
Demeke Ashagre	SNNPR Regional Lab	Lab Tech
Demise Denebo	SNNPR Regional Lab	
Demissie Assegu	SNNPR	Hospital Head
Dereje Feleke	Harari Regional Lab	
Dereje Teshome	EHNRI	Lab Head
Desalegn Sifer	EHNRI	Maintenance Engineers
Dr Aytenew Ashenafi	JHU-TSEHAI	Lab Support Program Lead
Elias Asfaw	EHNRI	M&E
Embabo Dede	Nekemt Regional Lab	Lab Head
Endris Mohamed	EHNRI	Lab Head
Fikir Asrie	Gonder University Hospital	Team Leader
Firehiwot Teka	EHNRI	
Fregenet Geletu	Adama Hospital	Nurse
Gebrehiwot Birhane	Axum St. Mary Hospital	CEO
Gemechu Tadesse	EHNRI	Lab Head
Getachew Belay	EHNRI	Training Manager
Genetu Alem	Bahir Dar Regional Lab	Lab Head
Girum Demissie	MSH HCSP	Lab Advisor
Gizachew Anteneh	EHNRI	Maintenance Manager
Gonfa Ayana	EHNRI	QA Officer

Dr. Gudeta Tibesso	EHNRI	Director
Hassen Miftah	Metu-Karl Hospital	Lab Head
Jemal Said	ALERT Hospital	
Kalid Alwa	Harari Regional Lab	
Kassa Eshetu	SNNPR	Officer
Kassaye Tekie	EHNRI	Quality Assurance Manager
Kefeni Kelbecha	Afar Regional Lab	Lab Head
Lemlem Legesse	Tigray Regional Lab	Lab Head
Leulseged Takele	Abt Associates	Lab Advisor
Masresha Agezie	Northern Command Hospital	
Mengistu Tadesse	St. Paul Hospital	Lab Head
Mesfin W/Giorgis	Federal Police Hospital	
Mezmur Ketema	ALERT Hospital	CEO
Mulualem Agonafir	EHNRI	Team leader
Seid Tesfaw	Dessie	
Solomon Dabi	St. Paul Hospital	Medical Director
Solomon Shimels	EHNRI	Director
Dr. Solomon Zewdu	JHU-TSEHAI	Country Director
Tadele Kebede	FMOH	Officer
Taodeya Abeje	AMRI	Lab Manager
Tebark Lega	St. Peter Hospital	Lab Head
Tekleab G/Silassie	Tigray RHB	Surveillance
Tekleweyni Mamo	Axum St. Mary Hospital	Lab Leader
Tesfaye Abreha	ICAP	Lab Advisor
Tesfaye Mekonen	SCMS/EHNRI	
Tigist Habtamu	EHNRI	
Tilaye Gudina	FMOH	
Tilahun Muchie	EHNRI	Quality Officer
Tina Falle	CHAI	Lab Program Manager
Tsehaynesh Elias	EHNRI	Public Relations Officer
Dr Tsehaynesh Messele	EHNRI	Director General
Wendmagegn Addisu	Jimma University Hospital	Lab Team Leader
Wondwossen Kassa	EHNRI	Logistics Officer
Dr. Yared Tedla	St. Peter Hospital	Clinical Officer
Dr. Yenew Kebede	CDC-Ethiopia	Branch Chief, Laboratory
Yonas Alemu	St. Paul Hospital	
Zelalem Gizachew	CHAI	Regional Lab Analyst
Dr. Zenebe Melaku	CU-ICAP	Country Director

Agenda

Day One: June 28, 2010

Welcome Address and Opening Remarks

After Dr. Gudeta Tibesso's Welcome Address, Dr. Yenew Kebede, CDC-Ethiopia Branch Chief for Laboratory, Dr. Betru Tekle, Director General of the HIV/AIDS Prevention and Control Office, and Dr. Tsehaynesh Messele, Director General of EHNRI, provided Opening Remarks on behalf of their institutions.

Meeting Objectives

Mr. Getachew from EHNRI shared the objectives of the meeting and EHNRI's vision for the meeting. He hoped that there would be productive discussions, increased understanding between various parties, and a strong commitment from the partners as the group worked together to develop recommendations and a plan for the 2003 Ethiopian Fiscal Year.

The following are the objectives of the Annual Review Meeting of the National Laboratory System:

- To provide all stakeholders – including program managers, RHBs, and all implementing partners and collaborators – with a review of the current status of the National Laboratory System,
- To identify opportunities for better collaboration, coordination and enhanced support of the health system,
- To identify key gaps and focus areas, and develop the Joint Plan for Ethiopian Fiscal Year 2003 with all stakeholders.

Review of the National Laboratory System and Focus Areas

Dr. Gudeta Tibesso, Director of Regional Laboratory Capacity Building at EHNRI, provided an overview of the status of the national laboratory system with information regarding background, achievements and challenges. Dr. Gudeta also laid out the focus areas of EHNRI's plan for EFY 2003. Dr. Yenew Kebede from CDC then presented an overview of PEPFAR/CDC Support for the National Lab System. These two overview presentations were followed by detailed discussions on four areas of focus: Referral Linkage, Early Infant Diagnosis (EID), Laboratory Support for Public Health Emergency, and Laboratory Accreditation. Each presentation shared evidence-based information taken from recent assessments conducted by EHNRI. This was followed by extensive discussion and question-answer sessions to allow for the participants to actively engage with EHNRI on the above mentioned topics.

Day Two: June 29, 2010

Group Work

While presentations on Day One introduced major areas of focus related challenges, the majority of the second day involved topical discussion and plan development. Supporting the

collaborative mission of the meeting, the attendees were divided into four groups and each group was tasked with carrying out an in-depth analysis of three major topics:

- Referral Linkage and Early Infant Diagnosis
- Laboratory Support for Public Health Emergency
- Supply Chain Management

Each group was tasked with identifying major challenges within each area, and to recommend possible solutions and next steps. After a full day of work, each group then presented their analysis. The EHNRI team consolidated insights from each group and incorporated major stakeholder input into a comprehensive list of challenges, solutions and actions. These consolidated results are shown in the “Action Items” Section of the report.

Day Three: June 30, 2010

Joint Planning

The last day of the meeting provided an opportunity to evaluate and further discuss the action items by focus area resulting from Day Two. Thereafter, the planning template for regions was shared, and regional representatives and partners began to work on their plan for the upcoming fiscal year (EFY 2003). The plans by regions will be finalized after representatives’ return to their regions and will be sent to EHNRI to be compiled into the 2003 Plan.

Presentation Content and Discussions

1. Opening Remarks

Speaker: Dr. Tsehaynesh Messele, EHNRI

Dr. Tsehaynesh highlighted that strengthening public health laboratories in Ethiopia is a critical element of the country's endeavor to improve the health care delivery system. She emphasized that a responsive laboratory system is needed to ensure early detection and management of outbreaks, proper treatment decisions, effective disease surveillance programs, and institution of appropriate response strategies.

As the country's reference laboratory, the Ethiopian Health and Nutrition Research Institute (EHNRI) assumes the highest level of a four-tiered laboratory system. Though considerable progress has been made in strengthening the national laboratory capacity since 2005, when EHNRI received the mandate from the Ministry of Health, challenges still remain, such as poor laboratory infrastructure, human resource constraints, equipment management, laboratory commodity supply systems, difficulties with monitoring and evaluation; and laboratory information management.

Dr. Tsehaynesh also introduced the new WHO-AFRO Accreditation Program which is in line with strengthening the laboratory quality management system and allows for stepwise certification of laboratories to strengthen laboratory quality systems and to focus on areas of critical importance, such as management, documentation, human resources, client focus, equipment, safety, information management and procurement and supply management. The national accreditation process provides a learning opportunity and a mechanism to identify resource and training needs, a measure of progress, and a link to the WHO-AFRO National Health Laboratory Service Networks.

Given the vital role the public laboratory plays, EHNRI is committed to expand and further develop reliable laboratory services, and does so with an understanding of the importance of strong relationships with partners. Dr. Tsehaynesh thus shared that an important goal of the National Review Meeting was to help identify opportunities for better collaboration, coordination and enhanced support of the health system.

2. Status of the National Laboratory System

Presenter: Dr. Gudeta Tibesso, EHNRI

Dr. Gudeta presented an overview of the status of the national laboratory system. EHNRI has been leading system strengthening activities since receiving the mandate from the Federal Ministry of Health to strengthen the national laboratory system in 2005. National laboratory system strengthening activities include infrastructure development, logistics and procurement support, HR development, quality management system development, and development of technical and financial support.

Status and Achievements

Infrastructure developments have included the following:

Activities	Regional Labs	Hospitals	Health Centers
Construction of new labs	2		
Renovation & equipping of labs for specialized tests (DNA-PCR, Viral load)	6	1	
Renovated labs for TB liquid culture	4	2	
General lab renovations		43	71
Equip labs with automated analyzers	8	118	5

Lab system strengthening has heavily focused on decentralization of services - services for hematology, chemistry and CD4 testing are provided at hospital and Regional Laboratory levels, and specialized testing for DNA PCR analysis of HIV, culture and sensitivity for epidemic-prone diseases, HIV viral load, TB liquid culture are provided at Regional Laboratory levels. Over the years, many standardized formats, forms, guidelines, job aids and manuals have been developed and distributed throughout the laboratory network. EHNRI has developed training modules and guidelines, conducted TOTs (training of trainers) and basic in-service, technical, and management and leadership trainings, as well as supported regional rollouts of training modules and pre-placement trainings.

To integrate and expand Quality Assurance (QA) activities, EHNRI has implemented Internal Quality Controls (IQC), provided on-site support, training, mentoring, and coaching, and set up international, national and regional EQA programs for a wide and expanding variety of tests, including ART monitoring, microbiology, parasitology and drug resistance, among others.

In the area of maintenance, EHNRI's maintenance team has provided 286 maintenance services nationwide in FY2001 and 281 in FY2002, respectively. At this time, EHNRI is

developing a maintenance strategy for sustainable, quality maintenance services, which includes strengthening the national maintenance center, decentralizing maintenance activities, establishing service contracts, ensuring a national stock of spares for major ART equipment, and collaborations with local agents.

In addition to financial support for sample transportation and testing in the regions, EHNRI provides ongoing technical assistance on the sample referral network, and develops national standards, e.g., SOPs for sample referral linkage. At this time, over 420 health centers are networked to hospital labs for testing services, and DBS for EID is referred from more than 300 sites to seven testing laboratories throughout the country.

Dr. Gudeta also shared the efforts toward achieving laboratory accreditation, including efforts toward WHO-AFRO Accreditation. This new Program by WHO-AFRO was selected by EHNRI as it focuses on quality system essentials and allows for stepwise accreditation of laboratories.

Challenges

After highlighting achievements, Dr. Gudeta laid out the challenges faced by the national laboratory system:

Infrastructure

- Infrastructure at many facilities needs renovation to meet standards
- 60% of the Regional Labs yet to meet required standards
- 48% of the existing hospital labs need renovations to reach acceptable standards

Instrumentation

- Many laboratories still require automated analyzers, other labs need updated analyzers
- High workload in some sites
- Equipment management system are underdeveloped

Maintenance

- Maintenance system are extremely weak
- Frequent breakdown of equipment due to lack of standard preventive maintenance
- Geographical distribution and high number of equipment influence service response times
- Lack of spare parts
- Some equipment failures need out-of-country expertise for maintenance

QA and EQA

- Weak documentation
- Shortage of reagents and consumables
- Poor IQC practices
- Low performance in some areas of EQA
- Lack of safety materials
- Logistic difficulties to carry out EQA and other national programs

Human Resources

- High turnover of staff requires constant re-training

Referral linkage

- Weak lab network for all types of lab services
- Means of specimen transportation do not meet standards

Budget

- Timely utilization and liquidation
- Cost and sustainability of programs

Under-utilization of specialized tests

- Lower-than-expected levels of requests for DNA-PCR testing, epidemic-prone disease testing

Communication

- Communication facilities (phone, fax, internet) underdeveloped
- Coordination and harmonization of efforts not optimal

Factors for Success

Given these challenges, the success factors and strategies for strengthening the lab system over the last five years were highlighted:

- The Federal Ministry of Health's commitment and prioritization of public health laboratory strengthening has been and remains absolutely crucial.
- Ensuring that the development of the national lab system is consistent with national policies and guidelines.
- Ensuring strengthening of the overall health system while developing the national lab program.
- Ensuring that the lab support provided is customized to the country's need.
- Strong collaboration with funders and partner institutions.
- Keeping a focus on standardization and harmonization of efforts and resources to avoid the duplication of efforts.
- Utilizing long-term, strategic planning, and implementing according to the plan.
- Planning jointly with partners, regions and all stakeholders.
- Focus on decentralization efforts, as they help build Regional Laboratory capacity, foster ownership, ensure sustainability, enable rapid scale-up of new services, and facilitate the strengthening of health systems and quality systems.

EHNRI's EFY 2003 Plan

EHNRI's focus areas for the upcoming fiscal year, EFY 2003, were shared:

1. Capacity building and infrastructure development

- Assist regions to establish Regional Labs and build additional Regional Labs
- Undertake additional renovations at hospital labs

2. Decentralization of lab services

- Establish 3 additional DNA-PCR labs
- Equip 4 RLs for TB liquid culture services
- Establish Viral Load testing at 6 additional labs

3. Furnish and equip labs

- Furnish Bahir Dar and Adama Regional Labs
 - Equip 690 health facilities with iLED microscopes
 - Equip 20 facilities with complete ART monitoring systems
 - Equip 205 facilities with chemistry and hematology machines.
4. **EQA expansion**
 - Expand integrated NEQAS to 30 additional hospital labs
 - Assist RLs on the expansion of REQAS for TB, HIV and malaria
 5. **Expand LIS** for 6 additional labs
 6. **Strengthen lab network for early identification of epidemic-prone diseases**
 7. **Strengthen QA activities at labs providing specialized testing services**
 8. **Improve maintenance services** through decentralization to the regions and outsourcing
 9. **Support lab accreditation efforts** (WHO-AFRO and other)
 10. **Enhance collaboration and communication with RHBs, partners and stakeholders**

3. PEPFAR/CDC Support of the National Laboratory System

Presenter: Dr. Yenew Kebede, CDC-Ethiopia

Dr. Yenew Kebede, Branch Chief-Laboratory, CDC-Ethiopia, presented an overview of PEPFAR support of the national lab system. Over the years, this support has included focus areas such as laboratory physical infrastructure development, introduction of better diagnostic technologies, strengthening of lab quality assurance programs, sample referral systems strengthening and laboratory networking, capacity development through training, and Laboratory Information Systems.

Dr. Yenew highlighted that the national laboratory system is important for the diagnosis of conditions such as HIV, TB, Malaria, OIs, STIs, monitoring of people on ART, and for surveillance purposes. He also described that the Regional Labs established have served as centers of excellence for training, research, and referral testing but require continued support for further strengthening. Laboratory infrastructure work has included:

- Strengthening regional reference laboratories,
- Providing training, QA, and establishing regional referral centers to address diseases of public health importance,
- Renovation and furnishing of Hospital and labs with the involvement of partners,
- Support with lab equipment, safety materials, accessories and reagents, and
- Financial support for equipment management.

As part of the CDC's efforts to introduce better diagnostic techniques, PEPFAR has also formed strong partnerships with EHNRI and the MoH to support the national influenza laboratory, conduct DNA PCR testing for Early Infant Diagnosis (EID), carry out HIV drug

resistance testing, TB Culture and DST testing, and to introduce dried tube specimen technology (DTS) for the EQA program. As part of the efforts to strengthen laboratory quality assurance programs, support areas have included financial and technical support to EHNRI, site level technical support for facilities, support for the WHO/AFRO lab accreditation, logistics support for distribution of panels, technical assistance to develop guidelines and training manuals, and a regular supply of reagents.

PEPFAR support for sample referral and laboratory networking has included financial and technical support for EHNRI to strengthen the system, site level technical support, and technical assistance on development of SOPs, training materials and guidelines. Dr. Yenew also highlighted that capacity-building initiatives have included the following activities, trainings, and investments:

- In-service training (on site and off site),
- Regional capacity development,
- Leadership and management training,
- Equipment for training schools,
- Standardization of pre-service training curriculum,
- Teaching methodology training for faculty members, and
- Provision of teaching materials (lab tops, reference books, photometers, etc.).

PEPFAR also collaborates with EHNRI on the expansion of LIS – including paper-based and electronic LIS in some sites. Furthermore, PEPFAR support includes strong logistic support, quantification and forecasting, procurement support, inventory control, and training and site level technical support.

Dr. Yenew also provided further information about the new Global Health Initiative (GHI), which is a six-year \$63 billion initiative by the United States government with particular focus on the health of women, newborns and children and a programmatic focus on HIV/AIDS, malaria, TB, maternal and child health, nutrition, family planning, reproductive health and neglected tropical diseases. Since Ethiopia represents one of the GHI plus countries, Dr. Yenew highlighted the opportunity of this new program to strengthen existing activities in the laboratory program, expand malaria and TB lab support, strengthen microbiology lab services, and ensure better diagnosis and monitoring of parasitic diseases.

4. Referral Linkage

Presenter: Mr. Gonfa Ayana, EHNRI

Given the resource-limited setting, a tiered system of laboratories working together as laboratory network, organized in alignment with the public health care delivery network, is suited to the countries' diagnostic needs. It enables nationwide access to a comprehensive range of laboratory services for disease prevention and control and for early identification of epidemic-prone diseases. Specimen referral linkage is an important function of the laboratory

network. It involves the management of specimens from collection, transportation and testing, to result feedback.

Referral linkage is important, especially for the ART monitoring system, and its proper functioning is most crucial for the expansion of HIV/AIDS Care and Treatment Services in resource-limited, remote settings. In Ethiopia, all hospitals and an ever-increasing number of health centers offer ART services. ART lab monitoring services, however, are mainly only available at hospital levels. Thus health centers are linked to the hospitals in order to offer patients ART lab monitoring services.

EHNRI conducted a survey in Health Centers to assess the status of Sample Referral Linkage in country. A total of 126 health centers from Amhara, SNNPR, Oromia and Tigray responded. At present, health centers refer clinical chemistry, hematology and CD4 samples to higher-level laboratories (hospital or Regional Laboratories). Of the sampled sites, 52% stated they also referred DBS samples of DNA PCR testing of HIV for early infant diagnosis. The following table provides an overview of results:

Assessed Topic	Results
1. Transportation	<ul style="list-style-type: none"> • Almost three quarters refer once per week (73%) • 11% of sites refer less than once per week • 3% refer as much as 3 times per week • At almost all sites, (92%), specimens are transported by lab techs using public transportation. Minimal use of other transportation methods
2. Distance	<ul style="list-style-type: none"> • 46% of sites are within 50 km of the testing labs • 31% of referral sites assessed are more than 100 km away • 57% are more than 50 km away
3. Turnaround time	<ul style="list-style-type: none"> • Almost three quarters of sites (73%) reported turnaround times of 1-3 days • Long turnaround time for some sites: 10% of sites reported results return after more than 1 week
4. Difficulties reported by health centers	<ul style="list-style-type: none"> • More than half (58%) of assessed sites reported a budget shortage for specimen transportation in past year • In 30% of these sites, budget issues interrupted testing services • Almost a third of sites (28%) reported that their testing lab limited the amount of samples referred by a quota • More than a third of health centers (37%) reported a shortage of sample collection materials, in particular vacutainer tubes

In addition, clinicians were asked about their satisfaction with these referred testing services for their sites. When asked whether they are comfortable with the referral linkage services provided, 39% answered they were very satisfied, half (50%) stated they were somewhat satisfied, and 11% stated they were unsatisfied. When asked whether they felt that the results received from the laboratory are reliable, two thirds (68%) answered reliable, a third (30%) stated services were somewhat reliable, and 2% said not reliable. The result for perceived reliability provides a vote of confidence, as two thirds of customers (clinicians) believe that the test results they receive are reliable. The satisfaction with the referral services provided, however, was lower (39%), and reasons for low satisfaction were budget shortages at sites, late or no payment of per diems for transport, shortage of sample collection materials, service interruptions due to machine failures, lack of equipment at health centers, long turnaround times and quotas.

Based on the findings of the assessment, Mr. Gonfa shared views on challenges faced by EHNRI regarding sample referral linkage and recommended the following actions steps for a way forward:

- Establish a national system for transportation of all referred samples.
- Procure additional equipment for health centers to take burden off hospital labs and the referral system, and to allow greater access for remote sites.
- Strengthen the maintenance system with increased focus on regular preventive maintenance and decentralization of maintenance services.
- Evaluate Point-of-Care testing equipment for potential use in remote, low volume facilities.

5. DNA PCR Testing for Early Infant Diagnosis of HIV

Presenter: Dr. Gudeta Tibesso, EHNRI

The ability to diagnose HIV as early as possible in infants is extremely important as HIV progresses rapidly in children. Without ART, 50% of children die before the age of two years. A DNA PCR test is required to diagnose HIV in children under 18 months of age, as the presence of maternal antibodies would distort an HIV antibody test result. The WHO recommendation is to immediately start treatment for all HIV-positive infants.

EHNRI initiated DNA PCR testing in 2006 and since then six Regional Labs have been renovated and equipped to provide DNA PCR services. The national DNA PCR lab network was established and launched in mid-2008. Services were scaled up to 120 hospitals and 300 health centers. All DNA PCR labs participate in an international EQA program (CDC Atlanta) and have shown 100% competency.

Samples are collected on DBS cards at health facilities, transported weekly to labs for testing, and results are sent back to each health facility. While the use of dried blood spots (DBS) has simplified sample collection, storage and transportation, and increased access, early diagnosis

of HIV infection still remains a critical issue with room for improvement to ensure efficient linkages of HIV-exposed infants to care and treatment.

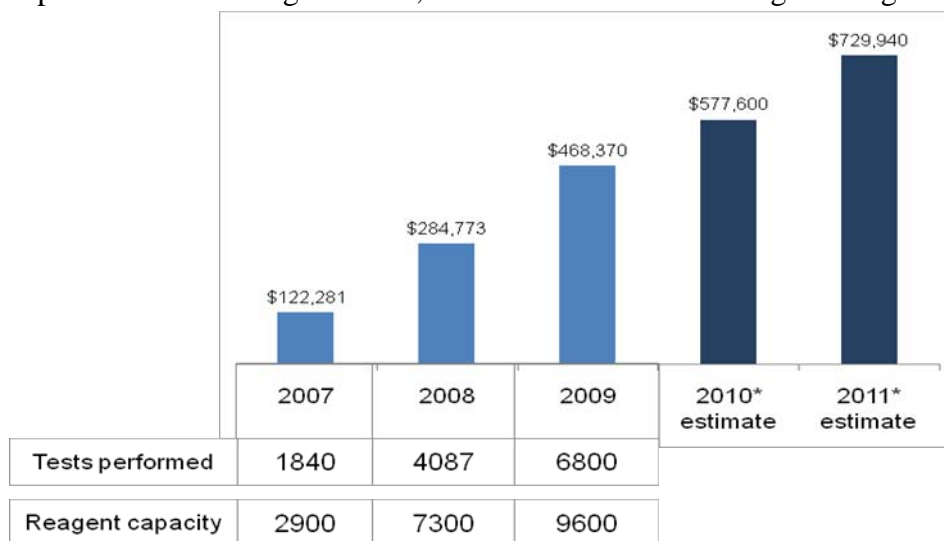
The quality assurance system for DNA PCR testing includes the following elements:

- Documentation such as SOPs, logbooks and formats,
- Quality control through IQC and International EQA Program,
- Supply chain management,
- Result feedback mechanism,
- Standardized training on specimen collection, drying and packaging,
- Job aids and SOPs for specimen collection,
- Infrastructure such as humidity indicators, silica gel, bundled package of DBS collection materials,
- Integrated supply delivery system, and
- Standard transport mechanisms.

EHNRI completed an analysis of EID laboratory services in country. It is estimated that about 8% of coverage for HIV-exposed infants was reached in 2009. While this is an increase from previous years (2% in 2007, 5% in 2008), the coverage is still very low. Testing volume has increased from 1840 tests in 2007 to 6800 tests nationwide in 2009. At the same time, MoH estimates that there were 84,000 positive pregnant women (in 2009), whose babies should be tested.

Given current practices and staffing levels, the 7 DNA PCR labs across Ethiopia have the capacity to conduct approximately 6160 tests every month. The current volumes across all labs (approximately 850 samples/ month) mean that only about 14% of lab capacity has been reached. Thus labs are ready for further scale-up and expansion of DNA PCR testing services.

Information on procurement volumes and budget was also shared. Given the lower-than-expected actual testing volumes, there has been some wastage in reagents, see graph below.



The following table shows estimates of the proportion of sites currently using different methods for sample transport and result feedback across the network:

Table: Proportion of DBS collection sites employing different sample transport and result feedback mechanisms:

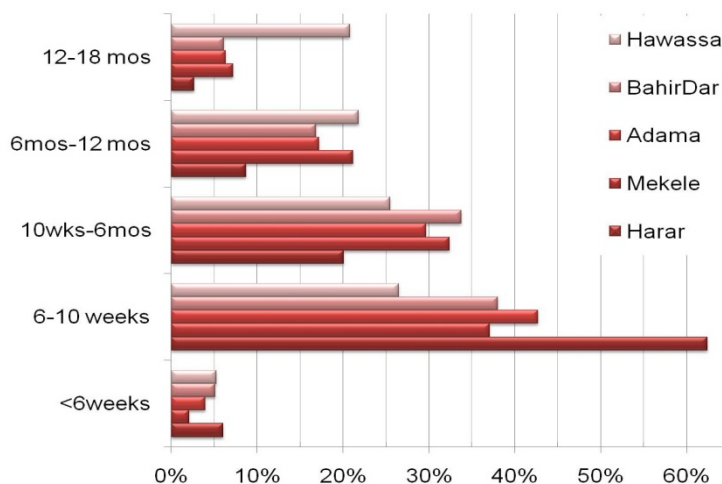
	DBS Transport	Result Feedback
Postal	31%	11%
Mentor	48%	44%
Courier	21%	17%
Phone		22%
Fax		9%

DNA PCR Assessment

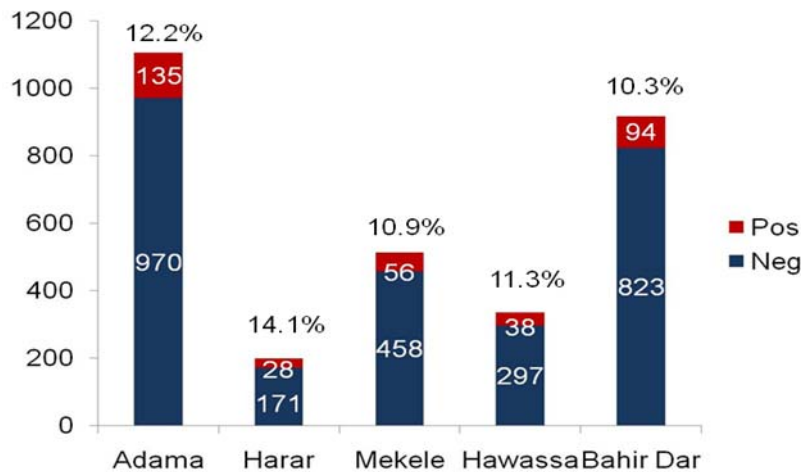
EHNRI conducted a study to assess DNA PCR lab services provided at Regional Labs for the 6-month time period from September 2009 to March 2010.

As part of this assessment, Infants' age at testing across Regional Labs was analyzed. The figure below shows that less than half of infants are tested at the recommended age of 6 weeks (here shown as range from 6-10 weeks). Since positive infants should be started on treatment immediately, it is important to test them as soon as possible (at 6 weeks). Testing before age 6 weeks is against the recommendations. A large proportion of infants were tested at older ages (6 to 18 months, see graph below).

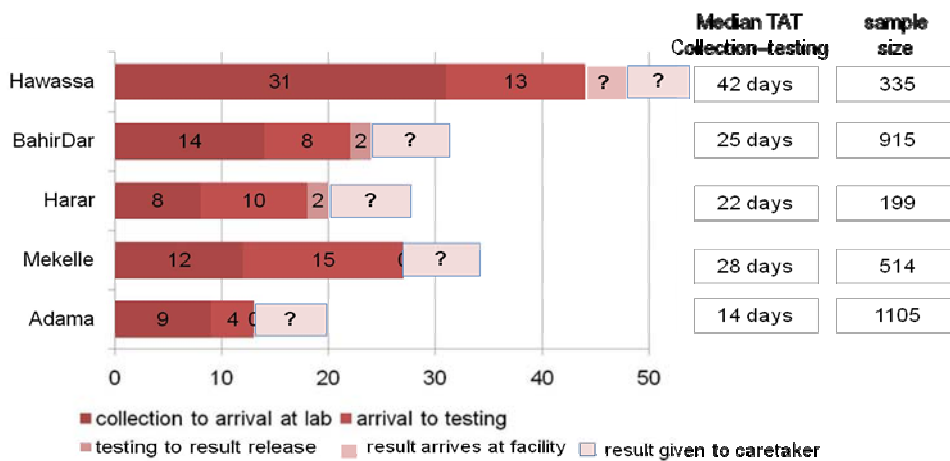
Graph: Age at DNA PCR testing, by Regional Lab:



Graph: Number and percentage of samples testing positive, by Regional Lab:



Graph: Median turnaround times from sample collection to result release:



In line with the EID program, Dr. Gudeta also shared information about a pilot project using SMS printers, which uses mobile phone (GSM) technology and allows for test results to be delivered instantaneously from a testing lab to a health facility. The pilot project was conducted using EID test results from February to September 2009 in 1 testing laboratory (Hawassa Regional Lab) and 4 health facilities in SNNPR. 70 results were sent via SMS.

Results of the pilot showed that in one site, 64% of samples were expedited by over a week or more, with some samples expedited by almost three weeks due to use of mobile technology. Dr. Gudeta recommended the SMS printer for use in remote sites and for use with specialized testing services (viral load, TB liquid culture). The next steps are to pilot this technology in all regions, selecting sites based on testing volumes and remoteness (limited accessibility).

Given EHNRI's experience with DNA PCR testing for Early Infant Diagnosis, Dr. Gudeta highlighted the following points as best practices:

- Good communication between health facility and Regional Laboratory (DBS referral linkage),
- Full time data clerk assigned for Regional Labs and hospitals,
- Logbook and electronic data capturing (easier for reporting, analysis),
- Availability of fax machine, phone line, internet at health facility to link health facilities and Regional Labs,
- Use of prepaid postal service for DBS and result transportation (also achieves greater sustainability),
- Monthly reporting mechanism (from testing labs to the center),
- Linking EID supplies to the existing supply chain management system,
- Establishment of QC and EQA programs for all testing sites, and
- Integration of DNA PCR lab with other lab services (e.g. TB liquid culture, viral load).

The major challenges regarding DNA PCR testing were presented as:

- Identifying exposed infants (missed opportunities),
- Age at testing,
- Accessibility (many remote sites),
- Long turnaround times,
- Result utilization, mechanisms to ensure that caretaker receives result,
- Low testing uptake,
- Power supply interruptions leading to service delivery challenges and cost implications,
- Trained staff turnover,
- Lack of periodical coaching, mentoring and supportive supervision,
- Lack of standardization of sample and result delivery systems,
- Need for standardized formats (requisition forms, logbooks, etc.), and
- Weak and irregular reporting system.

Given the challenges, Dr. Gudeta laid out that next steps for the early infant diagnosis laboratory program were to:

- Advocate for greater uptake of testing and for better linkages to PMTCT services.
- Continue decentralization and expansion of DBS collection sites.
- Improve accessibility of EID services and decrease turnaround time through expansion of testing sites.
- Standardize sample referral linkage through postal service for all DBS collection sites.
- Expand SMS Printers to all regions for use at inaccessible sites.
- Continue training for DNA PCR testing for Regional Labs, and for DBS collection for health facilities.
- Provide systematic mentoring and supportive supervision.
- Standardize documentation (requisition, result, report formats; logbooks).

6. Laboratory Support for Public Health Emergency

Presenter: Mr. Kassaye Tekie, EHNRI

Communicable diseases account for the majority of the disease burden in Ethiopia. Malaria, TB, HIV, STIs, and Opportunistic Infections (OIs) are major causes of mortality and morbidity. Since most of these diseases have a definitive laboratory diagnosis, the laboratory plays an important role in accurate diagnosis and thereby facilitates not only early treatment for the individual, but also outbreak investigation and disease surveillance for the population. Thus strengthening microbiological services is a critical step to addressing diseases of public health importance. Occurrence of frequent outbreaks and the emergence of drug resistance strains are other important public health challenges that require laboratory services. In Ethiopia, microbiology laboratory services are weak in many aspects including infrastructure, equipment, training and standardization. Laboratory support for public health emergency is limited to a few facilities and those often have many limitations.

EHNRI conducted an assessment on the provision of laboratory support for public health emergency between March and May 2010. The goal was to assess the current status and identify gaps and opportunities to improve laboratory-based case identification for epidemic-prone diseases.

Among the Regional Labs, all except Addis Ababa were providing Culture and Sensitivity testing, and all Regional Labs were providing testing for acute watery diarrhea (AWD). The number of tests performed in the past 12 months in the regions was fairly low, especially for samples from epidemic sites, which were mainly sent directly to EHNRI (80%). The most requested tests were for AWD (acute watery diarrhea) and Meningitis (CSF). Specimens were sent from epidemic sites, hospitals and private health facilities. Specimens were directly collected and transported by lab technicians, except in Adama.

The following table shows the current status of facilities regarding culture and sensitivity testing across the country:

Laboratory	Sufficient workspace	Basic equipment	SOP for specimen transportation	Availability of media	IQC strain available
Bahir Dar	✓	✓		✓	
Mekele	Limited	✓	✓	✓	
Hawassa	✓	✓	✓	✓	
Adama	✓	✓	✓	✓	
Addis Ababa	✓	✓	✓	✓	
Nekemt	✓	✓	✓	✓	
EHNRI	✓	✓	✓	✓	✓

Table: Reporting of Lab Results for Epidemic-Prone Diseases

Laboratory	RHB	Woreda	Health facility	EHNRI	MOH
Bahir Dar	✓	✓	✓	✓	
Mekele	✓	✓			
Hawassa	✓	✓	✓		
Adama	✓				
Addis Ababa					
Nekemt		✓	✓		
EHNRI					✓

Most labs report to their respective Regional Health Bureau or Woreda office. The table above shows that there is no standard result reporting system, and it is possible that the Regional Health Bureau and Ministry of Health may not get the necessary information in case of a public health emergency. In addition, following a patient result and forming an integrated intervention is very difficult.

The assessment also found a need for training for all the laboratories in the following areas: culture and sensitivity for clinical specimens, including biochemical test interpretation, bacteriological water analysis, and public health bacteriological and chemical analyses for food and water.

Given the current status of testing for epidemic-prone diseases, the following were highlighted as main challenges:

- Need for comprehensive training on microbiological specimen and water analysis.
- Lack of important media, anti-sera, antibiotic discs.
- Reagent expiry within coming 4 months in many labs.
- Lack of supportive supervision from EHNRI.
- Lack of know strain for IQC.
- Limited availability in local market of most of media, antisera and antibiotic discs.
- Lack of standard SOPs for sample transportation and lab procedures.
- Inadequate number of tests executed by some labs.
- Lack of de-centralized testing for epidemic-prone disease investigations such that most testing is conducted by EHNRI rather than in regions.
- Lack of standard reporting formats.

Based on the above challenges, the following way forward was recommended:

- Encourage partners and stakeholders to support lab services for public health emergency.
- Provide comprehensive training on microbiological testing.
- Ensure basic lab supplies and commodities are available for epidemic-prone disease testing.
- Conduct regular supportive supervision (EHNRI).
- Strengthen EQA for microbiology testing services.
- Strengthen referral linkage and specimen transportation for the diagnosis of epidemic-prone diseases.
- Ensure better coordination and communication between PHEM and Regional Laboratories at all levels
- Develop specimen collection and transportation guidelines for epidemic prone diseases.

7. Laboratory Accreditation

Presenter: Mr. Gonfa Ayana, EHNRI

Accreditation is a process in which certification of competency and compliance with quality standards/norms or credibility is presented by formally “accredited certification bodies”. Definitions for accreditation, standards and guidelines, and examples of international, regional and country-specific standards were outlined. Laboratory accreditation is beneficial since it is in the interest of patients, the community and the government that clinical labs operate at high quality standards. Since accreditation provides recognition for competence (at international standards), it helps ensure that clinical labs operate at high quality standards and provide reliable diagnostic services. Laboratory accreditation covers all aspects of laboratory management including infrastructure, pre- and post-analytic stages, quality assurance and EQA Programs, supply chain management, human resources and data. Furthermore, accreditation defines a vision and direction for laboratory development and a ‘finish line’ with clear targets, goals and standards to be reached.

Mr. Gonfa further described the elements of the accreditation process, requirements and steps leading toward accreditation. For Ethiopia, accreditation of clinical laboratories is a major goal included in the Laboratory Master Plan. Over the past couple of years, different accreditation schemes were pursued in country.

The WHO-AFRO Scheme, which was initiated by WHO-AFRO and partners in 2009, was found suitable to Ethiopian context, as it

- Takes a step-wise approach,
- Is based on ISO standard 15189,
- Is not disease-specific,
- Is affordable, sustainable, and effective, and
- Supports the development of national accreditation body for sustainable and continuous quality improvement.

Lab systems strengthening efforts over the last years including infrastructure development, improved quality, and increased staffing, have paved the way for optimism for Ethiopia on the way to laboratory accreditation. Since Fall 2009 EHNRI and partners have undertaken the following efforts on the WHO-AFRO Accreditation Scheme:

- Formed a National Laboratory Accreditation Steering Committee.
- Developed an Operational Plan for Accreditation, encompassing national and site-level activities.
- Implemented the Operational Plan (ongoing):
 - 19 labs were selected, baseline assessments at these labs were conducted.
 - Development of documents and records.

- Conducted trainings, additional trainings are planned, including the SLMTA (Strengthening Lab Management toward Accreditation), a long-term, hands-on training.
- Next steps are site-level gap identification and improvement planning.

The major challenge at this point is that there is limited capacity at all levels to effectively support the process. There are major gaps in meeting many of the requirements, including appropriate lab design and infrastructure, safety, documents, supply chain and inventory, QMS implementation, and the maintenance system.

Given the challenges, the way forward is outlined as such:

- At EHNRI, focus on national-level activities and coordination efforts.
- Continuously monitor the progress made, and adapt plans as necessary.
- Focus on the major gaps at sites.
- Closely collaborate with all partners to ensure site-level activities proceed as planned.
- Ensure engagement of site-level management in the accreditation effort.

8. Joint Planning

The discussion on the Joint Planning exercise brought forward the need for regular monitoring and evaluation of the Annual Plan.

The major points of discussion and suggestions for EHNRI were the following:

Planning

- The Joint Plan template should include information on EHNRI's plans to support health facilities with regard to infrastructure, equipping of laboratories and planning for infrastructure development.
- The gap with regard to equipment, the number and type of equipment and the number of laboratories should be considered in the plan.
- The required supplies should include manufacturer training.
- It is also important that there is a strong focus on monitoring and evaluation and that appropriate indicators are identified.

Monitoring and Evaluation

- EHNRI should set the next year's plan only after evaluating the achievements of the current year's planned activities.
- There's a need for regular reviews and follow-up of the implementation based on the plan. Suggestion to hold a review meeting twice a year.
- There's a need for frequent monitoring and an evaluation system to ensure proper implementation of activities and opportunities for improvement.
- There should be trend reporting of activities to EHNRI by regions.

9. Discussions and Action Items

Each presentation was followed by a question and answer session resulting in dynamic discussions. Later on participants were further divided into groups to work on the three areas of Laboratory Support for Public Health Emergency, Referral Linkage and Early Infant Diagnosis, and Supply Chain Management.

We will first share a summary of general comments, suggestions and feedback to EHNRI before going to the specific discussions from the group work and the resulting Action Items.

General Comments

- Kits and other resources:
 - Distribution of HIV test kits should be properly quantified and there should be uninterrupted services.
 - EHNRI should work with PFSA in regard to the quantification and distribution system.
 - Proper communication should be established with the regions for immediate corrective action.
- Reagent preparation:
 - Regions should plan on reagent preparation considering quality checks.
 - Regions should take the responsibility for utilization of quality reagents in all the health facilities of the regions especially for AFB reagents.
- Accreditation:
 - EHNRI should support regions to develop own operational plan for accreditation.
 - Regional operational plan on accreditation should be included in the final joint plan for evaluation.
- Training:
 - Trainings are conducted by different partners. EHNRI should avoid overlap of training and prevent unnecessary duplication of efforts.

The following pages include the summaries of the group work discussions, arranged by main and sub-challenges identified for each topic, including suggested action items, responsible parties and timelines for each challenge.

1. Laboratory Support for Public Health Emergency

The main problems identified were lack of effective communication, lack of supplies and equipment for testing, lack of documentation for lab operations, weak IQC and EQA, lack of human resource capacity, weak advocacy and partner engagement, and difficulty with logistics for specimen transportation. Specific short-term action items are to conduct a

baseline and fill the supply gaps immediately, provide training, mentoring and advice to sites, develop and disseminate guidelines, SOPs, job aids etc, ensure standard strains for EQA are available, ensure lab expertise in all public health emergency teams, devise a national guideline for public health emergency management to include a mapping of communication channels, and engage with partners and stakeholders for support. In the medium term, standard microbiologic services should be identified, a forecasting and quantification system for epidemic-prone diseases should be developed, pre-placement and in-service trainings should be held, and specimen transportation systems should be planned (For detailed information, please see the table below).

2. Referral Linkage and Early Infant Diagnosis

In terms of referral linkage, the biggest challenges identified were budget utilization and liquidation, difficulties with distribution of sample collection materials, lack of uniform specimen transportation methods, lack of effective communication, safety hazards during transportation, unavailability of standardized SOPs, logs etc, and long turnaround times for Early Infant Diagnosis. Follow-up and support to regions for budget utilization, communication with RHBs on liquidation, regular regional review meetings between sites and Regional Labs, developing sub-regional sample collection and testing schedules, distribution of available materials and training on documentation, filling of supply gaps for collection materials and improving the distribution system were identified as short-term solutions. For the medium to long term, sample transportation procedures should be standardized, transportation personnel identified, GIS mapping completed, SOPs for safety developed, and safety supplies for transportation should be available. For Early Infant Diagnosis, a separate action plan should be developed which is to address the challenge of efficient and reliable transportation channels (For detailed information, please see the table below).

3. Supply Chain Management

For Supply Chain Management, the main challenges were identified as specifications and vendor selection, low quality of reagents and supplies, lack of systematic inventory control and procurement systems, and a lack of guidelines for proper disposal of reagents. One main concern was that supply chain so far has only focused on HIV (ART). The recommended focus should be on integrated supply chains for all major diseases including malaria and TB. As short-term solutions, standardized SOPs for reagent preparation was identified. In addition, specifications for reagents and commodities, and material receipt and rejection protocols would be developed over the medium term. A comprehensive procurement system leveraging ART learnings, including a pooled purchasing system for items unavailable locally, and a structure for Regional Labs would be developed.

Laboratory Support for Public Health Emergency

Main Challenges	Sub-Challenges	Activities	Timelines	Responsibilities
Lack of Effective Communication	Vertical & Horizontal	Ensure lab membership in PHEM teams at all levels	3 months	EHNRI, RHBs & RLs for respective levels
	Communication Networking & Reporting Structure	Define communication channel for PHEM in nat'l guideline	3 months	EHNRI
Lack of Supplies & Equipment (appropriate & up to date)	Lack of forecasting & quantification	Fill supply gaps immediately	w/in 1 mo	EHNRI & Partners
		Baseline assessment	w/in 1 mo	EHNRI & RLs
		Establish forecasting and quantification system	6 months	EHNRI (w/ additional assistance)
		Secure appropriate equipment for existing microbiology labs	1 yr	EHNRI & Partners
		Define & implement std microbiology services	6 months	EHNRI & Partners
		Scale-up microbiology services: 10 additional sites	2004	EHNRI & RHBs & Partners
Lack of Documentation for Lab Op (Guideline, SOP, Plans) esp testing	Guidelines, Manuals, SOPs, Job Ads, ID Tools	Develop & Disseminate Documents	3 months	EHNRI, RLs, TWGs
Weak IQC & EQA		Ensure & Avail std strains	3 months	EHNRI
		Expand EQA to all test sites	2003 Feb	EHNRI
HR Capacity Building	Std Training Materials	Develop std materials	6 months	EHNRI & Partners
	Pre-placement Training	Conduct Training	9 months	EHNRI, Partners & Universities
	InService Training	Conduct Training	7 months	EHNRI, Partners & Universities
	Supervision: Mentoring & Coaching	Provide advice & training	3 months	EHNRI & Partners
Visit sites		3 months	EHNRI & Partners	
Weak Advocacy & Partner Engagement		Undertake consultative meetings w/ stakeholders	as of now	EHNRI & RLs
Logistics for specimen transportation		Devise best plan	6 months	EHNRI, RHBs, PHEM

Referral Linkage & Early Infant Diagnosis

Main Challenges	Sub-Challenges	Activities	Timelines	Responsibilities
Budget	Inefficient utilization	Follow-up & support regions for effective utilization	immediate	EHNRI
	Liquidation	Communicate w/ RHBs	immediate	EHNRI
Distribution channels for specimen collection materials	Lack of collection materials at collection site	Fill supply gaps immediately	3 months	EHNRI, PFSA & Partners
		Revisit & improve distribution system	3 months	EHNRI & Partners
Transportation & Geo-mapping	Lack of uniform procedures	Transport Needs Assessment	3 months	EHNRI & Partners
		Standardize sample transportation procedures	6 months	EHNRI & Partners
		Assess & identify transportation personnel	1 yr	EHNRI & Partners
		Mapping - GIS/GPS	1 yr	EHNRI & Partners
Communication	Site to Site (Horizontal)	Develop common schedule for sample collection & testing	3 months	RLs & Partners
	Site to Region (Vertical)	Regular Review Meeting	immediate	RLs
Safety	Disease specific transportation challenges	Ensure safety supplies for pertinent specimens	1 yr	EHNRI & Partners
		Develop safety SOPs	1 yr	EHNRI & Partners
Documentation	SOPs, logs, etc not available	Increase availability	2 months	EHNRI & RLs & Partners
	Training on available documentation	Conduct training	3 months	EHNRI & RLs & Partners
Long TAT for EID	Delay in DBS transportation	Investigate topic further and develop action plan	1 yr	EHNRI, RLs & Partners
	Delay in testing & result feedback	Establish efficient and reliable transportation channels	1 yr	EHNRI, RLs & Partners

Supply Chain Management

Main Challenges	Sub-Challenges	Solutions	Activities	Timelines	Responsibilities
Specifications	Limited capabilities for supply specifications, vendor selection	Set National Standards & Specifications	Develop specifications for reagents and lab commodities.	1 yr	EHNRI & DACA
	Inferior Quality of Reagents and Chemicals; especially for Malaria & TB Diagnosis		Develop SOPs for reagent preparation	3 months	EHNRI & RLs
Inventory Control	Supply of nearly expired materials	Develop systematical inventory control at each level	Create material receipt & rejection protocols	6 months	EHNRI & PFSA
	No inventory control systems & management		Implement LMIS at all sites	1 yr	EHNRI, RHBs & RLs
Lack of uniform procurement systems	System only supports ART Programs		Leverage ART capabilities & expand systems to include comprehensive procurement	1 yr	EHNRI, PFSA & Partners
	In-country market availability of reagents		Develop pooled purchasing systems especially for reagents that are usually unavailable in local markets	1 yr	EHNRI & PFSA
	No defined structure for RLs		Create defined structure & recommend for implementation	6 months	EHNRI, RHBs & RLs
No Guidelines for proper disposal systems			Develop guidelines	1 yr	EHNRI & DACA